

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

February 2008



RCOG Press

Published by the **RCOG Press** at the Royal College of Obstetricians and Gynaecologists, 27 Sussex Place, Regent's Park, London NW1 4RG

www.rcog.org.uk

Registered charity no. 213280

First published 2008

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ISBN 978-1-904752-45-5

NCC-WCH Editor: Andrew Welsh

Original design: FiSH Books, London

Typesetting: Andrew Welsh

Proofreading: Katharine Timberlake (Reedmace Editing)

Index: Jan Ross (Merrall-Ross (Wales) Ltd)

Printed by Henry Ling Ltd, The Dorset Press, Dorchester DT1 1HD

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Acknowledgements

Additional support was received from:

- Anna Bancsi, Martin Dougherty, Angela Kraut, Roz Ullman and Samantha Vahidi at the NCC-WCH
- Tim Stokes, Nicole Elliott, and Emma Banks at the National Institute for Health and Clinical Excellence (NICE)
- Sam Majumdar at the Royal Hallamshire Hospital
- Wendy Edwards from the Healing Foundation Patient Information Working Party
- Jonathan Sandy and Andy Ness and their team at University of Bristol Dental School who kindly gave access to their review prior to publication
- Simon Dixon, Senior Lecturer in Health Economics at the School of Health and Related Research (SchARR), University of Sheffield, for analysis used in the health economics appendix
- the Patient and Public Involvement Programme (PPIP) for NICE whose glossary was adapted for use in this guideline.

Stakeholder organisations

Addenbrookes NHS Trust
Afiya Trust, The
Association of Medical Microbiologists
Barnsley Hospital NHS Foundation Trust
Bedfordshire PCT
Berkshire Healthcare NHS Trust
Bolton Council
Bradford Hospitals NHS Trust
British Association for Paediatric Otorhinolaryngology
British Association of Audiovestibular Physicians
British Association of Paediatricians in Audiology (BAPA)
British Association of Otorhinolaryngologists – Head and Neck Surgeons
British Association of Teachers for the Deaf (BATOD)
British Homeopathic Association
British National Formulary (BNF)
Calderdale PCT
CASPE Research
Charing Cross Hospital
Chase Farm Hospital
Commission for Social Care Inspection
Connecting for Health
Cornwall & Isles of Scilly PCT
Department of Health
Derriford Hospital
Downs Syndrome Medical Interest Group (DSMIG)
Dudley Group of Hospitals NHS Trust
East & North Herts PCT & West Herts PCT
Glan Clwyd District General Hospital
Health Commission Wales
Healthcare Commission
Home Office
Kettering General Hospital
Leeds Teaching Hospitals NHS Trust
Lincolnshire PCT
Medicines and Healthcare Products Regulatory Agency
Medway NHS Trust
Milton Keynes PCT
Morecombe Bay Health Trust
MRC Multicentre Otitis Media Study Group
National Deaf Children's Society
National Patient Safety Agency
National Public Health Service – Wales
NCCHTA
NHS Health and Social Care Information Centre
NHS Plus
NHS Quality Improvement Scotland
North Tees PCT
Obesity Management Association
OCD Today
PERIGON Healthcare Ltd
PRIMIS+
Regional Public Health Group – London
Royal College of Midwives
Royal College of Nursing
Royal College of Paediatrics and Child Health
Royal College of Pathologists
Royal College of Physicians of London
Royal College of Speech and Language Therapists
Royal College of Surgeons of Edinburgh

Royal National Throat, Nose & Ear Hospital
Royal United Hospital
Scottish Intercollegiate Guidelines Network (SIGN)
Sheffield PCT
Sheffield Teaching Hospitals NHS Foundation Trust
Social Care Institute for Excellence (SCIE)
Specialist Advisory Committee on Antimicrobial Resistance (SACAR)
Suffolk Health Care Ltd
UK Clinical Pharmacy Association
University Hospital Birmingham NHS Foundation Trust
University of North Durham
Welsh Assembly Government
Welsh Otorhinolaryngology Association
Welsh Scientific Advisory Committee (WSAC)
Western Cheshire PCT
York NHS Trust

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

Glossary of terms

Absolute risk or risk	Measures the probability of an event or outcome occurring (e.g. an adverse reaction to the drug being tested) in the group of people under study. Studies that compare two or more groups of patients may report results in terms of the relative risk .
Active observation	Active observation is the process of regular review and follow-up of the child's condition including assessment for hearing, development and educational progress. It is a contemporary term used to give more appropriate emphasis to what has been called watchful waiting in the past.
Acute otitis media (AOM)	An acute infection of the middle ear which can be viral and/or bacterial in origin and which may result in the formation of pus and lead to perforation of the tympanic membrane.
Appraisal of evidence	Formal assessment of the quality of research evidence and its relevance to the clinical question or guideline under consideration, according to predetermined criteria.
Audiometry	The testing of hearing ability which includes determination of the hearing levels, ability to discriminate between various sound intensities, ability to distinguish speech from background noise and other aspects. Pure tone audiometry and impedance audiometry (tympanometry) are two of the commonly used tests for audiometric evaluation.
Autoinflation	A technique to open the Eustachian tube by raising the pressure in the nose, which allows air to enter the middle ear cavity.
Bias	Influences on a study that can lead to invalid conclusions about a treatment or intervention. Bias occurs as a result of defects in the study design or the way the study is carried out. It can occur at various stages in the research process, e.g. in the collection, analysis, interpretation, publication or review of research data.
Blinding or masking	The practice of keeping the investigators or participants in a study ignorant of the group to which a subject has been assigned. For example, a clinical trial in which the participating patients or their doctors are unaware of whether they (the patients) are taking the experimental drug or a placebo (dummy treatment). The purpose of 'blinding' or 'masking' is to protect against bias . See also double-blind study , single-blind study , triple-blind study .
Case report (or case study)	Detailed report on one patient (or case), usually covering the course of that person's disease and their response to treatment.
Case series	Description of several cases of a given disease, usually covering the course of the disease and the response to treatment. There is no comparison (control) group of patients.
Case-control study	A study that starts with the identification of a group of individuals sharing the same characteristics (e.g. people with a particular disease) and a suitable comparison (control) group (e.g. people without the disease). All subjects are then assessed with respect to things that happened to them in the past, e.g. things that might be related to getting the disease under investigation.
Cholesteatoma	An abnormal growth of skin in the middle ear. If left untreated, it can expand and damage vital surrounding structures.
Clinical audit	A systematic process for setting and monitoring standards of clinical care. Whereas 'guidelines' define what the best clinical practice should be, 'audit' investigates whether best practice is being carried out. Clinical audit can be described as a cycle or spiral. Within the cycle there are stages that follow a systematic process of establishing best practice, measuring care against specific criteria, taking action to improve care, and monitoring to sustain improvement. The spiral suggests that as the process continues, each cycle aspires to a higher level of quality.
Clinical effectiveness	The extent to which a specific treatment or intervention has a beneficial effect on the course or outcome of disease compared with no treatment or other routine care when implemented under <i>everyday conditions</i> . (Clinical trials that assess effectiveness are sometimes called management trials.) Clinical 'effectiveness' is not the same as efficacy .
Clinical question	This term is sometimes used in guideline development work to refer to the questions about treatment and care that are formulated in order to guide the search for research evidence. When a clinical question is formulated in a precise way, it is called a focused question .

Clinical trial	A research study conducted with patients which tests out a drug or other intervention to assess its effectiveness and safety. Each trial is designed to answer scientific questions and to find better ways to treat individuals with a specific disease. This general term encompasses controlled clinical trials and randomised controlled trials .
Cohort	A group of people sharing some common characteristic (e.g. patients with the same disease), followed up in a research study for a specified period of time.
Cohort study	An observational study that takes a group (cohort) of patients and follows their progress over time in order to measure outcomes such as disease or mortality rates and make comparisons according to the treatments or interventions that the participants received. Thus within the study group, subgroups of patients are identified (from information collected about patients) and these groups are compared with respect to outcome, e.g. comparing mortality between one group that received a specific treatment and one group which did not (or between two groups that received different levels of treatment). Cohorts can be assembled in the present and followed into the future (a concurrent or prospective cohort study) or identified from past records and followed forward from that time up to the present (a historical or retrospective cohort study).
Co-morbidity	Co-existence of a disease or diseases in the people being studied in addition to the health problem that is the subject of the study.
Conductive hearing loss	A type of hearing loss which occurs owing to a disorder of the middle ear or occlusion of the ear canal. This interferes with the transmission of sound to the inner ear resulting in a hearing loss which is usually of mild to moderate degree. If due to a middle ear effusion it may be transient and it may co-exist with other types of hearing loss (permanent conductive hearing loss , sensorineural hearing loss or non-organic hearing loss).
Confidence interval (CI)	A way of expressing certainty about the findings from a study or group of studies, using statistical techniques. A confidence interval describes a range of possible effects (of a treatment or intervention) that are consistent with the results of a study or group of studies. A wide confidence interval indicates a lack of certainty or precision about the true size of the clinical effect and is seen in studies with too few patients. Where confidence intervals are narrow they indicate more precise estimates of effects and a larger sample of patients studied. It is usual to interpret a '95%' confidence interval as the range of effects within which we are 95% confident that the true effect lies.
Confounder or confounding factor/variable	Something that influences the outcome measure in a study and can contribute to misleading findings if it is not understood or appropriately dealt with. For example, if a group of people exercising regularly and a group of people who do not exercise have an important age difference then any difference found in outcomes about heart disease could well be due to one group being older than the other rather than due to the exercising. Age is the confounding factor here and the effect of exercising on heart disease cannot be assessed without adjusting for age differences in some way.
Consensus methods	A variety of techniques that aim to reach an agreement on a particular issue. In the development of clinical guidelines, consensus methods may be used where there is a lack of strong research evidence on a particular topic.
Control group	A group of patients recruited into a study that receives no treatment, a treatment of known effect, or a placebo (dummy treatment) in order to provide a comparison for a group receiving an experimental treatment, such as a new drug.
Controlled clinical trial (CCT)	A study testing a specific drug or other treatment involving two (or more) groups of patients with the same disease. One (the experimental group) receives the treatment that is being tested, and the other (the comparison or control group) receives an alternative treatment, a placebo (dummy treatment) or no treatment. The two groups are followed up to compare differences in outcomes to see how effective the experimental treatment was. A CCT where patients are randomly allocated to treatment and comparison groups is called a randomised controlled trial .
Cost-benefit analysis	A type of economic evaluation where both costs and benefits of healthcare treatment are measured in the same monetary units. If benefits exceed costs, the evaluation would recommend providing the treatment.
Cost-effectiveness	Value for money. A specific healthcare treatment is said to be 'cost-effective' if it gives a greater health gain than could be achieved by using the resources in other ways.
Cost-effectiveness analysis	A type of economic evaluation comparing the costs and the effects on health of different treatments. Health effects are measured in 'health-related units', for example, the cost of preventing one additional heart attack.
Cost-utility analysis	A special form of cost-effectiveness analysis where health effects are measured in quality-adjusted life years . A treatment is assessed in terms of its ability to both extend life and to improve the quality of life.

Cross-sectional study	The observation of a defined set of people at a single point in time or time period – a snapshot. This type of study contrasts with a longitudinal study , which follows a set of people over a period of time.
Day care	Non-residential group care of infants outside the home.
Decibel	A logarithmic unit of sound intensity (loudness).
Decision analysis	Decision analysis is the study of how people make decisions or how they <i>should</i> make decisions. There are several methods that decision analysts use to help people to make better decisions, including decision trees .
Decision tree	A decision tree is a method for helping people to make better decisions in situations of uncertainty. It illustrates the decision as a succession of possible actions and outcomes. It consists of the probabilities, costs and health consequences associated with each option. The overall effectiveness or overall cost-effectiveness of different actions can then be compared.
Diagnostic study	A study to assess the effectiveness of a test or measurement in terms of its ability to accurately detect or exclude a specific disease.
Dominance	A term used in health economics describing when an option for treatment is both less clinically effective and more costly than an alternative option. The less effective and more costly option is said to be ‘dominated’.
Double-blind study	A study in which neither the participant nor the observer (investigator/clinician) is aware of which treatment/intervention the subject is receiving. The purpose of blinding is to protect against bias .
Economic evaluation	A comparison of alternative courses of action in terms of both their costs and consequences. In health economic evaluations the consequences should include health outcomes.
Effectiveness	See clinical effectiveness .
Efficacy	The extent to which a specific treatment or intervention has a beneficial effect on the course or outcome of disease compared with no treatment or other routine care under <i>optimal conditions</i> , e.g. in a laboratory.
Eustachian tube	A tube connecting the middle ear cavity with the pharynx at the back of the nose. The tube is normally closed and opens on swallowing. It helps to equalise the pressure between the middle ear and the atmosphere.
Evidence level (EL)	A code (e.g. 1++, 1+) linked to an individual study, indicating where it fits into the hierarchy of evidence and how well it has adhered to recognised research principles. Also called level of evidence.
Evidence table	A table summarising the results of a collection of studies which, taken together, represent the evidence supporting a particular recommendation or series of recommendations in a guideline.
Evidence-based clinical practice	Evidence-based clinical practice involves making decisions about the care of individual patients based on the best research evidence available rather than basing decisions on personal opinions or common practice (which may not always be evidence based). Evidence-based clinical practice therefore involves integrating individual clinical expertise and patient preferences with the best available evidence from research.
Experimental study	A research study designed to test if a treatment or intervention has an effect on the course or outcome of a condition or disease – where the conditions of testing are to some extent under the control of the investigator. Controlled clinical trial and randomised controlled trial are examples of experimental studies.
Experimental treatment	A treatment or intervention (e.g. a new drug) being studied to see if it has an effect on the course or outcome of a condition or disease.
Focused question	A study question that clearly identifies all aspects of the topic that is to be considered while seeking an answer. Questions are normally expected to identify the patients or population involved, the treatment or intervention to be investigated, what outcomes are to be considered, and any comparisons that are to be made. For example, do insulin pumps (intervention) improve blood sugar control (outcome) in adolescents with type 1 diabetes (population) compared with multiple insulin injections (comparison)? See also clinical question .
Forest plot	A graphical display of results from individual studies on a common scale, allowing visual comparison of results and examination of the degree of heterogeneity between studies.
Glue ear	Glue ear is used in the UK as a colloquial term for a middle ear effusion, often mucoid. The term originally implied a degree of severity and chronicity, but in the UK has become synonymous with otitis media with effusion (OME). This latter usage of the term glue ear is unfortunate because it subsumes common and mild or transitory conditions under a name appropriate for a rarer more serious and lasting condition, and does not encourage this needed distinction.
Gold standard	A method, procedure or measurement that is widely accepted as being the best available.
Grey literature	Reports that are unpublished or have limited distribution, and are not included in bibliographic retrieval systems.

Guideline	A systematically developed tool that describes aspects of a patient's condition and the care to be given. A good guideline makes recommendations about treatment and care based on the best research available, rather than opinion. It is used to assist clinician and patient decision making about appropriate health care for specific clinical conditions.
Guideline recommendation	Course of action advised by the guideline development group on the basis of their assessment of the supporting evidence.
Health economics	A branch of economics that studies decisions about the use and distribution of healthcare resources.
Hearing tests	The formal assessment of the hearing using a variety of tests appropriate to the stage of the child's development.
Heterogeneity	Or lack of homogeneity . The term is used in meta-analyses and systematic reviews when the results or estimates of effects of treatment from separate studies seem to be very different in terms of the size of treatment effects or even to the extent that some indicate beneficial and others suggest adverse treatment effects. Such results may occur as a result of differences between studies in terms of the patient populations, outcome measures, definition of variables or duration of follow-up.
Hierarchy of evidence	An established hierarchy of study types, based on the degree of certainty that can be attributed to the conclusions that can be drawn from a well-conducted study. A systematic review of good-quality randomised controlled trials (RCTs) with homogeneity in their results (which are statistically significant) is at the top of this hierarchy. Well-conducted studies of patients' views and experiences would appear at a lower level in the hierarchy of evidence.
Homogeneity	This means that the results of studies included in a systematic review or meta-analysis are similar and there is no evidence of heterogeneity . Results are usually regarded as homogeneous when differences between studies could reasonably be expected to occur by chance.
Impedance audiometry	See tympanometry .
Intention-to-treat analysis	An analysis of a clinical trial where patients are analysed according to the group to which they were initially allocated at randomisation, regardless of whether or not they had dropped out, fully complied with the treatment, or crossed over and received the alternative treatment. Intention-to-treat analyses are favoured in assessments of clinical effectiveness as they mirror the non-compliance and treatment changes that are likely to occur when the treatment is used in practice.
Intervention	Healthcare action intended to benefit the patient, e.g. drug treatment, surgical procedure, psychological therapy, etc.
Level of evidence	See evidence level .
Longitudinal study	A study of the same group of people at more than one point in time. (This type of study contrasts with a cross-sectional study , which observes a defined set of people at a single point in time.)
Masking	See blinding .
Meta-analysis	Results from a collection of independent studies (investigating the same treatment) are pooled, using statistical techniques to synthesise their findings into a single estimate of a treatment effect. Where studies are not compatible, e.g. because of differences in the study populations or in the outcomes measured, it may be inappropriate or even misleading to statistically pool results in this way. See also systematic review and heterogeneity .
Methodological quality	The extent to which a study has conformed to recognised good practice in the design and execution of its research methods.
Methodology	The overall approach of a research project, e.g. the study will be a randomised controlled trial , of 200 people, over 1 year.
Middle ear effusion (MEE)	The presence of fluid within the middle ear. See glue ear .
Multicentre study	A study where subjects were selected from different locations or populations, e.g. a cooperative study between different hospitals; an international collaboration involving patients from more than one country.
Myringosclerosis	A plaque-like thickening within the tympanic membrane but not involving the middle ear space.
Myringotomy	A surgical procedure in which an incision is made in the tympanic membrane. It may be performed as a single procedure or as a preparation for insertion of a ventilation tube.
Negative predictive value (NPV)	The negative predictive value expresses the probability that someone with a negative test result does not have the condition of interest.
Non-experimental study	A study based on subjects selected on the basis of their availability, with no attempt having been made to avoid problems of bias .
Non-organic hearing loss	A type of hearing loss which cannot be accounted for by a defect or damage in the entire auditory system. In children it is usually unintentional and caused by underlying, unrecognised stress or anxiety. It may co-exist with conductive hearing loss due to OME or with permanent conductive hearing loss or sensorineural hearing loss .

Objective measure	A physical or biological measurement that follows a standardised procedure and is less open to subjective interpretation by potentially biased observers and study participants.
Observational study	In research about diseases or treatments, this refers to a study in which nature is allowed to take its course. Changes or differences in one characteristic (e.g. whether or not people received a specific treatment or intervention) are studied in relation to changes or differences in other(s) (e.g. whether or not they died), without the intervention of the investigator. There is a greater risk of selection bias than in experimental studies .
Odds ratio (OR)	Odds are a way of representing probability, especially familiar for betting. In recent years odds ratios have become widely used in reports of clinical studies. They provide an estimate (usually with a confidence interval) for the effect of a treatment. Odds are used to convey the idea of 'risk' and an odds ratio of 1 between two treatment groups would imply that the risks of an adverse outcome were the same in each group. For rare events the odds ratio and the relative risk (which uses actual risks and not odds) will be very similar. See also relative risk, risk ratio .
Otoscopy	The clinical examination of the ear canal and tympanic membrane, usually by means of a hand-held otoscope (also known as an otoscope) providing illumination and magnification. Sometimes an attachment is used which permits insufflation of air into the ear canal so that the mobility of the tympanic membrane can be assessed, and this is known as pneumatic otoscopy.
Outcome	The end result of care and treatment and/or rehabilitation. In other words, the change in health, functional ability, symptoms or situation of a person which can be used to measure the effectiveness of care or treatment or rehabilitation. Researchers should decide what outcomes to measure before a study begins; outcomes are then assessed at the end of the study.
P value	If a study is done to compare two treatments then the <i>P</i> value is the probability of obtaining the results of that study, or something more extreme, if there really was no difference between treatments. (The assumption that there really is no difference between treatments is called the 'null hypothesis'.) Suppose the <i>P</i> value was $P = 0.03$. What this means is that if there really was no difference between treatments then there would only be a 3% chance of getting the kind of results obtained. Since this chance seems quite low we should question the validity of the assumption that there really is no difference between treatments. We would conclude that there probably is a difference between treatments. By convention, where the value of <i>P</i> is below 0.05 (i.e. less than 5%) the result is seen as statistically significant. Where the value of <i>P</i> is 0.001 or less, the result is seen as highly significant. <i>P</i> values just tell us whether an observed effect can be regarded as statistically significant or not.
Permanent conductive hearing loss	A type of hearing loss due to permanent defect in the structure of the outer and/or middle ear. This defect interferes with the transmission of sound to the inner ear resulting in a hearing loss which is usually of mild to moderate degree. It may co-exist with conductive hearing loss due to OME or with sensorineural hearing loss or non-organic hearing loss .
Pilot study	A small-scale study to 'test' the instrument, measure or viability of the study. For example, testing out (piloting) a new questionnaire with people who are similar to the population of the study, in order to highlight any problems or areas of concern, which can then be addressed before the full scale study begins.
Placebo	Placebos are fake or inactive treatments received by participants allocated to the control group in a clinical trial that are designed to be indistinguishable from the active treatments being given in the experimental group. They are used so that participants are ignorant of their treatment allocation in order to be able to quantify the effect of the experimental treatment over and above any placebo effect due to receiving care or attention.
Pneumatic otoscopy	See otoscopy .
Point estimate	A best single estimate (taken from research data) for the true value of a treatment effect or other measurement. For example, researchers in one clinical trial take their results as their best estimate of the real treatment effect – this is their estimate at their point in time. The precision or accuracy of the estimate is measured by a confidence interval . Another clinical trial of the same treatment will produce a different point estimate of treatment effect.
Portable tympanometry	Portable and hand-held equipment used to record a tympanogram . It is less precise but quicker than the standard tympanometer. See tympanometry .
Positive predictive value (PPV)	The positive predictive value expresses the probability that someone with a positive test result does have the condition of interest.
Power	See statistical power .
Prospective study	A study in which people are entered into the research and then followed up over a period of time with future events recorded as they happen. This contrasts with studies that are retrospective .

Protocol	A plan or set of steps that defines appropriate action. A research protocol sets out, in advance of carrying out the study, what question is to be answered and how information will be collected and analysed. Guideline implementation protocols set out how guideline recommendations will be used in practice by the NHS, both at national and local levels.
Pure tone audiogram	A graph depicting hearing threshold levels (dBHL) of frequencies ranging from 250 Hz to 8 kHz. The graph may show normal or abnormal hearing, which may be sensorineural or conductive. It also will show the degree of hearing loss.
Pure tone audiometry (PTA)	A procedure to establish the threshold of hearing (compared with normal) at a number of frequencies. Thresholds obtained by air conduction (through headphones) assess the overall level of hearing impairment; those obtained by bone conduction (through a vibrator on the mastoid bone) show inner ear function.
Qualitative research	Qualitative research is used to explore and understand people's beliefs, experiences, attitudes, behaviour and interactions. It generates non-numerical data, e.g. a patient's description of their pain rather than a measure of pain. In health care, qualitative techniques have been commonly used in research documenting the experience of chronic illness and in studies about the functioning of organisations. Qualitative research techniques such as focus groups and in-depth interviews have been used in one-off projects commissioned by guideline development groups to find out more about the views and experiences of patients and carers.
Quality-adjusted life years (QALYs)	A measure of health outcome that looks at both length of life and quality of life. QALYs are calculated by estimating the years of life remaining for a patient following a particular care pathway and weighting each year with a quality of life score (on a zero to one scale). One QALY is equal to 1 year of life in perfect health, or 2 years at 50% health, and so on.
Quantitative research	Research that generates numerical data or data that can be converted into numbers, for example clinical trials or the national Census that counts people and households.
Random allocation or randomisation	A method that uses the play of chance to assign participants to comparison groups in a research study, for example, by using a random numbers table or a computer-generated random sequence. The aim of random allocation is to ensure that the intervention and control groups are similar with respect to all potential confounding variables .
Randomised controlled trial (RCT)	A study to test a specific drug or other treatment in which people are randomly assigned to two (or more) groups: one (the experimental group) receiving the treatment that is being tested, and the other (the comparison or control group) receiving an alternative treatment, a placebo (dummy treatment) or no treatment. The two groups are followed up to compare differences in outcomes to see how effective the experimental treatment was. (Through randomisation, the groups should be similar in all aspects apart from the treatment they receive during the study.)
Relative risk (RR)	A summary measure which represents the ratio of the risk of a given event or outcome (e.g. an adverse reaction to the drug being tested) in one group of subjects compared with another group. When the 'risk' of the event is the same in the two groups the relative risk is 1. In a study comparing two treatments, a relative risk of 2 would indicate that patients receiving one of the treatments had twice the risk of an undesirable outcome than those receiving the other treatment. Relative risk is sometimes used as a synonym for risk ratio .
Retrospective study	A retrospective study deals with the present/past and does not involve studying future events. This contrasts with studies that are prospective .
Rinne test	A clinical test of middle ear function that compares the perceived loudness of sound generated by a tuning fork at 512 Hz as heard by air conduction with that heard by direct transmission to the bone of the skull.
Risk ratio	Ratio of the risk of an undesirable event or outcome occurring in a group of patients receiving experimental treatment compared with a comparison (control) group. The term relative risk is sometimes used as a synonym of risk ratio.
Sample	A part of the study's target population from which the subjects of the study will be recruited. If subjects are drawn in an unbiased way from a particular population, the results can be generalised from the sample to the population as a whole.
Selection bias	Selection bias has occurred if: <ul style="list-style-type: none"> • the characteristics of the sample differ from those of the wider population from which the sample has been drawn, or • there are systematic differences between comparison groups of patients in a study in terms of prognosis or responsiveness to treatment.
Selection criteria	Explicit standards used by guideline development groups to decide which studies should be included and excluded from consideration as potential sources of evidence.
Sensitivity	In diagnostic testing, sensitivity refers to the proportion of cases with the target condition correctly identified by the diagnostic test out of all the cases that have the target condition.

Sensorineural hearing loss	A type of hearing loss due to a defect or damage in the inner ear (cochlea), 8th cranial nerve (the pathway from the inner ear to brain), or the auditory parts of the brain (parts of brain associated with hearing). The hearing loss is permanent and may be of variable degree (mild, moderate, severe or profound). It may co-exist with conductive hearing loss due to OME or with permanent conductive hearing loss or non-organic hearing loss .
Single-blind study	A study in which <i>either</i> the subject (patient/participant) <i>or</i> the observer (clinician/investigator) is not aware of which treatment or intervention the subject is receiving.
Specificity	In diagnostic testing, specificity refers to the proportion of cases without the target condition correctly identified by the diagnostic test out of all the cases that do not have the target condition.
Statistical power	The ability of a study to demonstrate a statistically significant result with the selected study sample given that an association exists in the population.
Structured interview	A research technique where the interviewer controls the interview by adhering strictly to a questionnaire or interview schedule with pre-set questions.
Study population	People who have been identified as the subjects of a study.
Study quality	See methodological quality .
Study type	The kind of design used for a study. Randomised controlled trials , case-control studies , and cohort studies are all examples of study types.
Subject	A person who takes part in an experiment or research study.
Surveillance	A process of close observation leading to early detection of a medical condition and its management, aimed at preventing illness and promoting good health.
Systematic review	A study in which evidence from scientific studies has been identified, appraised and synthesised in a methodical way according to predetermined criteria. May or may not include a meta-analysis .
Systemic	Involving the whole body.
Target population	The people to whom guideline recommendations are intended to apply. Recommendations may be less valid if applied to a population with different characteristics from the participants in the research study, e.g. in terms of age, disease state, social background.
Triple-blind study	A study in which the statistical analysis is carried out without knowing which treatment patients received, in addition to the patients and investigators/clinicians being unaware which treatment patients were getting.
Tympanogram	A curve showing the transmission of energy through the middle ear at various air pressures in the external auditory canal (EAC). It gives a crude but objective assessment of conductive hearing loss, and various middle ear disorders yield distinctive patterns of tympanogram: <ul style="list-style-type: none">• tympanogram A: a symmetrical triangular graph with its peak at zero pressure level represents normal middle ear function• tympanogram B: a flat line on the graph represents the middle ear space filled with fluid, restricting movement of the tympanic membrane under the externally applied pressure• tympanogram C: this is found when there is a reduction of middle ear pressure relative to the air pressure in the EAC, which causes inward retraction of the tympanic membrane; the graph shows the shift of the tympanographic peak into the negative value range, but it is of a normal shape.
Tympanometry	Also known as impedance audiometry , the test measures how readily the middle ear system (the tympanic membrane and the middle ear ossicles) can be set into vibration with a change of air pressure in the external auditory canal (EAC). In the normal ear, maximum sound transmission occurs when the air pressure within the middle ear space is the same as atmospheric pressure, i.e. equal to the air pressure in the EAC.
Validity	Assessment of how well a tool or instrument measures what it is intended to measure.
Variable	A measurement that can vary within a study, e.g. the age of participants. Variability is present when differences can be seen between different people or within the same person over time, with respect to any characteristic or feature that can be assessed or measured.
Watchful waiting	The traditional process of taking no immediate definite action towards treatment but keeping the patient under review. Although consultation with the doctor was not discouraged, the responsibility to take action was often left to the patient (or parents in the case of a child). Wherever reported studies refer to it, the term watchful waiting has been retained in the guideline but it is an expression which has often been misinterpreted for 'no action at all'. Nowadays, active observation is the preferred term.
Weber test	A clinical test of hearing in which a tuning fork, placed on the centre of the head, is used to determine whether or not the patient perceives the sound better in one ear. Taken in conjunction with the Rinne test , it can help to distinguish between conductive and sensorineural hearing loss.

1 Scope and methodology

1.1 Introduction

Otitis media with effusion (OME) is a condition characterised by a collection of fluid within the middle ear without signs of acute inflammation. It is most common in young children, with a bimodal peak at 2 and 5 years of age. Eighty percent of children will have had a least one episode of OME by the age of 10 years. At age 7–8 years, about 8% of children will have middle ear effusions;¹ this incidence increases in winter. The mean duration of effusions is 6–10 weeks but some cases are more persistent.

OME is known to be a fluctuating condition with symptoms that vary with time and with age. The main symptom of OME is impaired hearing because the middle ear effusion causes a conductive hearing loss by reflection of the sound energy at the air–fluid interface. The diagnosis is based on suspicion of hearing loss, clinical history, clinical examination of the ears and appropriate audiometry and tympanometry.

While most cases of OME will resolve spontaneously, some children will need intervention because of the effects of hearing loss. This intervention may take the form of educational and social action or the provision of a hearing aid to minimise the impact of the hearing loss. No non-surgical intervention has yet been shown conclusively to be of benefit. Surgical management usually takes the form of myringotomy and insertion of a ventilation tube (grommet), with or without adenoidectomy.

Children with cleft palate are particularly susceptible to OME because of the impaired function of the Eustachian tube that results from the palatal anomaly, which in turn leads to a failure of middle ear ventilation. Similarly, children with Down's syndrome have a high incidence of OME, partly because of their impaired immunity and mucosal abnormality, with resulting susceptibility to ear infection. These groups of children need particular surveillance for OME so that proper action can be taken.

This guideline attempts to bring together the evidence related to surgical management of OME in children younger than 12 years, and to advise on best and safest practice; treatment decisions need to balance potential benefits against potential risks, reflecting the fact that the degree of benefit usually depends upon the severity and persistence of the condition.

1.2 Aim of the guideline

Clinical guidelines have been defined as 'systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions'.² The guideline has been developed with the aim of providing guidance on the appropriate criteria for referral, assessment and optimum surgical management of children younger than 12 years with a 'suspected diagnosis of OME' for use in the NHS in England, Wales and Northern Ireland.

1.3 Areas within the scope of the guideline

1.3.1 Population

- Children younger than 12 years with a suspected diagnosis of OME and suspected hearing loss including:
 - children with all types of cleft palate
 - children with Down's syndrome.

1.3.2 Healthcare setting

- Primary care and secondary care setting (including both community and hospital settings).

1.3.3 Clinical management (including key interventions)

- Who should be referred for specialist management of OME?
- Components of assessment which can be undertaken by a healthcare professional before being seen by an otolaryngologist. This will include requirements for hearing tests and the use of tympanometry.
- Which children with OME should be offered surgical management and what is the appropriate intervention?
 - selection criteria for insertion of ventilation tube and adenoidectomy (if indicated).
 - exclusion criteria for insertion of ventilation tube and adenoidectomy (if indicated)
 - benefits and harms of ventilation tubes and adenoidectomy (if indicated)
 - benefits and harms of key non-surgical interventions that may be offered instead of surgery: for example active observation ('watchful waiting'), hearing aids, etc.
- Specific information for parents on the likely benefits and possible harms of ventilation tubes and adenoidectomy (if indicated).

1.3.4 Key outcome measures

- Benefits and complications (both short term and long term) of ventilation tube insertion and adenoidectomy (if indicated):
 - Short term* – mortality, hearing loss, earache, ear discharge, infection, fever, nausea, vomiting, etc.
 - Long term* – persistent perforation, scarring, cholesteatoma, speech and language difficulty, behavioural problems, academic performance, poor balance, impact on parents, etc.
- Benefits and harms of key non-surgical interventions for example active observation, hearing aids.
- Resource use and costs.

1.4 Areas outside of the scope of the guideline

- Children with syndromal disorders other than Down's syndrome, for example cranio-facial dysmorphism or polysaccharide storage disease, and children with multiple complex needs are not considered in this guidance since they will need individual and specific management of their overall condition by a multidisciplinary group of experts.

1.5 For whom is the guideline intended?

This guideline is of relevance to those who work in or use the National Health Service (NHS) in England, Wales and Northern Ireland, in particular:

- general practitioners, paediatricians, otolaryngologists, audiologists, speech and language therapists, health visitors and any healthcare professional involved in the care of children younger than 12 years with OME, including members of multidisciplinary team for children with Down's syndrome and cleft palate.
- those responsible for commissioning and planning healthcare services, including primary care trust and local health board commissioners, Wales commissioners, and public health and trust managers
- parents/carers and families of children, school health workers.

A version of this guideline for parents/carers and the public is available, entitled 'Understanding NICE guidance: Surgical management of glue ear in children'. It can be downloaded from the National Institute for Health and Clinical Excellence (NICE) website (www.nice.org.uk/CG060) or ordered via the NHS Response Line (0870 1555 455) quoting reference number N1462.

1.6 Who has developed the guideline?

The guideline was developed by a multi-professional and lay working group (the Guideline Development Group or GDG) convened by the National Collaborating Centre for Women's and Children's Health (NCC-WCH). Membership included one paediatric ENT surgeon as the Guideline Leader, two ENT surgeons with special interest in children with cleft palate and

Down's syndrome, one paediatric audiovestibular physician, two general practitioners, two community paediatricians, one paediatric audiologist, one nurse, two patient/carer/consumer representatives and one external advisor.

Staff from the NCC-WCH provided methodological support for the guideline development process, undertook systematic searches, retrieval and appraisal of the evidence, health economics modelling and, together with the Guideline Leader, wrote successive drafts of the guideline.

All GDG members' interests were recorded on declaration forms provided by NICE. The form covered consultancies, fee-paid work, shareholdings, fellowships, and support from the healthcare industry.

1.7 Guideline development methodology

This guideline was commissioned by NICE and developed in accordance with the guideline development process outlined in the NICE *Technical Manual*.³

1.7.1 Literature search strategy

Initial scoping searches were executed to identify relevant guidelines (local, national and international) produced by other development groups. The reference lists in these guidelines were checked against subsequent searches to identify missing evidence.

Relevant published evidence to inform the guideline development process and answer the clinical questions was identified by systematic search strategies. Additionally, stakeholder organisations were invited to submit evidence for consideration by the GDG provided it was relevant to the clinical questions and of equivalent or better quality than evidence identified by the search strategies.

Systematic searches to answer the clinical questions formulated and agreed by the GDG were executed using the following databases via the OVID platform: MEDLINE (1950 onwards); Embase (1980 onwards); Cumulative Index to Nursing and Allied Health Literature (1982 onwards); PsycINFO (1967 onwards); Cochrane Central Register of Controlled Trials (3rd quarter 2007); Cochrane Database of Systematic Reviews (3rd quarter 2007); and Database of Abstracts of Reviews of Effects (3rd quarter 2007).

Search strategies combined relevant controlled vocabulary and natural language in an effort to balance sensitivity and specificity. Unless advised by the GDG, searches were not date specific. Language restrictions were not applied to searches. Both generic and specially developed methodological search filters were used appropriately.

Searches to identify economic studies were undertaken using the above databases, and the NHS Economic Evaluations Database (NHS EED) produced by the Centre for Reviews and Dissemination at the University of York.

There was no systematic attempt to search grey literature (conferences, abstracts, theses and unpublished trials). Hand searching of journals not indexed on the databases was not undertaken.

All searches were conducted between 14 June 2007 and 12 September 2007. In keeping with the NICE methodology for developing short clinical guidelines, the searches were not rerun before the start of the consultation period. Depending on the question, any evidence published after the date period above was not included. This date period should be considered the starting point for searching for new evidence for future updates to this guideline.

Further details of the search strategies, including the methodological filters employed, can be obtained from the NCC-WCH.

1.7.2 Synthesis of clinical effectiveness evidence

Evidence relating to clinical effectiveness was reviewed using established guides³⁻¹⁰ and classified using the established hierarchical system shown in Table 1.1.¹⁰ This system reflects the susceptibility to bias that is inherent in particular study designs.

Table 1.1 Levels of evidence for intervention studies⁹

Level	Source of evidence
1++	High-quality meta-analyses, systematic reviews of randomised controlled trials (RCTs) or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of RCTs or RCTs with a low risk of bias
1–	Meta-analyses, systematic reviews of RCTs or RCTs with a high risk of bias
2++	High-quality systematic reviews of case–control or cohort studies; high-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
2+	Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2–	Case–control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal
3	Non-analytical studies (for example case reports, case series)
4	Expert opinion, formal consensus

The type of clinical question dictates the highest level of evidence that may be sought. In assessing the quality of the evidence, each study receives a quality rating coded as ‘+++’, ‘+’ or ‘–’. For issues of therapy or treatment, the highest possible evidence level (EL) is a well-conducted systematic review or meta-analysis of randomised controlled trials (RCTs) (EL = 1++) or an individual RCT (EL = 1+). Studies of poor quality are rated as ‘–’. Usually, studies rated as ‘–’ should not be used as a basis for making a recommendation, but they can be used to inform recommendations. For issues of clinical presentation, the highest possible level of evidence is a cohort study (EL = 2++).

For each clinical question, the highest available level of evidence was selected. Where appropriate, for example, if a systematic review, meta-analysis or RCT existed in relation to a question, studies of a weaker design were not included. Where systematic reviews, meta-analyses and RCTs did not exist, other appropriate experimental or observational studies were sought.

The system described above covers studies of treatment effectiveness. However, it is less appropriate for studies reporting diagnostic tests of accuracy. In the absence of a validated ranking system for these types of study, NICE has developed a hierarchy for evidence of accuracy of diagnostic tests that takes into account the various factors likely to affect the validity of these studies (Table 1.2).³

Table 1.2 Levels of evidence for studies of the accuracy of diagnostics tests³

Level	Type of evidence
Ia	Systematic reviews (with homogeneity) ^a of level-1 studies ^b
Ib	Level-1 studies ^b
II	Level-2 studies ^c ; systematic reviews of level-2 studies
III	Level-3 studies ^d ; systematic reviews of level-3 studies
IV	Consensus, expert committee reports or opinions and/or clinical experience without explicit critical appraisal; or based on physiology, bench research or ‘first principles’

^a Homogeneity means there are no or minor variations in the directions and degrees of results between individual studies that are included in the systematic review.

^b Level-1 studies are studies that use a blind comparison of the test with a validated reference standard (gold standard) in a sample of patients that reflects the population to whom the test would apply.

^c Level-2 studies are studies that have only one of the following:

- narrow population (the sample does not reflect the population to whom the test would apply)
- use a poor reference standard (defined as that where the ‘test’ is included in the ‘reference’, or where the ‘testing’ affects the ‘reference’)
- the comparison between the test and reference standard is not blind
- case–control studies.

^d Level-3 studies are studies that have at least two or three of the features listed above.

For economic evaluations, the search strategies adopted were designed to identify any relevant economic studies. Abstracts of all papers identified were reviewed by the health economists and were discarded if they did not relate to the economic question being considered in the guideline. The relevant papers were retrieved and critically appraised. Potentially relevant references in the bibliographies of the reviewed papers were also identified and reviewed. All papers reviewed were assessed by the health economists against standard quality criteria for economic evaluation.¹¹

Evidence was synthesised qualitatively by summarising the content of identified papers in a narrative manner with brief statements accurately reflecting the evidence and producing evidence tables. Quantitative synthesis (meta-analysis) was performed where appropriate.

Summary results and data are presented in the guideline text. More detailed results and data are presented in the evidence tables on the accompanying CD-ROM. Where possible, dichotomous outcomes are presented as relative risks (RRs) with 95% confidence intervals (CIs), and continuous outcomes are presented as mean differences with 95% CIs or standard deviations (SDs). Meta-analyses of the diagnostic accuracy of a test are presented as pooled sensitivities and pooled specificities with corresponding 95% CIs.

1.7.3 Health economics

The aim of the economic input into this short guideline was to inform the GDG of potential economic issues relating to the surgical management of OME, and to ensure that recommendations represented a cost-effective use of scarce resources.

A single clinical question, what is the clinical and cost-effectiveness of various treatments of OME, was prioritised for economic analysis as it was thought that economic considerations would be particularly important in formulating recommendations on this.

A systematic search for published economic evidence was undertaken for this question. For economic evaluations, no standard system of grading the quality of evidence exists and included papers were assessed using a quality assessment checklist based on good practice in decision-analytic modelling.¹²

In addition to the review, a decision-analytic model was developed to compare four treatment options. The results of this analysis are summarised in the guideline text and a detailed description of the model is included in Appendix C alongside reviews of the relevant published economic literature.

1.7.4 Forming and grading recommendations

The evidence tables and narrative summaries for the key clinical questions being discussed were made available to the GDG one week before each scheduled GDG meeting, and all the members were expected to have read these in advance. For each clinical question, recommendations were derived using, and explicitly linked to, the evidence that supported them. Informal consensus methods were used by the GDG to agree evidence statements and recommendations, including the areas where important clinical questions were identified but no substantial evidence existed. The process by which the evidence statements informed the recommendations is summarised in a 'GDG translation' section in the relevant evidence review. Formal consensus methods were used to agree guideline recommendations and select five to seven key priorities for implementation.

1.7.5 External review

This guideline has been developed in accordance with the NICE guideline development process. This has included giving registered stakeholder organisations the opportunity to comment on the scope of the guideline at the initial stage of development and on the evidence and recommendations at the concluding stage.

1.8 Schedule for updating the guideline

Clinical guidelines commissioned by NICE are published with a review date 4 years from date of publication. Reviewing may begin earlier than 4 years if significant evidence that affects guideline recommendations is identified sooner. The updated guideline will be available within 2 years of the start of the review process.

2 Summary of recommendations and care pathways

2.1 Key priorities for implementation (key recommendations)

Formal assessment of a child with suspected OME should include:

- clinical history taking, focusing on:
 - poor listening skills
 - indistinct speech or delayed language development
 - inattention and behaviour problems
 - hearing fluctuation
 - recurrent ear infections or upper respiratory tract infections
 - balance problems and clumsiness
 - poor educational progress
- clinical examination, focusing on:
 - otoscopy
 - general upper respiratory health
 - general developmental status
- hearing testing, which should be carried out by trained staff using tests suitable for the developmental stage of the child, and calibrated equipment
- tympanometry.

Children with persistent bilateral OME documented over a period of 3 months with a hearing level in the better ear of 25–30 dBHL or worse averaged at 0.5, 1, 2 and 4 kHz (or equivalent dBA where dBHL not available) should be considered for surgical intervention.

Once a decision has been taken to offer surgical intervention for OME in children, the insertion of ventilation tubes is recommended. Adjuvant adenoidectomy is not recommended in the absence of persistent and/or frequent upper respiratory tract symptoms.

The following treatments are not recommended for the management of OME:

- antibiotics
- topical or systemic antihistamines
- topical or systemic decongestants
- topical or systemic steroids
- homeopathy
- cranial osteopathy
- acupuncture
- dietary modification, including probiotics
- immunostimulants
- massage.

Hearing aids should be offered to children with persistent bilateral OME and hearing loss as an alternative to surgical intervention where surgery is contraindicated or not acceptable.

Hearing aids should normally be offered to children with Down's syndrome and OME with hearing loss.

Insertion of ventilation tubes at primary closure of the cleft palate should be performed only after careful otological and audiological assessment.

Insertion of ventilation tubes should be offered as an alternative to hearing aids in children with cleft palate who have OME and persistent hearing loss.

2.2 Summary of recommendations

Presentation

Concerns from parents/carers or from professionals about features suggestive of OME should lead to initial assessment and referral for formal assessment if considered necessary. These features include:

- hearing difficulty (for example, mishearing when not looking at you, difficulty in a group, asking for things to be repeated)
- indistinct speech or delayed language development
- repeated ear infections or earache
- history of recurrent upper respiratory tract infection or frequent nasal obstruction
- behavioural problems, particularly lack of concentration or attention, or being withdrawn
- poor educational progress
- less frequently, balance difficulties (for example, clumsiness), tinnitus and intolerance of loud sounds.

All children with Down's syndrome and all children with cleft palate should be assessed regularly for OME.

Diagnosis

Formal assessment of a child with suspected OME should include:

- clinical history taking, focusing on:
 - poor listening skills
 - indistinct speech or delayed language development
 - inattention and behaviour problems
 - hearing fluctuation
 - recurrent ear infections or upper respiratory tract infections
 - balance problems and clumsiness
 - poor educational progress
- clinical examination, focusing on:
 - otoscopy
 - general upper respiratory health
 - general developmental status
- hearing testing, which should be carried out by trained staff using tests suitable for the developmental stage of the child, and calibrated equipment
- tympanometry.

Co-existing causes of hearing loss (for example, sensorineural, permanent conductive and non-organic causes) should be considered when assessing a child with OME and managed appropriately.

Timing of clinical intervention

The persistence of bilateral OME and hearing loss should be confirmed over a period of 3 months before intervention is considered. The child's hearing should be re-tested at the end of this time.

During the active observation period, advice on educational and behavioural strategies to minimise the effects of the hearing loss should be offered.

Which children will benefit from surgical intervention

Children with persistent bilateral OME documented over a period of 3 months with a hearing level in the better ear of 25–30 dBHL or worse averaged at 0.5, 1, 2 and 4 kHz (or equivalent dBA where dBHL not available) should be considered for surgical intervention.

Exceptionally, healthcare professionals should consider surgical intervention in children with persistent bilateral OME with a hearing loss less than 25–30 dBHL where the impact of the hearing loss on a child's developmental, social or educational status is judged to be significant.

Effectiveness of surgical interventions

Once a decision has been taken to offer surgical intervention for OME in children, the insertion of ventilation tubes is recommended. Adjuvant adenoidectomy is not recommended in the absence of persistent and/or frequent upper respiratory tract symptoms.

Children who have undergone insertion of ventilation tubes for OME should be followed up and their hearing should be re-assessed.

Effectiveness of non-surgical interventions

The following treatments are not recommended for the management of OME:

- antibiotics
- topical or systemic antihistamines
- topical or systemic decongestants
- topical or systemic steroids
- homeopathy
- cranial osteopathy
- acupuncture
- dietary modification, including probiotics
- immunostimulants
- massage.

Autoinflation may be considered during the active observation period for children with OME who are likely to cooperate with the procedure.

Hearing aids should be offered to children with persistent bilateral OME and hearing loss as an alternative to surgical intervention where surgery is contraindicated or not acceptable.

Children with Down's syndrome

The care of children with Down's syndrome who are suspected of having OME should be undertaken by a multidisciplinary team with expertise in assessing and treating these children.

Hearing aids should normally be offered to children with Down's syndrome and OME with hearing loss.

Before ventilation tubes are offered as an alternative to hearing aids for treating OME in children with Down's syndrome, the following factors should be considered:

- the severity of hearing loss
- the age of the child
- the practicality of ventilation tube insertion
- the risks associated with ventilation tubes
- the likelihood of early extrusion of ventilation tubes.

Children with cleft palate

The care of children with cleft palate who are suspected of having OME should be undertaken by the local otological and audiological services with expertise in assessing and treating these children in liaison with the regional multidisciplinary cleft lip and palate team.

Insertion of ventilation tubes at primary closure of the cleft palate should be performed only after careful otological and audiological assessment.

Insertion of ventilation tubes should be offered as an alternative to hearing aids in children with cleft palate who have OME and persistent hearing loss.

Information for children, parents and carers

Parents/carers and children should be given information on the nature and effects of OME, including its usual natural resolution.

Parents/carers and children should be given the opportunity to discuss options for treatment of OME, including their benefits and risks.

Verbal information about OME should be supplemented by written information appropriate to the stage of the child's management.

2.3 Research recommendations

Effectiveness of surgical procedures for treating OME

There is a need for good-quality randomised controlled trials documenting the adjuvant effect of adenoidectomy with ventilation tubes compared with ventilation tubes alone in the management of persistent bilateral OME in children. Trials should be sufficiently powered (large) to accurately document a probably small but continuing difference due to adjuvant adenoidectomy, and to identify sub-groups that would particularly benefit from surgical intervention.

Why this is important

Adjuvant adenoidectomy along with ventilation tube insertion is routinely performed in many countries for recurrent episodes of OME and chronic persistent OME, but the practice is not backed by sufficiently precise scientific evidence. A good number of trials have compared ventilation tube insertion alone with ventilation tubes plus adjuvant adenoidectomy, but differences in the study designs, population characteristics, outcomes measured and duration of follow-up among the trials, and particularly insufficient sample sizes to document a probably small but continuing difference, have made it difficult to come to any definite conclusion on the benefit of adjuvant adenoidectomy. There is a need for good-quality randomised controlled trials on larger samples than hitherto, addressing their power deficit not just for the proportion of time with ear fluid but also for the corresponding longer term benefits in hearing level. For this, the trials need to follow up children beyond 6–12 months after ventilation tube insertion as a high proportion of tubes would have fallen out during this time period, and so any advantage that may exist for adjuvant adenoidectomy becomes in principle demonstrable. Up to 2 years is a feasible follow-up period for formal outcome measurement, without high sample attrition. Because adenoidectomy is not risk-free, trials need particularly to be large enough to address sub-groupings that may receive particular benefit. The trials should also evaluate any benefits to respiratory and general health; these are expected from benefits seen in other ENT disease, but not so far demonstrated in uncomplicated OME. However, additional reductions in health care (such as reduced re-insertions of ventilation tubes) can also be documented and would add precision to the cost-effectiveness or cost-utility comparisons. Research is also needed to plot the balance between benefits and harms of ventilation tube insertion, as a function of the length of time for which the tube remains in place and functioning (due to the type of tube design).

Presentation and impact of OME

A combination of randomised trials, cohort studies and qualitative research is needed to accurately measure the developmental impact of persistent bilateral OME in children.

Why this is important

This scientific issue is core to many of the aspects of chronic OME that the GDG considered. Clinically, it has implications both for the baseline assessment (indications for intervention)

and appropriate outcomes in the studies. The GDG felt hampered by the almost exclusive predominance of hearing level as outcome measure in the available trials. A diversity of approaches (such as validated questionnaires, corroborated reports and performance tests) to measure the developmental outcomes should be incorporated in statistically well-controlled longitudinal studies to overcome this problem. The value of such a study relative to research costs might be maximised by bolting it on to a larger population cohort study, for example as a subset selected on a stratified basis. The GDG noted an embedded trial* (of good quality but with a small sample size) of ventilation tubes with speech recognition in noise as a measure of auditory disability: this study showed a greater benefit in children who had a larger baseline deficit on the same test. This result is promising for linking the rationales for sequelae and for treatment, but it needs to be generalised via a larger sample and adequately powered stratification, for example by age. Other markers of developmental impact between hearing (narrow, probably short-term) and speech/language and behaviour (broad, probably long-term) should also be considered, and the possibility that facets of OME other than hearing could contribute to developmental outcomes should not be ignored.

OME in children with Down's syndrome and children with cleft palate

Studies and national audit should evaluate the acceptability, effectiveness and consequences of the various treatment strategies for OME in children with Down's syndrome and children with cleft palate.

Why this is important

The GDG noted particular difficulties in organising research with children with Down's syndrome and those with cleft palate, and this seems to contribute to the lack of high-quality evidence for the questions of this guideline. Randomised controlled trials may not necessarily be the most cost-effective investment, and if undertaken would need to be conducted on a multicentre basis. However, high-quality designed national audits with statistical control for baseline characteristics would enable a fuller understanding of natural histories and sub-types, particularly in cleft palate, and could provide an informative and unbiased account of the consequences of locally varying management practices.

Effectiveness of non-surgical interventions for OME

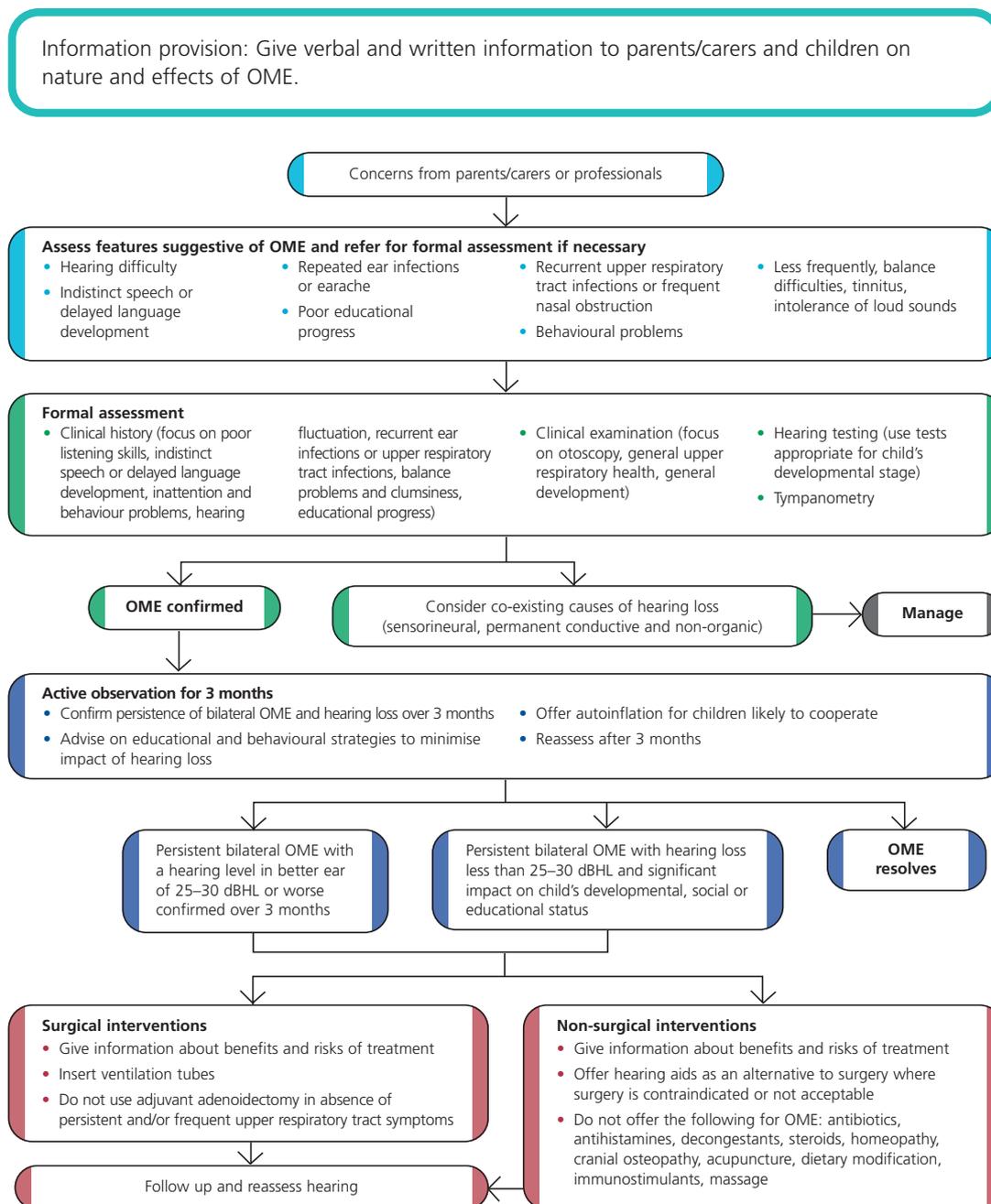
A comparative study on a representative sample of children with OME is required to assess the overall effectiveness of provision of hearing aids as an alternative to surgical treatment.

2.4 Care pathways

The care pathways on pages 11–13 are taken from the NICE Quick Reference Guide version of this guideline (www.nice.org.uk/CG060).

* MRC Multicentre Otitis Media Study Group. Speech reception in noise: an indicator of benefit from otitis media with effusion surgery. *Clinical Otolaryngology and Allied Sciences* 2004;29:497–504.

Care pathway 1. Children with suspected OME



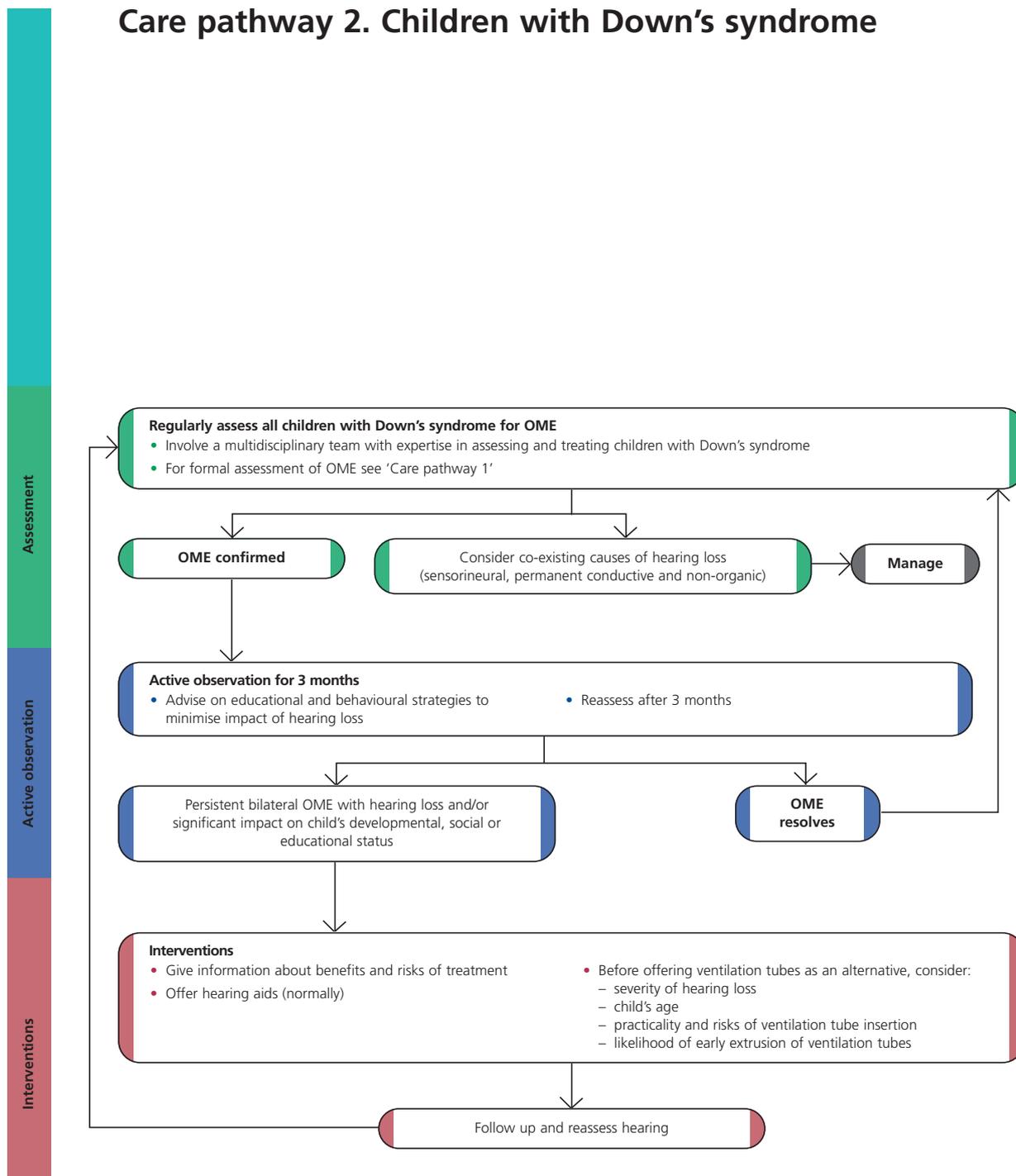
Presentation

Assessment

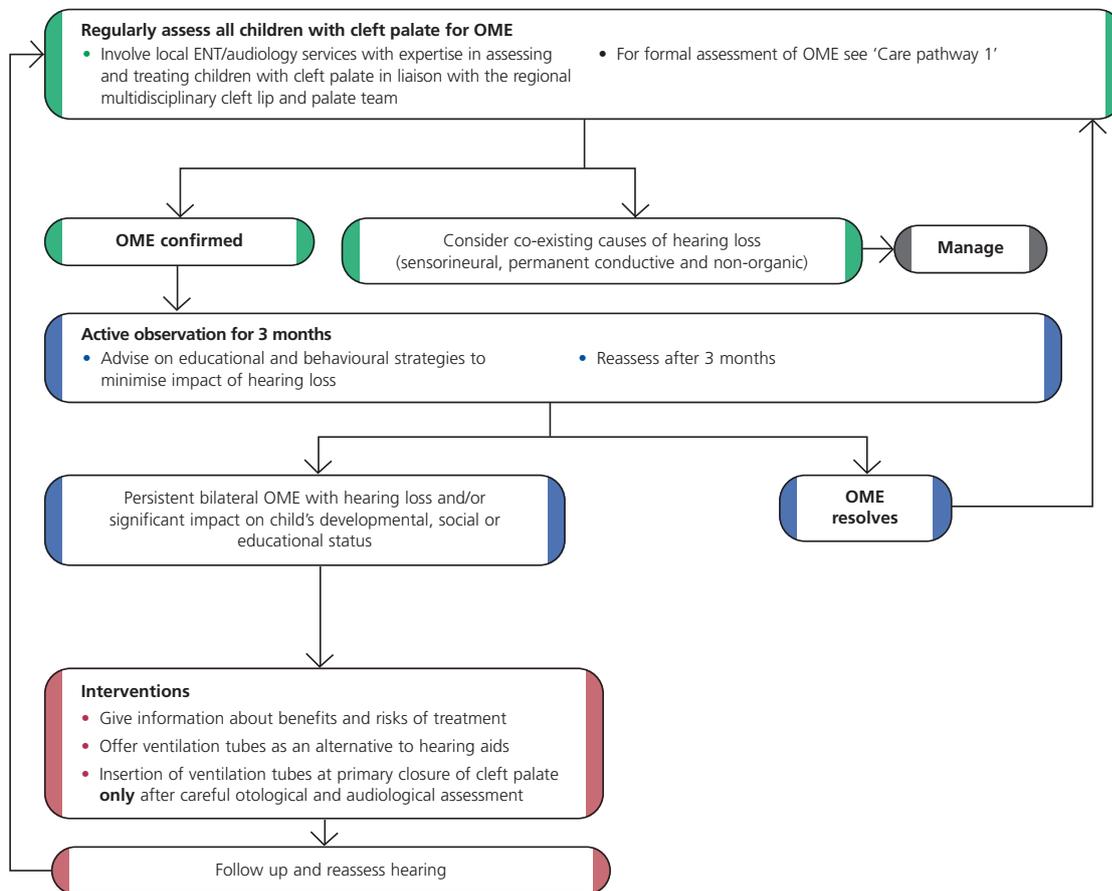
Active observation

Interventions

Care pathway 2. Children with Down's syndrome



Care pathway 3. Children with cleft palate



Assessment

Active observation

Interventions

3 Clinical presentation, diagnosis and management

3.1 Clinical presentation

Clinical question

What is the clinical presentation or the symptoms that raise the suspicion/are suggestive of OME in children?

Introduction

OME is a common childhood condition which usually produces little in the way of symptoms apart from fluctuating hearing loss. As a result, it may not be recognised promptly and may lead to consequences that would have been ameliorated by earlier diagnosis. The hearing loss, while usually mild and fluctuating in severity, can in some cases lead to behavioural and educational difficulties and to delay in the development of communication skills.

The condition is particularly prevalent in children with cleft palate and in those with Down's syndrome; in the latter group there may be more difficulty in obtaining a reliable assessment of the hearing. In both groups, the condition is likely to be both more constant and more prolonged.

This chapter considers the features that will lead to a suspicion of the presence of OME, leading to appropriate assessment.

Narrative evidence

The literature search based on this clinical question yielded 911 hits and, after reviewing the database, hard copies of 65 papers were retrieved. As OME in children is frequently asymptomatic and its presenting features are similar to its long-term impact and sequelae, there was lack of good-quality prospective studies for this clinical question. Many studies were conducted in the 1980s and 1990s and methodologically did not score well based on the NICE criteria for quality appraisal. Apart from individual group studies with and without comparator groups, many of the studies used a correlational design to evaluate the association between duration of OME and its long-term impact. The main reasons for the poor quality of studies were:

- retrospective studies without comparator groups
- the presence of bias (mainly selection bias)
- the small sample size in the studies
- the lack of adjustment for major confounding factors.

After reviewing the 65 papers retrieved, ten studies were selected for inclusion in this review.

A prospective survey¹³ carried out in the UK compared children with severe disease (having bilateral OME with hearing loss) with those with mild disease. The survey found a time lag of approximately 2 years from first suspicion of hearing loss to presentation in ENT departments for children 2–11 years of age. The most common presenting feature was related to hearing loss in both the groups (more than 60% of cases), while less common features were learning difficulty, speech and language problems, slow development and difficulty in articulation. It was found that the hearing loss was most frequently suspected by the child's mother (in about 50% of cases), followed by detection of 20–25% cases during the screening tests. No seasonal variation or periodicity was observed for the presenting features. However, the study population was highly selected and comprised children referred for further treatment. [EL = 3]

A cohort study¹⁴ in New Zealand compared a group of 47 children having bilateral OME with a group of 357 children who were otologically normal. The two groups were similar in socio-

economic status and maternal mental ability and training in child health, and children were assessed every second year for otological status starting from the age of 3 years. At the age of 5 years, children with bilateral OME were found to be significantly disadvantaged in speech articulation, verbal comprehension, intelligence, motor development and some aspects of behaviour (short attention span, restless, fidgety, weak goal orientation, etc.). All the outcomes were evaluated using validated instruments. Longitudinal follow-up of these children was done in another study¹⁵ by the same authors. Children having bilateral OME and significant hearing loss at age 5 years continued to have diminished hearing at 7, 9 and 11 years compared with children with no otological abnormality. They also had significantly lower average scores for verbal comprehension, verbal expression, speech articulation and reading tests. No difference was observed for mean intelligence levels but teachers reported more behaviour problems in children with bilateral OME. [EL = 2+]

Hearing sensitivity was examined every 2 months in a selected group of young children in the USA, starting from the age of 2.5 months till 3 years using age-specific audiometry.¹⁶ The children were classified into five groups:

- normal ($\geq 80\%$ of visits with normal middle ear function, $n = 56$)
- bilateral OME ($\geq 30\%$ of visits with bilateral OME, $n = 20$)
- unilateral OME ($\geq 50\%$ of visits with unilateral OME and no bilateral disease, $n = 8$)
- mixed ($< 30\%$ visits of with bilateral but $\geq 50\%$ with unilateral and bilateral OME, $n = 5$)
- infrequent ($> 20\%$ but $< 50\%$ of visits with a combination of unilateral and bilateral OME, $n = 25$).

There was a high drop-out rate of 43% in the study. A statistically significant difference was observed in the mean average hearing levels between the five groups during the 3 years of assessment. Furthermore, children with bilateral OME had significantly poorer mean hearing levels in all the 3 years of assessment when compared with children considered normal and with no OME. There was also no statistical evidence to show long-term effects of OME on hearing sensitivity after resolution of the disease. [EL = 2+]

A meta-analysis¹⁷ evaluated the effect of early OME on various aspects of speech and language. A total of 14 studies (both correlational and group comparison studies) were included and 11 aspects were analysed. The methodology was described in detail but quality appraisal of individual studies was not carried out. A significant negative association was found between OME and receptive and expressive language at preschool age (2–5 years) in group studies but not in correlation studies. During infancy (1–2 years of age), hearing loss was found to be correlated to receptive and expressive language, but there were no group comparison studies evaluating this association. However, no significant association was found between OME and vocabulary, syntax or speech during the preschool years. [EL = 2+]

A survey¹⁸ was carried out in 3675 primary school children in Turkey to determine the prevalence of OME and analyse its effect on their academic performance. A questionnaire completed by the teachers evaluated the academic performance of children as very good, good, fair, borderline or bad. Children in first grade had a significantly higher prevalence of OME than those in second grade. No statistically significant difference was found between the academic performance of students with and without OME, or between children with OME in the first and in the second grade. The authors attributed the difference in prevalence of OME to a positive immune effect of the BCG vaccine which was given to children in the second grade. [EL = 3] Another cohort study¹⁹ in the Netherlands evaluated the effect of OME on reading and spelling ability of children at 7–8 years of age by comparing three groups of children: those with untreated OME ($n = 151$), those with OME treated with ventilation tubes ($n = 37$) and a control group ($n = 82$). These children were part of an earlier birth cohort and were screened regularly between the ages of 2 and 4 years through quarterly tympanometry examination. Early bilateral OME was found to be associated with lower scores for spelling ability (in two of the three spelling tests) but not for reading ability. Moreover, teachers judged children with OME to have lower writing ability than children in the control group, but not lower reading or arithmetic abilities. [EL = 2+]

Prospective evaluation of vestibular function and balance was conducted in a selected group of 4-year-old children who had monthly evaluation of middle ear status from the age of 2–3 years but were free of middle ear effusion at the time of testing.²⁰ Rotational testing was carried out to

evaluate the gain, phase and asymmetry at three different stimuli: 0.02 Hz at 50° per second, 0.1 Hz at 50° per second and 0.1 Hz at 150° per second. Balance was assessed by the moving posture platform test. Children with a significant history of OME (more than 10% cumulative percentage of time with effusion between infancy and time of testing, $n = 40$) had a lower average gain to a rotational stimulus of 0.1 Hz at 150° per second compared with children without a significant history of OME ($n = 131$). However, no significant difference was observed for other tests of vestibular function or for balance testing. [EL 2+]

A longitudinal cohort study²¹ of all UK births from 5 to 11 April 1970 was carried out to evaluate the association between history of middle ear disease and psychosocial outcomes. History of middle ear disease was assessed subjectively by parental reporting of 'suspected hearing loss' and 'purulent ear discharge', but the diagnosis of OME could not be confirmed. Four aspects of behavioural problems (antisocial, neurotic, hyperactive, poor conduct) were objectively evaluated in children using validated instruments at the age of 5 years ($n =$ about 12 000) and 10 years ($n = 5000$). In addition, cognition tests were administered to both these ages, and behaviour problems were rated at 10 years only by the child's teacher. Data were analysed separately for behaviour problems as a continuous (mean score) and dichotomous variable (cut-off at 90th centile of distribution), and after controlling for the main confounding variables. The largest effect of ear discharge and hearing difficulty was seen for the mean group values of neurotic and hyperactive behaviour at 5 years, while at 10 years it was for neurotic and inattentive behaviour. Analysing behavioural score as a dichotomous variable, all aspects of behavioural problems were strongly associated with ear discharge and hearing loss at both 5 and 10 years, except poor conduct with ear discharge at 5 years and antisocial behaviour with hearing difficulty at 10 years. Significant lower language test scores were found in children with a positive history at age 5 years, but not at 10 years. [EL = 2+]

A well-conducted quasi-qualitative study²² from the UK with large sample size and quantitative data collection aimed to document the similarities and differences in how the signs, symptoms and developmental impact of OME are attributed and construed among three groups of people responsible for its referral and management: parents ($n = 154$), teachers ($n = 118$) and ENT surgeons ($n = 178$). A questionnaire elicited the frequency and concern-value of various presenting features of OME, and factor scores were compared between the three groups. Teachers accorded high importance to language and education problems and parents to hearing problems, compared with the other two groups, and the difference was statistically significant. The smallest differences between the groups were observed for behaviour and balance problems. Both teachers and parents weighted behaviour and balance problems similarly and placed behaviour higher than balance, while ENT surgeons accorded higher weight to balance problems. [EL = 2++]

Evidence summary

Results from a prospective survey indicate that hearing loss is the most common presenting feature of OME in children and it is most frequently suspected by the child's mother, but the evidence is not of high quality.

Good-quality evidence from cohort studies indicates that children with bilateral OME have poor hearing levels compared with other children.

There is conflicting evidence regarding other presenting features of OME in children.

Some prospective studies have found that children with bilateral OME have greater problems in speech and language development than children with no OME, but a good-quality meta-analysis failed to find evidence for an association between OME and various aspects of speech and language development. Children with OME were found to have lower spelling but not reading ability in a prospective cohort, but results of another survey showed no difference in academic performance between children with and without OME. Vestibular function but not balance was found to be impaired in children with a history of OME, and again there were inconsistencies in the results.

Evidence from cohort studies shows that children with bilateral OME or a history of the disease are more likely to have behavioural problems (e.g. poor attention span, hyperactivity, neurotic behaviour) compared with children without the disease or a positive history.

Evidence from a quasi-qualitative study showed significant differences in the perspectives of teachers, parents and ENT surgeons regarding the presenting features of OME in children.

Translation from evidence to recommendations

OME is known to be a fluctuating condition with symptoms that vary with time and with age. Evidence, albeit not of the highest level, demonstrates that OME most often presents as a result of parental/carer concern about hearing loss, which should stimulate further assessment. The evidence shows that parental reports in general have poor sensitivity for hearing loss; in the short term at least, this hearing loss may not be highly symptomatic. However, at clinical presentation, specificity is more relevant so the GDG felt that this evidence did not undermine the clinical recommendation to take parental reports of poor hearing seriously. The GDG recognises that different groups of observers (parents, carers, teachers, health professionals) lay different emphasis on the various features of OME and this has been reflected in the recommendations.

The consensus of the GDG was that the possibility of OME should be considered in children presenting with recurrent upper respiratory tract infections since the two conditions are commonly associated.

Children with Down's syndrome and children with cleft palate are highly susceptible to OME and present particular problems because of the earlier age of onset, prolonged course, greater risk of complications and potential diagnostic difficulties.

Recommendations on presentation

Concerns from parents/carers or from professionals about features suggestive of OME should lead to initial assessment and referral for formal assessment if considered necessary. These features include:

- hearing difficulty (for example, mishearing when not looking at you, difficulty in a group, asking for things to be repeated)
- indistinct speech or delayed language development
- repeated ear infections or earache
- history of recurrent upper respiratory tract infection or frequent nasal obstruction
- behavioural problems, particularly lack of concentration or attention, or being withdrawn
- poor educational progress
- less frequently, balance difficulties (for example, clumsiness), tinnitus and intolerance of loud sounds.

All children with Down's syndrome and all children with cleft palate should be assessed regularly for OME.

Research recommendation on presentation and impact of OME

A combination of randomised trials, cohort studies and qualitative research is needed to accurately measure the developmental impact of persistent bilateral OME in children.

Why this is important

This scientific issue is core to many of the aspects of chronic OME that the GDG considered. Clinically, it has implications both for the baseline assessment (indications for intervention) and appropriate outcomes in the studies. The GDG felt hampered by the almost exclusive predominance of hearing level as outcome measure in the available trials. A diversity of approaches (such as validated questionnaires, corroborated reports and performance tests) to measure the developmental outcomes should be incorporated in statistically well-controlled longitudinal studies to overcome this problem. The value of such a study relative to research costs might be maximised by bolting it on to a larger population cohort study, for example as a subset selected on a stratified basis. The GDG noted an embedded trial* (of good quality but with a small sample size) of ventilation tubes with speech recognition in noise as a measure of auditory disability: this study showed a greater benefit in children who had a larger baseline deficit on the same test. This result is promising for linking the rationales for sequelae and for treatment, but it needs to be generalised via a larger sample and adequately powered stratification, for example by age. Other markers of developmental impact between hearing (narrow, probably short-term) and speech/language and behaviour (broad, probably long-term) should also be considered, and the possibility that facets of OME other than hearing could contribute to developmental outcomes should not be ignored.

* MRC Multicentre Otitis Media Study Group. Speech reception in noise: an indicator of benefit from otitis media with effusion surgery. *Clinical Otolaryngology and Allied Sciences* 2004;29:497-504.

3.2 Diagnosis of OME

Clinical question

How should the diagnosis be confirmed in a child suspected of suffering from OME? What is the predictive accuracy of the various methods?

Introduction

Parents or carers usually suspect hearing loss in a child because of observed failure to hear or to respond to sound. Other features may raise suspicion of hearing loss indirectly and by implication: slow or inaccurate speech development, inattention, poor behaviour, or slow educational progress.

Once suspicion of hearing loss is raised, a medical, developmental and behavioural history should be taken. This will provide details of the child's upper respiratory, otological and general health and, with appropriately targeted questioning, will help to give an impression of the severity of the hearing loss and its impact on the child's life. Not all affected children have noticeable symptoms at home, and the opinions of other professionals, particularly teachers and speech and language therapists may be helpful.

It is a good practice to always undertake a clinical examination. This will give information about the child's developmental and linguistic status and may also give an insight into the child's behaviour. Otoscopy should be performed to evaluate the state of the ears and examination of the nose and throat will help in the assessment of any factors predisposing to OME.

More definitive information about the hearing is normally obtained by testing. Behavioural hearing tests should be appropriate to the child's age and stage of development. They should be carried out by fully trained staff using calibrated equipment in appropriately sound-proofed conditions.

Tympanometry is routinely performed when the hearing is tested. It gives valuable information about the state of the middle ear. Tympanometry does not require a behavioural response from the child or active cooperation and can be performed on very young and inattentive children. While it is not a hearing test as such, it does give deductive information about hearing and is, therefore, valuable in confirming the presence of OME. Portable tympanometry is handheld and easy-to-use equipment, often used during screening programmes. Further technical information on tympanometry is provided in the Glossary.

OME is a common condition and may co-exist with permanent hearing loss (sensorineural or conductive). Assessment is not complete until the examining professional is confident that the information obtained about the level of hearing and the type of hearing loss is accurate.

If doubt remains, electro-physiological means of testing are available in most audiology departments and are particularly useful in hard-to-test children.

Persistent and/or fluctuating OME, resulting in a hearing loss of 25–30 dBHL or greater may have adverse effects on a child's speech and language development, behaviour, emotional development and school progress. This 25–30 dBHL value is of necessity somewhat notional. Hearing levels fluctuate with time and would not predict the impact precisely even if the hearing history over time were known, because of differing susceptibilities.

Narrative evidence

Primary screening of 456 titles and abstracts identified from the systematic search of the literature led to 95 papers being retrieved. These papers were then reviewed against the following predefined selection criteria:

- prospective studies
- reference test and test performed within 48 hours time interval
- reference test to be a standard one (myringotomy, tympanocentesis)
- data extractable for a 2 × 2 table.

Apart from one nested case-control study included for the diagnostic accuracy of clinical history, the rest of the studies are prospective in nature. Most of the studies were conducted on a

selected group of children undergoing myringotomies for OME. Many good-quality studies were identified comparing the diagnostic performance of pneumatic otoscopy and tympanometry against myringotomy as the reference standard. For the other four diagnostic tests – clinical history, tuning fork tests, otoscopy and pure tone audiometry (PTA) – limited evidence was found, with many studies not comparing them against the reference standard or within the stipulated time interval. As a consequence, the study selection criteria for these tests were relaxed.

A total of 26 studies have been included for this review. No study was identified where the diagnostic accuracy of these tests was assessed in children with Down's syndrome or in children with cleft palate. The diagnostic value of a test is given in terms of its sensitivity and specificity, and the results were pooled using the statistical programme MetaDiSc. Meta-analysis was conducted for studies using the same threshold only if the number of such studies was three or more.

3.2.1 Clinical history

Three studies have been included under this section. All the studies evaluated parental reporting of a child's history using a questionnaire, but the instrument used was a validated one in only one of the studies.

In a prospective longitudinal study in the Netherlands,²³ validity of parental reporting on acute otitis media (AOM), OME and hearing impairment were assessed in a group of 150 full-term and 66 preterm infants. The study population was selected at birth and examined at 3 monthly intervals until the age of 24 months. During each visit, parents were asked to report the likely presence of AOM, OME and hearing impairment by means of a questionnaire, and the diagnosis was confirmed by otoscopy, tympanometry and PTA performed by trained personnel. During follow-up, OME was diagnosed 424 times in 131 full-term infants and 143 times in 42 preterm infants. Sensitivity of parental reporting of OME for full-term infants was 16% and specificity 93%, while for preterm infants the values were 18% and 88%, respectively. When the parents were informed about the presence of OME during their preceding visit, sensitivity rose to 20% in full-term and 21% in preterm infants but these changes were not statistically significant. Conversely, when parents were informed about the absence of OME during the preceding visit, there was a decline in the sensitivity values for both full-term and preterm infants, but again the change was not statistically significant. The diagnostic value of parental reporting was also evaluated by stratifying the results according to the various background characteristics (sex, age, birth order, socio-economic status, family history of OME, and the degree of hearing loss). The only difference observed was for positive predictive value (PPV) for birth order: 53% (95% CI 39% to 67%) for the firstborn infant and 80% (95% CI 69% to 90%) for the not-firstborn infant. No other difference was found to be statistically significant. [EL = II]

Another prospective study from the USA²⁴ evaluated the accuracy of parental assessments of a child's hearing in a selected group of 186 children with chronic or recurrent OME. A 6-item quality-of-life questionnaire was completed by the parents or primary caregiver, and their perception of hearing status was correlated with hearing loss evaluated through age-appropriate PTA. Questions on hearing loss had a good test–re-test reliability ($R = 0.79$), but did not correlate with the audiometry results ($R = -0.13$, $P = 0.09$). Only when the caregiver reported hearing to be an 'extreme problem' in their child was the median hearing level significantly greater than the median response (31 dB versus 20 dB). Parent's assessment of change in hearing status after their child's treatment also did not correlate well with changes in the audiometric results ($R = 0.07$, $P = 0.65$). Findings on PTA were also compared against middle ear status using a validated 4-point clinical profile based on otoscopy and tympanometry. When the clinical profile was normal or Level 1, the sensitivity and specificity for normal hearing were 17% and 96%, respectively, while the values for abnormal hearing with a Level 4 profile were 66% and 82%, respectively. [EL = II]

In the third study, a nested case–control study using data from a school screening programme in China,²⁵ the value of parent-suspected hearing loss was assessed in the prediction of OME and PTA thresholds. A self-administered questionnaire and a binary choice question asking about hearing impairment was sent to parents prior to screening that included otoscopy and tympanometry. Children who failed the screening (positive screens) and a random sample of negative screens were sent for re-examination after 2–3 weeks for diagnosis of OME. Re-examination included

history, microscopy, repeat tympanometry and stapedius reflex testing, as well as standard PTA. The study population included 117 cases and 159 controls. The mean PTA conductive threshold level in children with OME was 17.0 dB (range 3.8 to 40.0 dB). Parental suspicion of hearing loss was significantly associated with OME ($P < 0.001$), but the sensitivity was only 20% and specificity 97%. Statistically, no significant association was found between parental reporting and PTA findings ($P = 0.69$) and the sensitivity was 12%. [EL = III]

Evidence summary

Evidence shows that parental reporting of a child's history has limited sensitivity as a diagnostic instrument for OME and hearing impairment, but it correlates moderately with hearing loss and cross-tabulates more strongly with it when hearing levels above 30dB are involved.

3.2.2 Tuning fork tests

Of the three included studies, two did not use a standard reference test for estimation of diagnostic accuracy. In the third study, myringotomy was used as the reference standard but the methodological quality of the study was poor.

The first study was a double-blind prospective study from the USA,²⁶ and the population comprised patients with complaints of hearing loss, tinnitus and/or vertigo randomly selected from a clinic. Hearing assessment was performed using tuning fork tests (Rinne and Weber) at 256, 512 and 1024 Hz by one of the authors, and OME was diagnosed by the second author with otoscopy, PTA and tympanometry as the reference standard. Conductive hearing loss was established in 56 ears. Results for the Rinne test showed that the negative responses (positive test results) decreased as the tuning fork frequency increased. The test had a high specificity of 99% at all three frequencies but values for sensitivity were poor: 43% at 256 Hz, 16% at 512 Hz and about 20% at 1024 Hz. In cases of unilateral conductive deafness, the Weber test was lateralised to the bad ear in 43% of cases at 256 Hz, 54% at 512 Hz and 46% at 1024 Hz. In bilateral conductive deafness, the Weber test was in midline in 82%, 64% and 91% cases at the three frequencies, respectively. [EL = II]

The second study was conducted in the UK²⁷ to investigate the accuracy of tuning fork tests in a group of 125 children with bilateral glue ear presenting to out-patient clinics. Rinne and Weber tests were carried out using a 512 Hz tuning fork by one of the authors, while the reference standard used for comparison was PTA performed by an experienced audiologist. Data from 331 visits were analysed, and the visits of children varied from one to six. Results with the Rinne test showed that most children changed from a positive to a negative response when the level of conductive hearing loss reached a threshold of 19 dB. In all age groups, the sensitivity of the test was 87% and specificity 55%, but these dropped to 80% and 50%, respectively, for children aged 4–5 years. For the Weber test, the sensitivity was 65% and specificity 75%. [EL = II]

In the last study,²⁸ Rinne and Weber tests were performed with a 512 Hz tuning fork on 100 children aged 2–12 years. These children were admitted for myringotomy (reference test) based on clinical diagnosis. Ninety-four children were evaluated with both the tuning fork and reference test, and 83 had OME. The Rinne test had a sensitivity of 89% and a specificity of 73% when the results of both unilateral and bilateral effusion were taken together. In cases of unilateral OME only, the Weber test showed a sensitivity of 79% and a specificity of 91%. [EL = III]

Evidence summary

There is conflicting evidence regarding the diagnostic value of tuning fork tests in children. While one study with EL II showed the Rinne test to have sensitivity and specificity of 87% and 55%, respectively, the other study found 43% sensitivity and 99% specificity. Moreover, the evidence is characterised by a lack of clarity regarding the examiner's capability, the methodology used and the time interval between the tests and the reference test.

3.2.3 Pure tone audiometry

Three studies were included for the diagnostic accuracy of PTA, one EL II and two EL III. As the three studies had used different thresholds, their results were not pooled and they are presented separately.

In the first study from the UK,²⁹ the diagnostic accuracy of pneumatic otoscopy, PTA and tympanometry was assessed as well as that of two new instruments – portable audioscope and portable tympanometer. The study population was a selected group of 100 children who were diagnosed with OME and admitted for myringotomies. PTA was performed at four frequencies (500 Hz and 1, 2 and 4 kHz) and failure at 25 dB was considered pathological, while the threshold for tympanometry was either a type B or a type B/C2 curve. The reference test (myringotomies) was performed within 24 hours of otoscopy and tympanometry, and OME was found in 67.5% of total ears. The highest sensitivity of PTA was 68% at 500 Hz, while the highest value for specificity was 95% at 2 kHz. Overall, PTA had a sensitivity of 52% and specificity of 92% in detecting OME. Sensitivity was better with tympanometry when type B or C2 was taken as the threshold compared with type B as the threshold, while the converse was true for specificity. Pneumatic otoscopy had a sensitivity of about 90% and a specificity of 75%. [EL = II]

Another study from the UK³⁰ evaluated the diagnostic value of PTA, tympanometry and acoustic reflectometry in a group of 50 consecutive children with suspected glue ear. PTA was performed at 500 Hz and 1 and 2 kHz, and hearing loss greater than 20 dB was taken as the threshold, while for tympanometry a type B curve was the threshold. Results were compared with myringotomy performed within 24 hours. Only 67 of 100 ears could be tested by PTA, and it showed a sensitivity of 80% and a specificity of 69% in diagnosing OME (results based on average threshold of all frequencies). Sensitivity and specificity for tympanometry were 88% and 53%, respectively, for the 84 ears examined using this technique. [EL = III]

The third study was conducted in Finland³¹ and compared the results of audiometric and tympanometric examinations done as a part of routine screening for hearing assessment among 687 schoolchildren of grades 1, 4 and 8. The mean age of the study population was 10.5 years (SD 3 years). PTA was performed in an acoustically treated booth and air conduction thresholds were determined from 0.25 to 8.0 kHz. Tympanometry and stapedius reflex measurements were made using different thresholds for a positive test. Otomicroscopy and paracentesis uncovered middle ear effusion (MEE) in 37 ears, but not all children underwent tympanocentesis. With hearing loss more than 15 dB as the threshold for a positive test, PTA showed high diagnostic value in detecting OME with a value of 83% for both the sensitivity and the specificity. [EL = III]

Evidence summary

There is lack of good-quality evidence on the diagnostic value of PTA for OME. Results from the higher quality study (EL II) indicate PTA to have sensitivity of 52% and specificity of 92%, while results from the other two studies with EL III show much higher values for the sensitivity (88% and 83%) but variable values for the specificity (53% and 83%).

3.2.4 Otoscopy

Only three studies could be identified for otoscopy and two of them have a poor quality rating of EL III. One study evaluated the diagnostic accuracy of otoscopy compared with myringotomy, while the other two studies used non-standard reference tests for comparison.

In the first study, from the USA,²⁶ otoscopic findings of OME were compared with the reference standard of PTA plus tympanometry. Although the tests and reference test were carried out within a short time interval, the exact time interval between the tests was not specified. The results of the various tests were blinded from the examiners. Otoscopic findings were classified as normal or abnormal (for OME). The study population comprised patients with complaints of hearing loss, tinnitus and/or vertigo randomly selected from a clinic, but the age range was not specified. Fifty-eight ears were diagnosed to have conductive hearing loss, and otoscopy was able to correctly diagnose 45 ears, resulting in a sensitivity of 78%. The specificity in this study was 95%. [EL = II]

The second study was conducted in the UK³² and evaluated the predictive accuracy of otoscopy, PTA, tympanometry and sonotubometry. The study population was a selected one and the time interval between the tests and the reference standard (myringotomy) was not specified. A total of 209 ears were evaluated but otoscopic results were available for 89 ears only and showed a sensitivity of 100% and a specificity of 28% in diagnosing OME. No data were provided for calculating the diagnostic value of other tests used in the study. [EL = III]

In the last study, which was also conducted in the UK,³³ otoscopy results were compared with findings at myringotomy in 120 children referred with a presumptive diagnosis of OME. These children also underwent audiometric and tympanometric assessment preoperatively but the exact time interval between the tests and myringotomy was not specified. Otoscopic findings were classified as effusion probable, possible or unlikely. When possible effusion ears are included as false positive cases, the sensitivity and specificity of otoscopy in predicting OME were 86% and 87%, respectively. When including possible effusion as true positive cases, the sensitivity increased to 98% but the specificity fell to 36%. [EL = III]

Evidence summary

Good-quality evidence on the diagnostic performance of otoscopy is lacking. The available evidence shows it to have high sensitivity but poor specificity, and the evidence is characterised by variation in the reference test used for comparison and lack of information regarding the time interval.

3.2.5 Pneumatic otoscopy

Description of included studies

Eight studies have been included in this section – three are methodologically of high quality (EL Ib)^{34–36} while the rest are EL II.^{29,37–40} The study population in most studies was a selected one and all studies used findings at myringotomy as the reference standard. In two studies,^{36,39} the tympanic membrane was visualised by two examiners at two different places and their results were given separately. In one study,³⁹ the diagnostic value of different appearances of the tympanic membrane (colour, position, mobility) were calculated individually. The threshold for diagnosing OME with pneumatic otoscopy was based on colour, appearance, and mobility of the tympanic membrane in five studies, while in the other three it was based solely on the criterion of immobility or decreased mobility. Owing to the heterogeneity of the criteria used for diagnosing OME, meta-analysis of the results was performed separately for these two thresholds.

Review findings

(a) Pneumatic otoscopy versus myringotomy (threshold: presence or absence of OME):

The sensitivity of individual studies ranged from 85% (95% CI 78% to 90%) to 98% (95% CI 94% to 100%), while the specificity ranged from 71% (95% CI 62% to 80%) to 81% (95% CI 74% to 87%). From the meta-analysis, the pooled sensitivity was 91% (95% CI 90% to 93%) but there was strong evidence of statistical heterogeneity ($\chi^2 = 32.57$, $P < 0.001$). The pooled specificity was 77% (95% CI 74% to 80%) and there was no evidence of statistical heterogeneity ($\chi^2 = 5.13$, $P = 0.527$) (Figure 3.1).

(b) Pneumatic otoscopy versus myringotomy (threshold: immobility or decreased mobility of tympanic membrane):

In the three studies included for meta-analysis, the sensitivity and specificity ranged from 87% (95% CI 80% to 92%) to 99% (95% CI 97% to 100%), and 69% (95% CI 39% to 91%) to 90% (95% CI 85% to 94%), respectively. There was strong evidence of statistical heterogeneity ($P = 0.000$) for both sensitivity and specificity when the results of individual studies were combined. The pooled sensitivity was 95% (95% CI 93% to 96%) and pooled specificity 83% (95% CI 79% to 86%) (Figure 3.2).

Evidence summary

High-quality evidence shows pneumatic otoscopy to have a high pooled sensitivity of 91% and a moderate pooled specificity of 77% for diagnosing OME when the criteria for diagnosis include mobility, colour and appearance of tympanic membrane. When the criterion is restricted to tympanic membrane mobility, the pooled sensitivity and specificity improves to 95% and 83%, respectively, but the evidence is characterised by variation in the results of individual studies.

3.2.6 Tympanometry

Description of included studies

As a large number of studies were identified comparing the diagnostic value of tympanometry with myringotomy as the reference standard, only studies of EL II and above were included.

Thirteen studies have been included in this section and three of them evaluated the diagnostic accuracy of portable tympanometry.⁴¹⁻⁴³ There are eight studies with evidence level Ib,^{34,36,41-46} while the rest are EL II.^{29,32,38,40,47,48} Most of the studies were carried out in groups of selected children undergoing myringotomies for suspected OME. Tympanometry was performed at the conventional frequency of 226 Hz in most studies, although a few did not specify the frequency. In one study,³⁸ higher frequencies were also used, but data have been taken for the conventionally used frequency only. Various thresholds for diagnosing OME were used in these studies: seven used tympanogram type B, four type B or C2 and one type B or C. Three studies evaluated diagnostic accuracy results for different peak admittance or compliance values of 0.1, 0.2 and 0.3, and of different gradients such as 0, 0.1, 0.2, etc.

Review findings

(a) Tympanometry versus myringotomy (threshold: tympanogram type B or C2):

For the individual studies, sensitivity ranged from 89% (95% CI 82% to 94%) to 95% (95% CI 90% to 98%), while there was wide variation in the results for specificity – from a low value of 23% (95% CI 13% to 36%) to a high of 88% (95% CI 74% to 96%). Meta-analysis showed no evidence of statistical heterogeneity for sensitivity and the pooled value was 93% (95% CI 91% to 95%). For specificity the pooled value was 70% (95% CI 65% to 75%) but there was strong evidence of heterogeneity ($\chi^2 = 88.20$, $P < 0.001$) (Figure 3.3). One study with evidence level II³⁸ used tympanogram type B or C as the threshold, and the results showed a sensitivity of 82% and specificity of 61%. The results of this study were not pooled with the other four studies because of the different threshold used.

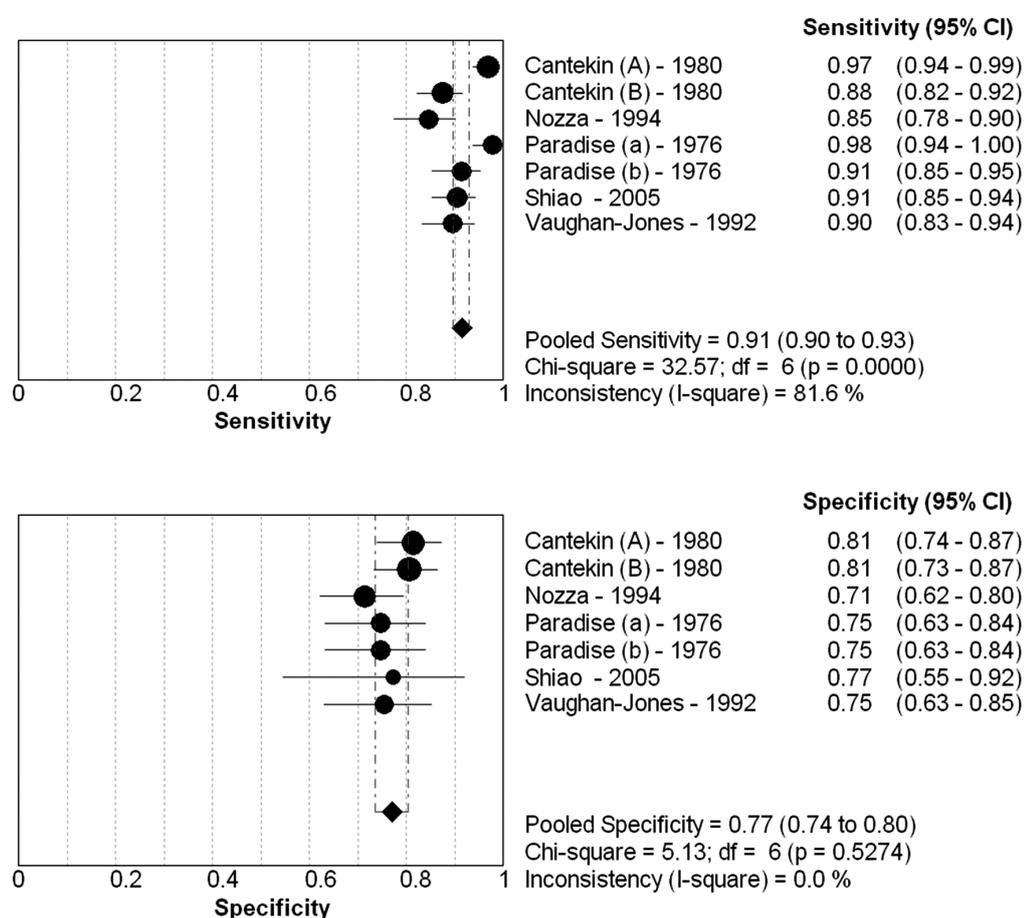


Figure 3.1 Pneumatic otoscopy versus myringotomy (threshold: presence or absence of OME)

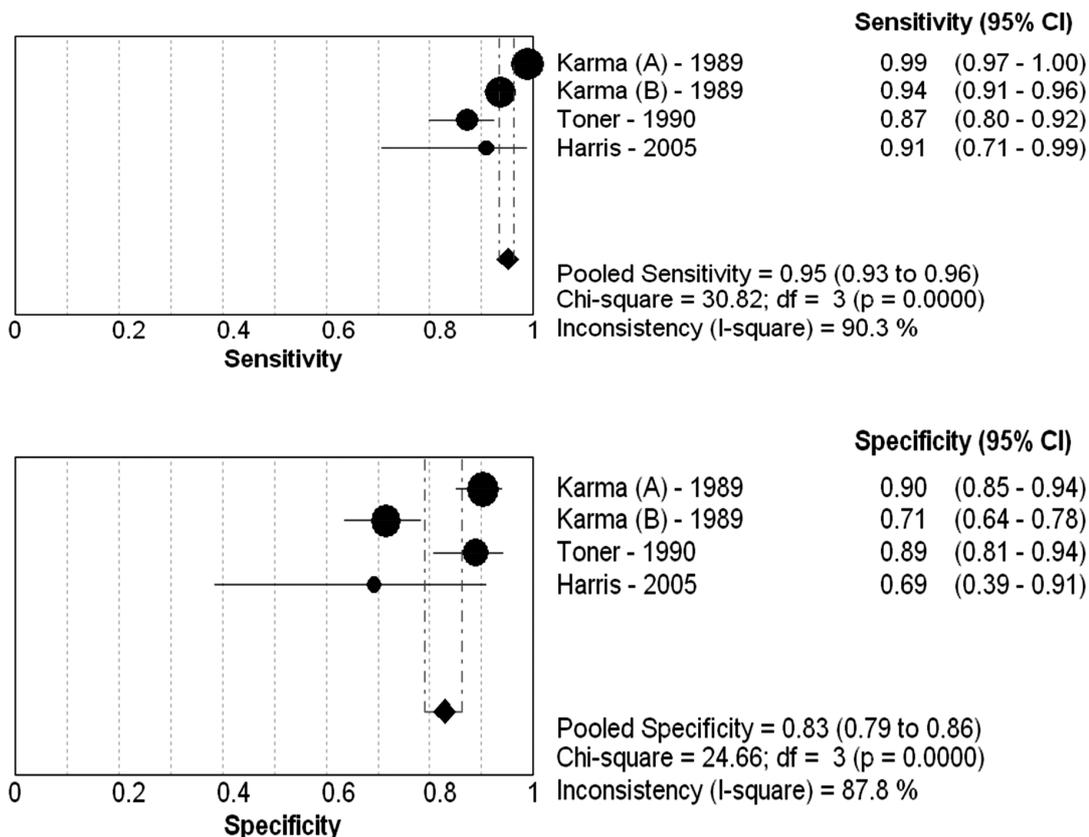


Figure 3.2 Pneumatic otoscopy versus myringotomy (threshold: immobile or mobile tympanic membrane)

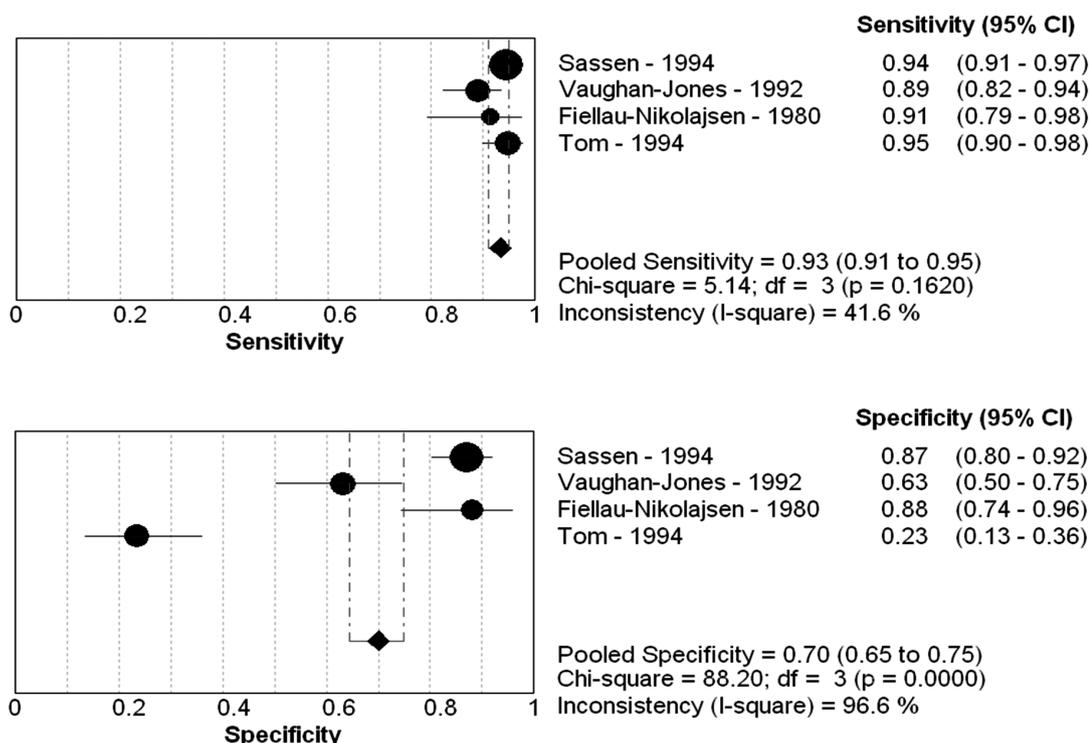


Figure 3.3 Tympanometry versus myringotomy (threshold: tympanogram type B or C2)

(b) Tympanometry versus myringotomy (threshold: tympanogram type B):

Wide variation was seen in the values of sensitivity and specificity of individual studies. The sensitivity ranged from 55% (95% CI 32% to 76%) to 91% (95% CI 89% to 93%), while the specificity ranged from 63% (95% CI 55% to 71%) to 100% (95% CI 75% to 100%). Significant statistical heterogeneity was seen for both sensitivity and specificity ($P < 0.001$ for both) on combining the results of individual studies. The pooled values for the sensitivity and specificity were 84% (95% CI 82% to 86%) and 79% (95% CI 76% to 83%), respectively (Figure 3.4).

(c) Tympanometry versus myringotomy (threshold: peak compliance or admittance < 0.3):

One study⁴⁴ showed poor values of sensitivity and specificity at this threshold: 35% (95% CI 21% to 50%) and 24% (95% CI 12% to 39%), respectively. The other two studies, which were both by the same author,^{34,35} had similar results for both sensitivity (70% and 73%) and specificity (80% and 80%). Statistically significant heterogeneity ($P < 0.001$) was observed for both sensitivity and specificity when the results of individual studies were pooled together. The summary value for sensitivity was 65% (95% CI 59% to 71%) and that for specificity was 67% (95% CI 60% to 74%) (Figure 3.5).

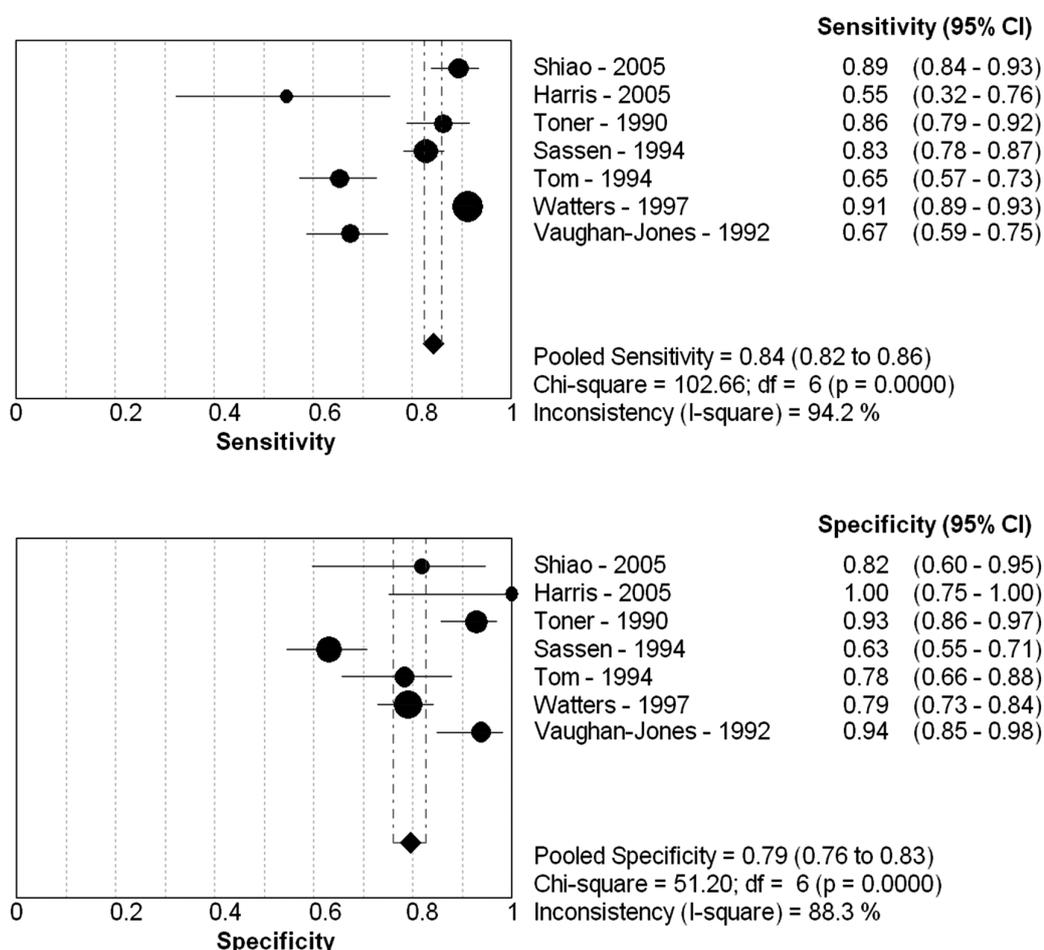


Figure 3.4 Tympanometry versus myringotomy (threshold: tympanogram type B)

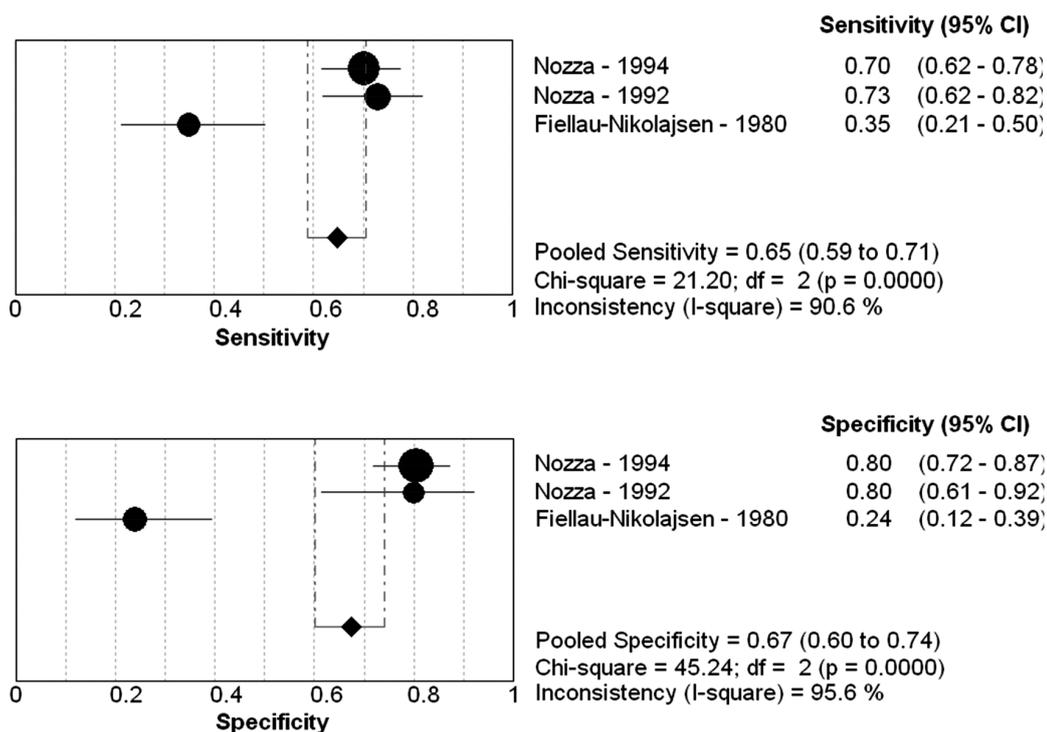


Figure 3.5 Tympanometry versus myringotomy (threshold: peak admittance or compliance < 0.3)

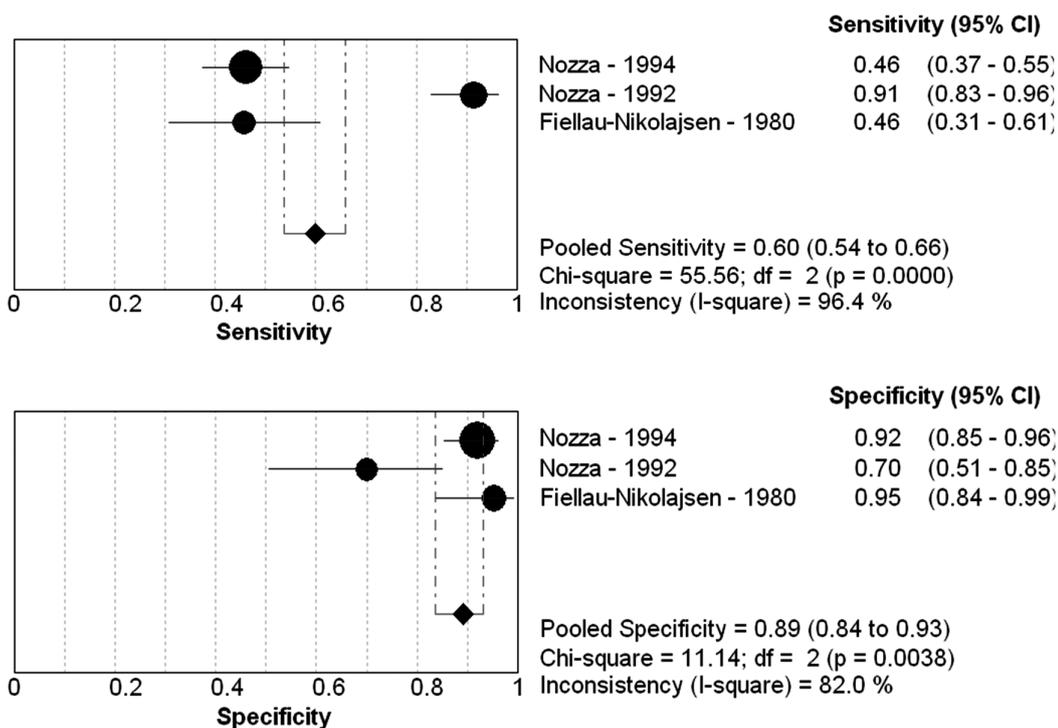


Figure 3.6 Tympanometry versus myringotomy (threshold: peak admittance or compliance < 0.2)

(d) Tympanometry versus myringotomy (threshold: peak compliance or admittance < 0.2): Two studies^{34,44} showed low values for sensitivity (46% in both) but high specificity (92% and 95%). Sensitivity and specificity in the third study was 91% (95% CI 83% to 96%) and 70% (95% CI 51% to 85%), respectively. On pooling the results, strong evidence of statistical heterogeneity was seen for both diagnostic indices. The pooled sensitivity was 60% (95% CI 54% to 66%) and the pooled specificity was 89% (95% CI 84% to 93%) (Figure 3.6).

(e) Portable tympanometry versus myringotomy:

Meta-analysis could not be performed for the three studies included for diagnostic value of professional tympanometry (all with evidence level Ib) as they had used different thresholds. One of the studies⁴² showed a sensitivity of 91% and specificity of 73% with tympanogram type B as the threshold. When type C2 was also included as the criterion for diagnosing OME, the sensitivity increased to 94% but the specificity dropped to 53%. Similar results were seen in the second study with tympanogram type B or C2 as the threshold.⁴³ The values for sensitivity and specificity were 94% and 48%, respectively. In the last study,⁴¹ flat curve type B only was used to diagnose OME and it showed a sensitivity of 78% with a specificity of 82%.

Evidence summary

There is high-quality evidence (meta-analysis of diagnostic studies with EL I and EL II) to show that tympanogram type B or C2 has a pooled sensitivity of 93% and a pooled specificity of 70% for diagnosing OME. When type B only was used for diagnosis, the sensitivity and specificity changed to 84% and 79%, respectively, and great variation was observed in the results of individual studies.

There is conflicting evidence on the diagnostic performance of tympanometry with the other thresholds (peak admittance/compliance levels).

The sensitivity of portable tympanometry is very high when type B or C2 is used as the threshold, but the specificity is low.

3.2.7 Translation from evidence to recommendations

The assessment of OME depends on the integration of diverse measures and observations and cannot be determined by a single technique.

Although parental reporting of hearing loss has limited sensitivity, history taking is an indispensable part of the evaluation of children with OME and the GDG regards targeted questioning as helpful in assessing disability.

Despite the limited evidence on the diagnostic accuracy of otoscopy for OME, its use is essential to identify any other ear conditions. The evidence on tuning fork testing is insufficient to support its routine use in young children.

The GDG recognised that the scope of the guideline does not include details of audiometric tests; these are laid out in various standards with due regard for what is suitable for the child's stage of development.

The literature shows comparable results for diagnostic accuracy between tympanometry and pneumatic otoscopy. Tympanometry is widely available and practised in the UK, unlike pneumatic otoscopy. The GDG agreed that the inclusion of pneumatic otoscopy would not add diagnostic value.

A proportion of children referred with suspected OME will also have underlying sensorineural or permanent conductive hearing loss. The GDG wished to emphasise the need to identify any such component.

Children with Down's syndrome present particular problems in diagnosis because of small ear canals, wax accumulation and audiometric testing difficulties, and need expert assessment. Ideally, they should undergo audiometry with the same level of rigour as other children.

Recommendations on diagnosis of OME

Formal assessment of a child with suspected OME should include:

- clinical history taking, focusing on:
 - poor listening skills
 - indistinct speech or delayed language development
 - inattention and behaviour problems
 - hearing fluctuation
 - recurrent ear infections or upper respiratory tract infections
 - balance problems and clumsiness
 - poor educational progress
- clinical examination, focusing on:
 - otoscopy
 - general upper respiratory health
 - general developmental status
- hearing testing, which should be carried out by trained staff using tests suitable for the developmental stage of the child, and calibrated equipment
- tympanometry.

Co-existing causes of hearing loss (for example, sensorineural, permanent conductive and non-organic causes) should be considered when assessing a child with OME and managed appropriately.

3.3 Management of OME

Clinical question

What is the clinical effectiveness and cost-effectiveness of various treatments of OME?

Introduction

OME is a very common condition which is usually mild and which usually resolves spontaneously. It is often transient, sometimes recurrent and sometimes persistent. The symptoms it produces vary in severity between individuals and there are no easily applied, simple clinical measures of disability as opposed to hearing impairment. There are no strong predictors of persistence of symptoms for the individual patient. There is poor evidence to allow identification of which patients are most likely to benefit from active treatment. The clinical judgement to be made requires a balance between alleviating prolonged hearing loss which is having adverse effects on the child, and performing surgery on infants and children for a condition which is known in many instances to resolve spontaneously. It is clear that surgical intervention is not required in every case.

This guideline has been commissioned to review specifically the evidence for surgical management of OME, but this cannot be done satisfactorily without some comparison with non-surgical options particularly with 'no treatment'.

Persistence of symptoms is the chief reason for considering surgery. The purpose of surgery is to reduce the hearing loss, minimising the likelihood of recurrence of OME while minimising risk of any intervention.

There are misconceptions over the role of ventilation tube insertion, which is not curative of OME but renders the child symptom free while natural resolution continues. Recurrence of OME after extrusion of the ventilation tube is not uncommon and repeat surgery may be required. Surgery can be demonstrated to improve hearing and other symptoms but the benefits of surgery must be set against the risks of short- and long-term complications.

This chapter attempts to identify the treatment options, the level of risk and the consequent cost implications.

Systematic literature searches for the questions related to effectiveness of various interventions (both surgical and non-surgical) were carried out separately for children with Down's syndrome and those with cleft palate using no study restriction, and for those without these abnormalities

using the study filter of RCTs and cohort studies. Some of the studies were also identified with the help of GDG members. After primary and secondary screening of the studies, 16 studies were included in this section.

3.3.1 Appropriate time for intervention

Clinical question

What is the appropriate time for intervening (medical or surgical treatment) in children with OME?

Eleven studies were retrieved after primary screening of the literature search for this question. After assessing the hard copies of these studies, one systematic review was selected for inclusion.

Description of included studies

A well-conducted systematic review⁴⁹ estimated the natural history and spontaneous resolution rate of untreated OME in children aged 0–18 years with evidence drawn from cohort studies and RCTs having an untreated control group. Retrospective, non-randomised comparative studies and non-English language papers were excluded. The inclusion criteria were studies with OME of new onset or unknown prior duration diagnosed by tympanogram type B or an algorithm containing tympanometry, and chronic bilateral OME documented prospectively for 3 months or longer in groups/subgroups managed with watchful waiting. Primary screening of the articles identified from the systematic literature search was carried out by two reviewers, and data were independently extracted by two examiners with discrepancies resolved by mutual consensus. Resolution of OME determined through tympanometry was the preferred outcome, followed by an OME algorithm or pneumatic otoscopy. Meta-analysis was performed using a random effects model, and $P < 0.05$ was taken as significant for the test of heterogeneity. [EL 2++]

Review findings

Altogether 27 studies were included in the review: 18 cohort studies of OME natural history, seven cohorts or RCT control groups of chronic OME natural history, and two enrolment cohort studies of OME therapy. Duration of OME was calculated starting from the time of entry into the study irrespective of its prior duration. Many studies excluded children with baseline OME, immune deficiencies, cleft palate, craniofacial anomalies and Down's syndrome. When OME resolution was defined using a strict criterion (change of tympanogram from type B to A), the combined resolution rate was 20% (95% CI 7% to 34%) at 3 months and 28% (95% CI 17% to 40%) at 6 months for newly diagnosed OME of unknown duration, but there was evidence of significant statistical heterogeneity for both these results. With a relaxed criterion for resolution (change of tympanogram from type B to A/C1), the resolution rate at 3 months was similar at 28% (95% CI 14% to 41%) but increased to 42% (95% CI 35% to 49%) at 6 months and 56% (95% CI 30% to 82%) at 9 months. Heterogeneity was observed for the 3 month cumulative rate only. When the criterion for resolution was further relaxed (tympanogram type B to non-B), the combined resolution rate increased at all three time periods and there was no evidence of heterogeneity: 56% (95% CI 51% to 61%) at 3 months, 72% (95% CI 68% to 76%) at 6 months and 81% (95% CI 77% to 85%) at 9 months. Studies rarely provided data for resolution beyond 12 months of observation. One of the included studies reported a 3 year resolution rate of 51% using a strict criterion and 65% using a relaxed criterion, but no information was provided for follow-up between 6 months and 3 years as many children had undergone surgery during this time period. Chronic bilateral OME cases documented for 3 months or longer had spontaneous resolution rates comparable with rates of newly diagnosed OME cases when the criterion for resolution was change of tympanogram from type B to A. The resolution rates were 19% (95% CI 13% to 24%) at 3 months, 25% (95% CI 13% to 39%) at 6 months, 31% (95% CI 19% to 43%) at 1 year and 33% (95% CI 27% to 39%) at 2 years. Evidence of statistical heterogeneity was found for the 1 year resolution rate only. In one of the studies, follow-up was done until 10 years using pneumatic otoscopy findings as the criterion for resolution. This study found a resolution rate of 59% at 4 years, 69% at 5 years, 85% at 7 years, and 95% at 10 years.

Evidence summary

Results from a well conducted systematic review show that the natural course of newly diagnosed OME of unknown duration is favourable for spontaneous resolution. When the criterion of resolution was taken as change of tympanogram from type B to non-B, the cumulative resolution rate was 56% at 3 months, 72% at 6 months and 81% at 9 months. Lower rates were observed with other criteria for resolution, while cases with documented chronic bilateral OME had much lower resolution rates at corresponding time intervals.

Translation from evidence to recommendations

At first presentation it is uncertain how long the condition has been present and a number of cases will resolve spontaneously. The evidence shows that a period of observation for 3 months will allow resolution of many cases and obviate the need for clinical intervention. A waiting period of more than 3 months would entail the child's remaining with a hearing impairment for longer than many parents or carers would accept because of the risk of increased behavioural and educational problems.

The presence of bilateral disease predicts a higher likelihood of more severe hearing loss and longer persistence and so should be considered for treatment.

The GDG agreed that during the period of observation, advice on educational and behavioural strategies to minimise the effects of the hearing loss should be offered to parents and carers.

Recommendations on timing of clinical intervention

The persistence of bilateral OME and hearing loss should be confirmed over a period of 3 months before intervention is considered. The child's hearing should be re-tested at the end of this time.

During the active observation period, advice on educational and behavioural strategies to minimise the effects of the hearing loss should be offered.

3.3.2 Factors predicting benefit from surgical intervention

Clinical question

Which of the children with OME can be predicted to get high benefit from surgical intervention?

Many studies looking at risk factors for the persistence of OME in childhood were found, but only one study attempted to identify the children who might benefit more from surgery than from watchful waiting.

Description of included studies

An individual-patient data meta-analysis of RCTs⁵⁰ was carried out to identify subgroups of children with OME that might benefit more than others from treatment with ventilation tubes. Trials comparing short-term ventilation tubes with watchful waiting for OME in children had to be randomised to a high standard for inclusion, and those where children had undergone adenoidectomy or where individual-patient data were unavailable were excluded. The population comprised children aged 0–12 years with tympanometrically and/or otoscopically confirmed persistent bilateral OME. Separate analysis was conducted for trials that randomised children (short-term bilateral ventilation tubes versus watchful waiting) and trials that randomised ears (unilateral ventilation tube versus contralateral ear as control). Outcomes studied were mean time spent with effusion, mean hearing levels and language development. Data on subgroups of children distinguished by effect modifier variables was collected before randomisation in the included trials. Predictors of poor outcome (defined as score worse than the median values for the three outcomes) were identified using regression modelling, and subsequently the effects of ventilation tubes were analysed within each of the subgroups to identify possible interaction/effect modification. No details were provided about the application of inclusion criteria or quality appraisal of individual studies. [EL = 1+]

Review findings

Individual-patient data were available for seven RCTs ($n = 1234$ children) and all of these trials had been conducted in Europe. The mean time spent with effusion was statistically significantly lower in children with ventilation tubes than children in the watchful waiting group (19.7 weeks versus 37 weeks, $P < 0.001$) at the 12 month follow-up. Predictors of poor outcome for mean time spent with effusion were attending day-care centre, gender and seasonality, but none of these had an independent effect on the outcome.

The mean hearing level at the 6 month follow-up was significantly better in children with bilateral ventilation tubes compared with children in the watchful waiting group (26.6 dB versus 31.1 dB, $P = 0.001$), but there was no difference at the 12 or 18 month follow-up. Baseline hearing loss, attendance in day care, age, season, and having been breastfed were found to be the predictors of poor hearing, but only day-care attendance showed statistical evidence for effect modification. A difference of 7 dB in the hearing level was found between the two groups in children attending day care compared with a difference of only 0.9 dB in children not attending day care ($P = 0.02$ for interaction).

In trials where a unilateral ventilation tube was inserted and the contralateral ear was taken as control, poor predictors were baseline hearing level, age and gender. All these trials had enrolled older children at school. The mean hearing improvement in ventilation tube ears versus other ears at 6 month follow-up was 10 dB when the baseline hearing loss was 25 dB or more, compared with 4 dB hearing gain when the baseline hearing loss was less than 25 dB ($P = 0.02$ for interaction). Moreover, the mean hearing level in children with a functioning ventilation tube was significantly better (6 dB) than that of children with a non-functioning ventilation tube, both after 6 and 12 month follow-up ($P = 0.001$ for both).

No significant difference was found in language development between the children with a ventilation tube and children in the watchful waiting group.

Evidence summary

There is good-quality evidence to show that younger children attending day-care centres and schoolchildren with a hearing loss of 25 dB or greater persisting bilaterally for at least 3 months might benefit more from ventilation tube insertion. The evidence is limited by the potential for omission of data from other relevant trials.

Translation from evidence to recommendations

The GDG recognises that not all children with OME will require surgery and thus attempted to identify those most likely to benefit. By 12–18 months after intervention, no significant benefit in hearing levels has been demonstrated from surgery unless the ventilation tubes are still in place and functioning. There is weak evidence from trial data that children attending day nursery care and children with confirmed persistence of OME with an averaged hearing loss of 25 dB or more are the most likely to gain benefit from surgery.

The GDG recognises that there are some groups of children with OME who may benefit from early ventilation tube insertion. Examples are children requiring urgent surgery for airway impairment secondary to adeno-tonsillar hypertrophy and children with coexistent severe and profound hearing loss. Detailed study of such groups is outside the scope of this short guideline, which is not intended to restrict clinical judgement in exceptional circumstances.

Recommendations on which children will benefit from surgical intervention

Children with persistent bilateral OME documented over a period of 3 months with a hearing level in the better ear of 25–30 dBHL or worse averaged at 0.5, 1, 2 and 4 kHz (or equivalent dBA where dBHL not available) should be considered for surgical intervention.

Exceptionally, healthcare professionals should consider surgical intervention in children with persistent bilateral OME with a hearing loss less than 25–30 dBHL where the impact of the hearing loss on a child's developmental, social or educational status is judged to be significant.

3.3.3 Effectiveness of surgical interventions

Clinical question

What is the effectiveness of various surgical procedures in children with OME?

Five studies have been included under this section: one systematic review on effectiveness, two studies on parents' perception about ventilation tubes, and two studies on the sequelae of ventilation tube insertion. An attempt was made to present the results of the systematic review stratified by the age of the participants and duration/severity of OME, but it was not possible to do so owing to the small number of relevant studies and different outcomes measured in them. The available evidence for myringotomy or tonsillectomy is not presented as these interventions are not used alone for the management of OME.

Description of included studies

A high-quality systematic review⁵¹ was carried out to evaluate the effectiveness of ventilation tube insertion compared with myringotomy or non-surgical treatment/watchful waiting in children aged 1–12 years with unilateral or bilateral OME. All identified RCTs comparing unilateral ventilation tube insertion (randomised by ears) with no surgery or myringotomy in the other ear as control, or bilateral ventilation tube insertion (randomised by children) with non-surgery in the control group for comparisons were included. The review was limited to studies using common types of ventilation tubes only (mean function time of 6–12 months) and where the diagnosis of OME was confirmed using otoscopy or pneumatic otoscopy and tympanometry or otomicroscopy. Children having a short course of antibiotics or analgesics for episodes of acute infections or in the pre-randomisation period, and those using decongestants freely were also considered for inclusion. The outcomes studied were hearing level, duration of effusion, wellbeing (quality of life) and prevention of developmental sequelae possibly attributable to the hearing loss (language development, verbal intelligence, behaviour, etc.). [EL = 1++]

Review findings

A total of 13 RCTs were included in this review but they were a heterogeneous group of trials with different designs and outcome measures. Concerns were expressed regarding the generalisability of the review results because of the low proportions of the study populations opting for participation, high drop-out rates during follow-up and the provision of an additional intervention in the control groups in some of the included trials. None of the included trials had evaluated effectiveness of ventilation tubes in children with unilateral OME. The studies were grouped according to the study design into those randomised by ears to unilateral ventilation tube with contralateral ear as control (seven trials) and those randomised by children to bilateral ventilation tubes or watchful waiting (six trials). These were further classified based on whether all children had adenoidectomy or whether the children were further randomised to adenoidectomy or not – unilateral ventilation tube insertion where all participants had adenoidectomy (three trials) or they were further randomised to adenoidectomy or no adenoidectomy (four trials), and bilateral ventilation tube insertion where none of the participants had adenoidectomy (five trials) or they were further randomised to adenoidectomy or no adenoidectomy (one trial).

(a) Effectiveness of ventilation tube insertion:

In the trials that studied the effect of unilateral ventilation tube insertion without adenoidectomy with the contralateral ear as the control, improvement in hearing levels and risk of adverse effects were analysed as the outcomes. Hearing levels improved by 7.5 dB (95% CI 4.2 to 10.8 dB) at 1–3 months, 9.4 dB (95% CI 4.3 to 14.5 dB) at 4–6 months and 6.1 dB (95% CI 3.0 to 9.2 dB) at 7–12 months but significant statistical heterogeneity was seen at both the 4–6 month and 7–12 month periods. The effect diminished to 4 dB (95% CI 1.7 to 6.4 dB) at 2 year follow-up. An increased risk of tympanosclerosis, retraction or atrophy and perforation at 1 year was found in the ears with unilateral ventilation tube insertion (with or without adenoidectomy), but the difference was found to be statistically significant only for tympanosclerosis. Moreover, no statistically significant difference was found in the hearing loss between the ear with a ventilation tube and the control ear.

Trials that compared insertion of bilateral ventilation tubes with watchful waiting (or early versus delayed ventilation tube insertion) used a variety of outcome measures and their results

could not be pooled together except for improvement in hearing level, time spent with effusion, and expressive and comprehensive language development. The mean hearing levels improved by 9.8 dB (95% CI 2.2 to 17.4 dB) at 1–3 months and by 4.2 dB (95% CI 0.7 to 7.8 dB) at 4–6 months, with no evidence of statistical heterogeneity. Children with bilateral ventilation tubes spent 32% (95% CI 17% to 48%) less time with effusion in the first year after insertion but this effect decreased to 13% (95% CI 8% to 17%) when the time period of follow-up was extended to include the first 2 years after insertion. No statistically significant difference was found between the bilateral ventilation tube group and watchful waiting group for expressive and comprehensive language development scores. For all other outcomes – developmental (behaviour, general development) and quality of life – where the results could not be pooled together, individual trials reported either no benefit or only a marginal benefit with bilateral ventilation tube insertion.

(b) Effectiveness of ventilation tube insertion plus adenoidectomy:

In the trials that evaluated the combined effect of unilateral ventilation tube insertion and adenoidectomy, the improvement in hearing level was less than that seen for the insertion of unilateral ventilation tubes only at the corresponding time intervals, and there was no evidence of statistical heterogeneity for any of the results. The hearing levels improved by 5.2 dB (95% CI 3.5 to 7.1 dB) at 1–3 months, 3.6 dB (95% CI 2.0 to 5.3 dB) at 4–6 months and 1.4 dB (95% CI 0.1 to 2.7 dB) at 7–12 months. No significant improvement was observed at 2 and 5 year follow-up.

Only one trial assessed the effectiveness of bilateral ventilation tube insertion combined with adenoidectomy and found a reduction of 14% (95% CI 8% to 20%) in the time spent with effusion for the first 2 years after ventilation tube insertion, and a reduction of 9% (95% CI 5% to 13%) in the time spent with hearing loss more than 20 dB in the best ear. It also showed reduction in the number of surgical re-insertions ≥ 1 following bilateral ventilation tube insertion plus adenoidectomy compared to bilateral ventilation tube insertion only (11% versus 24%, $p=0.007$), but did not measure improvement in hearing levels *per se*.

Evidence summary

Evidence from a high-quality systematic review indicates that ventilation tube insertion is associated with an improvement in the mean hearing levels of 7–9 dB in ears with unilateral tubes and 4–10 dB in children with bilateral tubes during the first 6 months of follow-up. However, this effect diminishes with time. When adenoidectomy was performed in addition to unilateral ventilation tube insertion, the hearing improvement (1–5 dB) was less than that seen with unilateral ventilation tube insertion alone (6–9 dB) during 1 year of follow-up, but strong evidence of statistical heterogeneity was seen in the results for unilateral ventilation tube insertion alone. With bilateral ventilation tube insertion plus adenoidectomy, there was a reduction in the time spent with effusion, time spent with abnormal hearing, and in the number of surgical re-treatments at 2 years of follow-up. There was no evidence of benefit favouring bilateral ventilation tube insertion only compared with watchful waiting for expressive and comprehensive language development scores or other outcomes measured individually in the included trials, except for time spent with effusion. Studies of unilateral ventilation tube insertion only showed a higher risk of tympanosclerosis associated with the tubes but no risk of increased hearing loss.

Parental perception about ventilation tube insertion

Description of included studies

A prospective postal survey⁵² was carried out in the UK to investigate parental perceptions of the effectiveness of ventilation tube insertion in children. Parents of 150 consecutive children admitted for bilateral ventilation tube insertion were handed a close-ended questionnaire preoperatively, and a postoperative questionnaire was mailed out to them 12 months after surgery. The questionnaire had been piloted beforehand and asked questions relating to both the standard outcomes (change in hearing, number of infections) and alternative outcomes of general health and social skills. No control group was taken for comparison and confounding variables were not controlled. [EL = 3]

Another survey⁵³ used a retrospective postal questionnaire to seek parental opinion about the effect of ventilation tube insertion. This survey was carried out at three centres in the UK and children younger than 15 years with ventilation tubes inserted between 3 and 12 months previously were

identified from hospital records. A confidential and anonymous postal questionnaire was sent to the parents and it included close-ended questions. Medical notes of the children were not inspected to ascertain degree of hearing loss or the diagnosis of OME. The questionnaire was not piloted or validated before use, and there was no comparator group. [EL = 3]

Review findings

The response rate for the first postal survey was 71%. Almost 90% of the children were 4 years or younger. Parental responses showed that there was a statistically significant reduction in the episodes of earache and courses of prescribed antibiotics for children after ventilation tube insertion ($P < 0.001$ for both). Disturbed nights caused through earache also reduced significantly in the postoperative period. When parents were asked whether they thought that ventilation tube insertion had changed their child's health, 62.6% rated it better in general than prior to surgery, and 67.2% of parents felt that their child's ability to listen to television after surgery had improved. There was a reduction in reporting of both the behaviour problems and speech/language difficulties at school after the surgery (48.5% versus 6.5% for behaviour problems, and 37.3% versus 20.5% for speech difficulties).

The second retrospective survey had a response rate of 65.3%. The mean age of the children was 5.7 years (range 1 to 15 years). Ninety-two percent of the parents reported better hearing in their children, 74% reported reduced frequency of ear infections, 87% reported reduction in postoperative GP visits and 70.7% reported less time missed from school. Overall 96.7% of the parents were satisfied that the decision to insert ventilation tube in their child had been correct.

Evidence summary

There is lack of good-quality evidence regarding parental perception of surgery for OME. The available evidence shows that parents perceive improvement in general health, behaviour and social skills in their children following ventilation tube insertion apart from the hearing gain associated with the intervention but the studies had selected populations with a poor response rate, used non-validated questionnaires and did not control for confounding variables.

Complications of ventilation tube insertion

Description of included studies

A systematic review⁵⁴ was carried out to estimate the incidence of complications of ventilation tube insertion. The study selection criteria were cohort studies/RCTs or case series with otitis media (recurrent or chronic) as the primary indication for tube placement. All the studies identified 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. No *a priori* definitions of any particular outcome were established (except otorrhoea) and the author statement was relied on for extracting quantitative data. Subgroup analysis was performed to estimate the impact of influencing factors such as tube type (short-term versus long-term) and study design (case series versus cohort/RCT) on the outcomes. Meta-analysis was performed for adverse outcomes by including only those studies that provided separate outcomes for both long-term and short-term tubes. Quality appraisal of individual studies was not carried out. [EL = 2+]

The second study was a prospective cohort study⁵⁵ carried out in Canada to determine the long-term effects of ventilation tube insertion on hearing thresholds and tympanic membrane pathological abnormalities in children with OME. The study population was derived from 125 children who participated in an earlier RCT of medical treatment (sulfisoxazole for 6 months) or surgical treatment (bilateral ventilation tube insertion). Each patient was assessed once 6–10 years following the last trial visit, and children in the medical group who received ventilation tube insertion or those in the ventilation tube group who received more than one ventilation tube were excluded. Otomicroscopy, audiometry and tympanometry of the participants were carried out along with an interview with all the parents by personnel/audiologists who were blinded to the treatment. Logistic regression modelling was used to adjust for potential confounding variables. [EL = 2+]

Review findings

Altogether 134 articles (70 case series and 64 cohort studies/RCTs) were included for the review and 79% of these studies did not include a comparator group. Short-term tubes were employed in 46% of the studies, long-term in 11%, both short-term and long-term in 21%, and in 22% the tube type was unspecified. Otorrhoea was a common complication of ventilation tube insertion, affecting 17% of intubated ears and 26.2% of the patients. The incidence of all types of otorrhoea was more common in patients than in ears, reflecting the bilateral contribution of the ears to the total incidence. The most frequent adverse outcome was the blockage of lumen (6.9%) followed by granulations which did not require surgery (4.2%) and premature extrusion of tubes (3.9%). Tympanosclerosis occurred in about one-third of ears (32%) after tube extrusion while atrophy or retraction at the tube site occurred in 24.6% of ears. Perforation was more common with long-term tubes than with short-term tubes (16.6% versus 2.2%).

Long-term tubes were associated with a significantly higher incidence of unspecified otorrhoea, otorrhoea requiring tube removal, perforation and cholesteatoma compared with short-term tubes ($P < 0.001$ for all). When the results were segregated by the type of study, rates of tympanosclerosis, postoperative otorrhoea and atrophy/retraction at tube sites were 1.6–1.7 times higher in cohorts/RCTs ($P < 0.001$). The incidence of chronic perforation and cholesteatoma was higher in the case series but the difference was not statistically significant.

Meta-analysis of the impact of tube type (long-term versus short-term) showed an increased incidence of otorrhoea, chronic perforation and cholesteatoma with long-term tubes, but the risk was statistically significant only for chronic perforation and cholesteatoma. The results also confirmed a higher prevalence of tympanosclerosis (RR 1.7; 95% CI 1.1 to 2.7) and atrophy or retraction (RR 3.5; 95% CI 2.6 to 4.9) in ears with ventilation tubes inserted compared with ears where no surgery or myringotomy was done.

In the cohort study, 27 medical patients who never received ventilation tubes were compared with 38 randomised to the surgery/ventilation tube group and who received only one set of tubes. The baseline demographic characteristics of the two groups were similar. Tube insertion was associated with a statistically significant increase in the risk of myringosclerosis (RR 4.5; 95% CI 1.8 to 11.3), other tympanic membrane abnormalities such as perforation, retraction or atelectasis (RR 9.9; 95% CI 1.4 to 71.2) and all tympanic membrane abnormalities combined together (RR 4.4; 95% CI 2.0 to 9.9). When analysed by intention-to-treat, the risk of all tympanic membrane abnormalities was still higher in the surgical group (RR 1.5; 95% CI 1.2 to 1.9). Regression analysis did not reveal any other statistically significant predictor of tympanic membrane abnormality except the treatment itself, that is, ventilation tube insertion. When hearing thresholds in the two groups were analysed as a continuous variable, children in the ventilation tube group had mean thresholds that were 2.1–8.1 dB worse than those of the medically treated group at all frequencies, with a statistically significant difference between the two groups at 0.25, 0.5, 1 and 6 kHz. Examined dichotomously using a 15 dB cut-off, children randomised to the ventilation tube group had a significantly higher risk of elevated hearing thresholds than the medical group (RR 3.3; 95% CI 1.1 to 10.4). When analysed by intention-to-treat, differences in hearing thresholds were 2.1 to 4.7 dB poorer in surgical subjects but these differences were statistically not significant.

Evidence summary

Evidence shows that otorrhoea, focal atrophy or retraction of the tympanic membrane and tympanosclerosis are relatively common complications of ventilation tube insertion. Serious complications such as perforation of the tympanic membrane are almost twice as common with long-term tubes than with short-term tubes. Tube insertion is also associated with an increased risk of focal atrophy/retraction and tympanosclerosis compared with myringotomy or no surgery.

Results from an EL 2+ cohort study show that children undergoing ventilation tube insertion for OME persisting for 3 months or more have an increased risk of tympanic membrane pathological abnormalities and elevated hearing thresholds at 6–10 years following the surgery, compared with children who did not have tube insertion.

Cost-effectiveness

The GDG identified the various treatment alternatives as being a priority for economic analysis within this guideline and the results of this are summarised here; further details are given in Appendix C.

The health economic model suggested that ventilation tubes were a cost-effective strategy for the treatment of persistent bilateral OME. The model posited a relationship between hearing levels and QALYs and showed that ventilation tubes was unambiguously more cost-effective than ventilation tubes plus adjuvant adenoidectomy providing the latter did not produce greater hearing gain over time and did not reduce re-insertion rates by more than 13.1 percentage points. The model also showed ventilation tubes to be more cost-effective than hearing aids, even with full adherence, as long as ventilation tubes resulted in a gain of at least 0.022 QALYs more than would be achieved with hearing aids. The incremental cost-effectiveness ratio (ICER) for ventilation tubes was calculated at just under £16,000 per QALY.

Translation from evidence to recommendations

Evidence shows that insertion of ventilation tubes is effective in correcting the conductive hearing loss from OME as long as they remain in place and functioning. An economic model developed for this guideline (Appendix C), while subject to certain data limitation caveats, suggested that the insertion of ventilation tubes is a cost-effective treatment for persistent bilateral OME.

The GDG cannot recommend routine adjuvant adenoidectomy on the basis of the currently available evidence since the literature does not demonstrate that the procedure improves hearing levels. At the same time, the GDG members recognised that the trials included in the evidence (the systematic review) comparing the hearing status for patients with ventilation tubes alone and for those with ventilation tubes plus adenoidectomy suffer from the following difficulties:

1. different study designs used for comparison (randomised by ears or randomised by children) or designs suited only to efficacy and not effectiveness of the intervention (tube in a single ear)
2. variability in the duration and severity of OME in the sample population (for example, two trials failed to mention the duration of OME)
3. small sizes of the sample population raise the question about their power to detect a statistically significant difference between the groups (for example, Dempster *et al.*,⁵⁶ with $n = 78$ so size in a four-group design would be ≤ 20 ; Black *et al.*,⁵⁷ with $n = 127$ so group size ≤ 33)
4. failure to collect data on hearing levels in the long term (after 1 year), which is an important period considering the fact that the majority of tubes extrude spontaneously after 7–12 months.
5. inability to analyse data on the intention-to-treat principle (high drop-out rate and crossing-over of treatment in some trials).

The GDG was also aware that a large trial from the USA (Gates *et al.*⁵⁸ with $n > 100$ for each group in the four-group design) included in the systematic review had regular long-term follow-up, but it measured only the proxy measure of proportion of time free of effusions rather than improvement in hearing levels. The results showed a sustained reduction of 10–15% in the proportion of time spent with effusion during the first 2 years of follow up with ventilation tubes plus adenoidectomy compared with ventilation tubes alone. These findings, along with an associated reduction in numbers of re-insertions seen in two studies (24% down to 11% in this study, and 54% down to 26% in another study⁵⁹), have made clinicians believe that adenoidectomy has a place in the management of OME. The GDG recognises that upper respiratory symptoms commonly co-exist with OME and many clinicians feel that adjuvant adenoidectomy adds to benefits other than improvement in hearing levels only. This guideline did not study the evidence for adenoidectomy and upper respiratory health.

The complication rate from simple ventilation tube insertion is low and the complications, such as otorrhoea, myringosclerosis, localised atrophy and perforation of the tympanic membrane, are usually of a minor nature. Adenoidectomy is normally free of complications but when they occur they may be more severe, for example haemorrhage. This would require further surgical intervention and possibly an extended stay in hospital.

The GDG is therefore unable to recommend adenoidectomy in a high proportion of children with OME. However, in children with OME and persistent and/or frequent upper respiratory

tract symptoms, clinicians should consider possible benefits from adjuvant adenoidectomy to the OME and to the co-existing respiratory symptoms.

Once a decision to treat the child has been taken, it is self-evident that the surgery should take place without undue delay.

Recommendations on effectiveness of surgical interventions

Once a decision has been taken to offer surgical intervention for OME in children, the insertion of ventilation tubes is recommended. Adjuvant adenoidectomy is not recommended in the absence of persistent and/or frequent upper respiratory tract symptoms.

Children who have undergone insertion of ventilation tubes for OME should be followed up and their hearing should be re-assessed.

Research recommendation on effectiveness of surgical procedures

There is a need for good-quality randomised controlled trials documenting the adjuvant effect of adenoidectomy with ventilation tubes compared with ventilation tubes alone in the management of persistent bilateral OME in children. Trials should be sufficiently powered (large) to accurately document a probably small but continuing difference due to adjuvant adenoidectomy, and to identify sub-groups that would particularly benefit from surgical intervention.

Why this is important

Adjuvant adenoidectomy along with ventilation tube insertion is routinely performed in many countries for recurrent episodes of OME and chronic persistent OME, but the practice is not backed by sufficiently precise scientific evidence. A good number of trials have compared ventilation tube insertion alone with ventilation tubes plus adjuvant adenoidectomy, but differences in the study designs, population characteristics, outcomes measured and duration of follow-up among the trials, and particularly insufficient sample sizes to document a probably small but continuing difference, have made it difficult to come to any definite conclusion on the benefit of adjuvant adenoidectomy. There is a need for good-quality randomised controlled trials on larger samples than hitherto, addressing their power deficit not just for the proportion of time with ear fluid but also for the corresponding longer term benefits in hearing level. For this, the trials need to follow up children beyond 6–12 months after ventilation tube insertion as a high proportion of tubes would have fallen out during this time period, and so any advantage that may exist for adjuvant adenoidectomy becomes in principle demonstrable. Up to 2 years is a feasible follow-up period for formal outcome measurement, without high sample attrition. Because adenoidectomy is not risk-free, trials need particularly to be large enough to address sub-groupings that may receive particular benefit. The trials should also evaluate any benefits to respiratory and general health; these are expected from benefits seen in other ENT disease, but not so far demonstrated in uncomplicated OME. However, additional reductions in health care (such as reduced re-insertions of ventilation tubes) can also be documented and would add precision to the cost-effectiveness or cost-utility comparisons. Research is also needed to plot the balance between benefits and harms of ventilation tube insertion, as a function of the length of time for which the tube remains in place and functioning (due to the type of tube design).

3.3.4 Effectiveness of non-surgical interventions

Clinical question

What is the effectiveness of various non-surgical interventions in children with OME?

Good-quality systematic reviews were available for evaluating the effectiveness of steroids, antihistamines and/or decongestants, antibiotics and autoinflation, but not for homeopathy or hearing aids. The two studies included for hearing aids are surveys assessing the compliance and subjective improvement with their use, while the single study included for homeopathy is a poorly conducted pilot RCT. No published studies were identified for acupuncture, cranial osteopathy, dietary modification, immunostimulants, massage or probiotics.

Steroids

Description of included studies

A good-quality systematic review⁶⁰ was carried out to determine the beneficial and harmful effects of treatment with steroids for children with hearing loss associated with OME. The review criteria included RCTs of oral or topical intranasal steroids compared with placebo or non-intervention control, and additional treatments were included as long as they were provided equally to the treatment and the control group. Studies reporting outcomes only with ears as the unit of analysis and those comparing steroids plus additional treatment with placebo plus placebo were excluded. The study population comprised children up to the age of 12 years diagnosed with OME and significant hearing loss using different criteria. The primary outcomes sought were changes in hearing, while the secondary outcomes were effect on effusion and adverse effects of treatment. [EL = 1++]

Review findings

The review included a total of 11 trials, out of which nine involved assessment of oral steroids while the other two assessed topical intranasal steroids. Most studies documented OME by a combination of pneumatic otoscopy and tympanometry, but no study documented hearing loss from OME two or more times in the 3 months prior to study entry. Adverse effects were reported in five trials of oral steroids and two trials of topical steroids. Although mild adverse effects such as vomiting, diarrhoea and dermatitis were reported with oral steroids in some of the included trials, none of them reported any serious or lasting adverse effects. Owing to variation in the follow-up periods and in the outcomes measured, meta-analysis could be performed only for limited number of outcomes. Results were given after grouping the studies into four categories:

(a) Oral steroids versus control:

The odds ratio for OME persisting after short-term follow-up (2 weeks or less) was 0.2 (95% CI 0.1 to 0.6), which indicates a statistically significant reduction in the risk with oral steroids. However, this effect was not seen at the intermediate-term follow-up (at 1–2 months). Only one trial gave complete data on audiometry outcomes at the intermediate follow-up, and it showed a statistically non-significant hearing gain of almost 10 dB in the treatment group (RR 1.5; 95% CI 0.4 to 5.6).

(b) Oral steroids plus antibiotics versus control plus antibiotics:

The results were similar to those seen with oral steroids alone. There was a significant reduction in the odds ratio of OME persistence at short-term follow-up (OR 0.4; 95% CI 0.2 to 0.6) but the results were characterised by statistically significant heterogeneity between the studies. No significant effect on OME resolution was found after 1–2 month follow-up or after 6 month follow-up.

(c) Topical intranasal steroids versus control:

Only one study evaluated this comparison and it found no significant reduction in OME resolution after 3 weeks.

(d) Topical intranasal steroids plus antibiotics versus control plus antibiotics:

The single study evaluating this comparison found no significant reduction in the risk of OME persistence at both the short and intermediate follow-up period.

Evidence summary

Results from a well-conducted systematic review show that oral steroids alone or in combination with antibiotics lead to a quicker resolution of OME in the shorter term (2 weeks) but not in the longer term. However, none of the included trials had documented hearing loss with a diagnosis of OME before starting treatment. There is insufficient good-quality evidence regarding the effectiveness of intranasal steroids.

Antihistamines and/or decongestants

Description of included studies

A well-conducted systematic review⁶¹ of RCTs using antihistamines, decongestants or antihistamine/decongestant combinations as treatment for OME in children was carried out.

The intervention of interest was the use of oral decongestant and/or antihistamine as compared with no medication or placebo, and the study population comprised children below 18 years of age with a diagnosis of OME and not having AOM, anatomical deformity or other chronic immunocompromised states. Studies with a mixed population were included only if they contained extractable data for the population meeting the review's selection criteria. The primary outcome measured was resolution of effusion. [EL = 1++]

Review findings

Fifteen RCTs involving 1516 participants provided dichotomous outcomes and were included for statistical meta-analysis in this review. Five trials reported outcomes using ears as the unit of analysis but the data were converted into a usable, consistent format. All except three trials used tympanometry to diagnose OME. The results were grouped according to the study design into:

(a) Antihistamine versus control:

No significant reduction in the risk of OME persistence at 1–3 months was found (RR 0.9; 95% CI 0.6 to 1.4). The risk of AOM as a complication was also not different between the two groups.

(b) Decongestants versus control:

There was no evidence of increased OME cure at or before 1 month or at 1–3 months in the treatment group compared with the placebo. Hearing at or about 1 month and OME complications of AOM and surgery were also evaluated in the trials but again statistically no significant difference was found between the two groups.

(c) Antihistamine/decongestant combination versus control:

Treatment with the combination led to increased chances of cure at or before 1 month, but the results were not statistically significant. The control group had a better cure rate at 1–3 months and after 3 months but again the results were not significant. For all the other outcomes (hearing at less than 3 months and at 1 year, school performance, complications of AOM, surgery, recurrent OME), no statistically significant difference was found between the two groups.

(d) Any medication (antihistamine, decongestants or antihistamine/decongestant combination) versus control:

Even after combining all the medications into a common treatment group, no significant difference was found between the intervention and the control group for the various outcomes measured (cure rate at before 1 month, 1–3 months and after 3 months, hearing at about 1 month and at 1 year, school performance at 1 year, complications of AOM and recurrent OME). However, there was a significant increase in the risk of medication side effects in the intervention group (17% versus 6%, RR 2.7; 95% CI 1.9 to 3.9).

Evidence summary

Evidence from a well-conducted systematic review shows no statistical evidence of benefit with antihistamines, decongestants or antihistamine/decongestant combinations in the treatment of OME in children. Moreover, there was a greater risk of side effects in the treated group compared with the control group.

Antibiotics

Description of included studies

A meta-analysis⁶² was conducted to test whether a 10–30 day course of oral antibiotics is efficacious for the short-term cure of OME in children. Articles considered for inclusion were RCTs that compared children receiving antimicrobial therapy with concurrent controls who received placebo or no drug. The population comprised children recruited from a hospital-based practice or research setting with varying degrees of OME duration and bilaterality. The outcome assessed was cure rate or resolution of middle ear effusion at the first post-treatment visit, and subgroup analysis was performed according to the natural cure rate in the control groups. The review focused on a clearly defined question but did not provide details about the methodology used or the reasons for exclusion of relevant articles. Individual studies were appraised for their quality but the ratings were not taken into account when presenting the results. Both placebo-controlled and

non-placebo-controlled trials were pooled together for analysis, and no effort was made to explain the heterogeneity arising in the results. [EL = 1–]

Another meta-analysis⁶³ was conducted to determine the effectiveness of antibiotic therapy for OME in children, along with a critical appraisal of the above-mentioned study. Results from placebo-controlled and non-placebo-controlled trials were pooled separately and a sensitivity analysis was done to investigate the effects of quality differences among the included trials on the estimated effects. The methodology was not described in detail and the authors failed to specify predefined inclusion/exclusion criteria for the review although they did give reasons for including or excluding specific studies. [EL = 1+]

Review findings

In the first meta-analysis, ten RCTs were included and the pooled analysis of 1325 children yielded a statistically significant improvement of almost 23% (RD 22.8%; 95% CI 10.5% to 35.1%) in the cure rate at the first post-treatment visit, but there was strong evidence of statistical heterogeneity among the studies. Subgroup analysis found an inverse relationship between the antibiotic cure rates and the natural resolution rate of the study group. Groups with a low natural cure rate of < 15% showed significantly improved results with antibiotic treatment (RD 31.0%; 95% CI 22.4% to 39.6%), while no such improvement was seen in groups having a high natural cure rate > 25% (RD 13.9%; 95% CI –3.1% to 30.9%).

Sixteen RCTs were included in the second meta-analysis – eight each for placebo-controlled and non-placebo-controlled trials. Significant improvement with antibiotic usage was found in the non-placebo-controlled trials (RD 32%; 95% CI 26% to 39%) but not in the placebo-controlled trials (RD 4%; 95% CI 0% to 9%). The antibiotic cure rate in the placebo-controlled trials was significantly lower than that in the non-placebo-controlled trials (4% versus 32%; $P < 0.001$). An inverse relationship was also found between the estimated efficacy of the included trials and their quality index. With non-placebo-controlled trials being given a low quality rating and strong evidence of statistical heterogeneity in the results, the authors concluded that the efficacy of antibiotics for OME is insignificant.

Evidence summary

There is conflicting evidence regarding the effectiveness of antibiotics in the management of OME in children. Results from one of the meta-analyses shows a 23% increase in the likelihood of resolution with antibiotics usage, while the other meta-analysis, which used a more robust methodology, found no benefit with their use.

Autoinflation

Description of included studies

A high-quality systematic review⁶⁴ evaluated the effects of autoinflation in children with OME by comparing any form of autoinflation with no autoinflation. RCTs with other type of treatments (such as analgesia, decongestants or antibiotics) were included provided these were provided equally to the two groups. The population comprised 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. Primary outcomes measured were improvement in tympanogram, differences in hearing level on PTA and a composite improvement measured by change in either tympanogram or audiometry. [EL = 1++]

Review findings

Five of the six RCTs included in the review studied children aged between 3 and 16 years. Two trials included only participants with bilateral OME while the other four included those with both unilateral and bilateral OME. None of the included studies were of high quality, and pooling data from these studies was difficult owing to a lack of consistent reporting of common outcomes.

(a) Improvement in tympanometry:

Autoinflation showed a non-significant improvement with initial tympanometry defined by type B or C2 tympanogram at less than 1 month (RR 1.6; 95% CI 0.5 to 5.6). However, subgroup

analysis showed tympanographic improvement with initial tympanogram analysed separately as type B (RR 2.7; 95% CI 1.4 to 5.1) and type C2 (RR 3.8; 95% CI 1.9 to 7.6). These results were based on the results of single trials and when the participants were followed for longer than 1 month, no improvement was observed.

(b) Improvement in audiometry:

No significant improvement in the hearing levels was seen in the intervention group when an average hearing gain of 10 dB or more was analysed as a binary variable or when audiometric improvement was analysed as a continuous variable.

(c) Composite outcomes:

On combining results of five studies and using improvement in either tympanogram or audiometry as a binary variable, significant improvement with autoinflation was seen at more than 1 month (RR 2.2; 95% CI 1.7 to 2.8) but not at less than 1 month. Further subgroup analysis was done depending on the type of device used. The Politzer device showed a statistically significant improvement at both less than 1 month and more than 1 month, while no improvement was seen when the Otovent device or a carnival blower plus balloon were used.

(d) Adverse effects:

None of the studies demonstrated a significant difference in the incidence of side effects between the intervention and the control group.

Evidence summary

The systematic review for the effectiveness of autoinflation in the management of OME in children is characterised by a limited number of relevant studies and heterogeneity in both the outcomes and follow-up period. The available evidence shows some improvement in the composite measure of tympanogram or audiometry at more than 1 month, but no benefit when these two outcomes are analysed separately.

Hearing aids

Description of included studies

A prospective survey⁶⁵ was carried out in the UK to analyse the acceptance, effectiveness and any complications arising from the use of hearing aids in children with OME. The study population comprised children with at least 25 dB averaged mid-frequency PTA bilateral hearing loss, otoscopic evidence of OME and type B or C tympanogram on at least two occasions over 3 months. Initially, behind-the-ear hearing aids were offered to only those children who had recurrence of OME after surgical treatment, but later they were also offered to children with newly diagnosed OME. The children were assessed at 3 month intervals with audiometry and otoscopy, while the child's symptoms and disability was evaluated by a closed-ended questionnaire administered to the parent/child. No details were given about the validity of the questionnaire or the confounding variables, and the study sample was a selected one. [EL = 3]

Another survey⁶⁶ from the UK assessed the compliance and acceptance of hearing aids for the management of children with OME. Parents of children diagnosed with persistent bilateral middle ear effusion for 3 months were given the choice of an in-the-ear (ITE) or behind-the-ear (BTE) hearing aid, and an initial follow-up was undertaken by an audiologist at 6 weeks. After 6–9 months of starting the treatment, a clinician reviewed these children and also administered a closed-ended questionnaire asking details about stigma, usage and problems with the aid. The questionnaire used was not piloted or a validated instrument, and there was no comparator group. [EL = 3]

Review findings

In the first study, the average age of the study population ($n = 48$) was 6.8 years and 44% of them had undergone surgery (ventilation tube insertion or ventilation tubes plus adenoidectomy) for OME. The average duration of hearing aid use at the time of study was 6 months and 65% of the children wore them all day and every day while the rest wore them at specific times (at school/watching TV). Almost all the parents noticed a definite and sustained improvement in the child's hearing (98%) and in speech and language development (97%). In 14/48 children, either the

parents or the child had some reservations over using the hearing aids, and self-consciousness was the main reason for disliking it in 10–20% of them. None of the parents/children reported significant problems with otalgia, infection/otorrhoea or balance during the follow-up period. PTA could be performed in 44 children at 6 month follow-up and 55% of them had unaided bilateral thresholds worse than 25 dB hearing loss. However, six children continued to use hearing aids even though their hearing thresholds had returned to normal.

Of the 39 patients (71%) who accepted the trial of hearing aids in the second study, 28 used binaural ITE aids while the other 11 used BTE aids. The median age of the study population was 6 years (range 4 to 11 years), and 66% were male. The main problems cited by parents for seeking treatment were hearing, behaviour and speech. All the parents felt that the hearing aids were easy to use and all of them reported improvement in hearing while using them. One parent did not use them for her child because of the stigma attached to it. Seventy percent of the parents reported a great improvement in hearing while the rest reported a moderate one. Behaviour problems were reported to improve in 50% of all children and in all children whose parents stated behaviour as the main problem. Speech reportedly improved in one-third of the children and concentration in two-thirds. The aided hearing thresholds improved by an average of 17 dB (range 10 to 30 dB) although 27 of the children still had persistent bilateral OME.

Evidence summary

There are no good-quality comparative studies evaluating the effectiveness of hearing aids for the treatment of OME in children. Results from the two surveys show that hearing aids are well accepted by the parents/child for the treatment and are associated with an improvement in hearing, speech and development, but the evidence is characterised by a lack of objective assessment, selected populations and the absence of comparator groups.

Cost-effectiveness

An economic model developed for the guideline (Appendix C) suggested that hearing aids were a cheaper option than surgical alternatives. Comparative data are lacking but if hearing aids had good adherence and delivered improvement in hearing within 2.5 dB of that achieved by surgery over 12 months, then the model suggests that they would be cost-effective.

Homeopathy

Description of included studies

A pilot RCT⁶⁷ was carried out at two general practice (GP) centres in the UK to determine whether homeopathic treatment of children with glue ear is more effective than standard GP care. The study population comprised children aged 18 months to 8 years with a positive diagnosis of OME by the patient's GP, hearing loss > 20 dB and an abnormal tympanogram. Children were randomised to the homeopathy or standard GP care group, but the process of randomisation was not described and there was no concealment of allocation or blinding of the participants. The standard care involved 'watchful waiting' with autoinflation and in some cases a course of low-dose antibiotics for 4–6 weeks. The sample size was small and the two groups were not compared for baseline demographic characteristics except the age range. Audiometry and tympanometry were conducted during the 1 year follow-up in this study, and results were given without intention-to-treat analysis. [EL = 1–]

Review findings

A total of 33 children were randomised to either the homeopathic care group ($n = 17$) or the standard care group ($n = 16$). Children in the two groups had similar age ranges but there was a significant difference with regard to their initial hearing loss. After 12 months of follow-up, a higher proportion of children in the homeopathic care group had normal tympanograms and audiometric improvement (hearing loss < 20 dB), but the difference reached statistical significance only for improvement in tympanograms (76.4% versus 31.3%; $P = 0.01$). Children in the intervention group also had fewer courses of antibiotics in 12 months and fewer referrals to specialists, but again the difference was not statistically significant.

Evidence summary

Results from a pilot trial show some improvement in tympanogram in children treated with homeopathy after 12 months of follow-up compared with standard care, but there was no benefit for the other outcomes.

Surgical versus non-surgical intervention

Only one study was found which compared surgical treatment with medical treatment for children with OME.

Description of included study

The effectiveness of medical treatment was compared with surgical treatment in an RCT⁶⁸ carried out in Canada. The study population comprised children aged 2.5–7 years with a longstanding OME (documented) and history of hearing loss greater than 3 months, and having a hearing loss of at least 25 dB documented in at least one ear. Children were randomised to ‘medical treatment’ consisting of sulfisoxazole 75 mg/kg daily for 6 months, or ‘surgical treatment’ with bilateral myringotomy and ventilation tube insertion. At 6 months, 12 months and 18 months each child was classified as treatment success or failure based on the presence/absence of one of the three criteria – persistent or recurrent middle ear effusion and associated hearing loss, allergic reaction to drug, or three or more episodes of AOM. Other outcomes measured were the hearing thresholds, episodes of recurrent AOM, and side effects of treatment. No mention was made of the process of randomisation and concealment of allocation. Though *a priori* sample size calculation was done, results were analysed without intention-to-treat. The original study protocol failed to specify treatment for the failures and as such there was crossing over of the treatment between the two groups. [EL = 1+]

Review findings

Of the 139 children selected for this study, 71 were randomised to the medical treatment group and 68 to the surgical group. There was no difference in the baseline characteristics (age, gender, mean hearing loss, mean number of AOM episodes) between the two groups. Treatment success was significantly better in the surgical treatment group compared with the medical treatment group at all three time periods ($P = 0.02$). Children in the surgical treatment group were hearing significantly better than those in the medical group at 2 months ($P < 0.001$) and at 4 months ($P = 0.01$) but not at 6, 12 or 18 months. When hearing thresholds were dichotomised to normal or abnormal hearing (abnormal hearing defined as hearing loss > 25 dB at two or more frequencies in the worse ear), a significantly greater proportion of those in the medical treatment group had abnormal hearing at 2 and 4 months but not at the other time periods. There was no statistically significant difference between the two groups for episodes of AOM, but a significantly greater proportion of surgical subjects experienced complications of surgery than medical subjects experiencing side effects from the medicine ($P < 0.001$).

Evidence summary

There is a lack of evidence comparing the effectiveness of surgical with non-surgical intervention for the management of OME in children. Results from a RCT comparing surgical treatment (ventilation tube insertion) with medical treatment (an antibiotic – sulfisoxazole – for 6 months) indicate that the success rate of ventilation tube insertion is superior to that of medical treatment. It also leads to better hearing in the short term but has an increased risk of complications.

Translation from evidence to recommendations

Children with OME are managed at different stages in the healthcare system, where the condition will either resolve naturally or the child will be considered for treatment. A variety of treatment approaches are used as a temporising management policy in the community or in the hospital, in an attempt to alleviate symptoms in children and prior to surgery. However, the GDG decided that very few current treatment approaches were supported by a sufficiently strong evidence base to justify their recommendation, and there are significant harms associated with certain types of intervention that make them particularly unsuitable for a recurrent condition such as OME in childhood.

Mild adverse effects (such as vomiting, diarrhoea and dermatitis) were reported with oral steroids in some of the trials included in the review but none of them reported any serious or lasting adverse effects. This may be a limitation of the studies evaluated in the Cochrane review, because it is clearer from work where children have taken oral steroids repeatedly, such as cystic fibrosis, that there are reports of growth restriction and also serious idiosyncratic reactions, such that the potential harms of oral steroids in OME should preclude their use. Similarly, with antibiotics the relatively modest or small effects shown in the meta-analyses have not been evaluated as part of a global risk assessment, i.e. in relation to their generally known risks and costs, which include poor compliance with longer courses, diarrhoea, rashes, anaphylaxis, antibiotic resistance and medicalisation. Thus, until any subgroups of children with OME can be clearly identified as demonstrating benefit from antibiotics, their general use cannot be recommended by the GDG.

Evidence has shown that decongestants and antihistamines are both ineffective and harmful. Homoeopathy, cranial osteopathy, acupuncture, dietary modification, massage, immunostimulants and probiotics, although of potential interest as treatments, all lack a published evidence base for effectiveness in OME. There is currently insufficient evidence on the effectiveness of intranasal steroids, but the GDG was aware of an ongoing trial in the UK whose results could be used to inform future practice.

Autoinflation has been shown to be effective in two meta-analyses. Those techniques using standardised or purpose-manufactured approaches are more widely feasible during watchful waiting, and may be of benefit in older children who are more likely to cooperate. They have no known harms. However, because of methodological limitations in the studies, their combined results are not conclusive.

The GDG decided that, although hearing aids have no high-quality evidence from pragmatic open randomised trials, they nonetheless should be offered to children as an alternative to surgical intervention. For a conductive hearing loss, the major concern in OME, a hearing aid provides hearing level gains similar in magnitude to the best (early) results of surgery. It is probably for this reason that there is no effectiveness trial but only those of acceptability. Moreover they offer a less interventionist approach in children whose parents/carers refuse surgery. Also, if hearing aids are chosen in preference to more expensive surgical treatment, opportunity costs are not imposed on other NHS patients, providing subsequent surgical intervention in this group is not too high.

Recommendations on effectiveness of non-surgical interventions

The following treatments are not recommended for the management of OME:

- antibiotics
- topical or systemic antihistamines
- topical or systemic decongestants
- topical or systemic steroids
- homeopathy
- osteopathy
- acupuncture
- dietary modification, including probiotics
- immunostimulants
- massage.

Autoinflation may be considered during the active observation period for children with OME who are likely to cooperate with the procedure.

Hearing aids should be offered to children with persistent bilateral OME and hearing loss as an alternative to surgical intervention where surgery is contraindicated or not acceptable.

Research recommendation on effectiveness of non-surgical interventions

A comparative study on a representative sample of children with OME is required to assess the overall effectiveness of provision of hearing aids as an alternative to surgical treatment.

3.4 Management of OME in children with Down's syndrome

Introduction

Down's syndrome is the most common chromosomal disorder in the UK, with an incidence of 6.2 per 10 000 live births. Many such children will have upper respiratory tract problems. OME is almost universal in children with Down's syndrome and occurs at a younger age. It is likely to persist to an older age than in other children and there is also a higher incidence of sensorineural hearing loss. Testing the hearing requires particular expertise and patience to arrive at a reliable threshold.

Description of included studies

A case-control study⁶⁹ was carried out in Japan to determine the efficacy of and the clinical course following ventilation tube insertion in children with Down's syndrome. Children having Down's syndrome (clinical features plus chromosomal analysis) who underwent ventilation tube insertion for the treatment of chronic OME persisting for 3 months or more and resistant to conservative therapy were included as cases, and age-matched children with chronic OME and without Down's syndrome were randomly selected as controls. All the children were 7 years or older at the last visit and followed for more than 2 years after ventilation tube insertion using a well-defined protocol. Outcomes compared between the two groups were cure rate, complications of ventilation tube insertion and improvement in hearing levels. The population was a selected one and no adjustment was made for confounding variables. Moreover, no comparison was made between the two groups for the baseline hearing levels before ventilation tube insertion. [EL = 2+]

Another prospective study⁷⁰ was carried out in Australia to determine improvement in the hearing levels following ventilation tube insertion in children with Down's syndrome. Consecutive children aged 6 years or older with Down's syndrome and bilateral OME were recruited for the study from a multidisciplinary clinic, and those considered incapable of cooperating and those already having a ventilation tube inserted were excluded. A control group of healthy, non-dysmorphic children with bilateral OME and no abnormality other than hearing impairment or speech delay was selected for comparison. All the children had bilateral ventilation tube insertion and no other treatment was given. Hearing was tested at less than 5 weeks before ventilation tube insertion and 6–9 weeks postoperatively, and hearing loss was classified as mild (mean 20–40 dB), moderate (41–60 dB) or severe (61–80 dB). The study population was a selected one, baseline characteristics of the two groups were not compared and the confounding variables were not adjusted in the analysis. [EL = 2-]

A longitudinal study from the USA⁷¹ examined the effect of close monitoring and aggressive treatment (medical and surgical) of chronic otitis media in children with Down's syndrome. The study population was either referred for participation from a specialised clinic or through a parent support group and word of mouth. The only criteria for inclusion were an age of 2 years or less and ability to speak English. Of the 54 children enrolled in the study, 48 had at least two reliable hearing evaluations and these children formed the study group. Forty-four percent of these children were females. A detailed ENT examination was carried out every 6 months or earlier if required, and it included otomicroscopy and a complete audiological examination but the exact hearing levels were not specified. [EL = 3]

A UK retrospective review⁷² of care records of children with Down's syndrome was reported. A total of 93 children were known to have Down's syndrome in the district, and 70 of them who required frequent ENT consultations were the focus of this study. The children were usually seen at age 18–24 months and were subsequently reviewed every 6 months. The examination included otoscopy and tympanometry for diagnosing OME, and a formal hearing assessment was made in 22 children with a PTA and in other children by a reactometer. [EL = 3]

Review findings

The first study included 56 children (28 cases, 28 controls) and ventilation tubes were inserted at the mean age of 5.4 years (range 2 to 13 years) in the cases and 5.2 years (range 2 to 9 years) in the controls. There was no significant difference between the two groups for periods of tube placement, age at last visit or follow-up period after tube insertion. The cure rate for OME (normal or retraction) was significantly lower in children with Down's syndrome compared with

the controls (26% versus 78%; $P < 0.001$). Otorrhoea through the tube occurred in 20 children with Down's syndrome compared with ten children in the control group and the difference was statistically significant. After extrusion of the ventilation tube, the incidence of complications (atelectasis, perforation, cholesteatoma) was significantly higher in the ears of the children with Down's syndrome than in the ears of the children in the control group (26% versus 10%; $P < 0.05$). The authors also reported a greater improvement in the mean hearing levels of control children after ventilation tube insertion compared with that of children with Down's syndrome, although they did not compare the baseline hearing levels.

In the Australian study, there were 24 children with Down's syndrome, representing 12% of the clinic attendance, and 21 children in the control group, but their demographic characteristics were not compared. Preoperatively, 61% of the ears in children with Down's syndrome had a 20–40 dB hearing loss compared with 67% for the control group, and 37% compared with 33% for 41–60 dB hearing loss. Postoperatively, there was a greater improvement in the hearing levels in the control group: the proportion of children with 20–40 dB hearing loss was 23% for Down's syndrome and 2% for the control group, while for 41–60 dB hearing loss the figures were 17% and 3%, respectively. Overall, 40% of the ears in children with Down's syndrome continued having hearing loss compared with 9% in the control ears.

After 2 years of follow-up in the study from the USA, only two of the 48 children had no ear infections while six had occasional episodes which responded to antibiotics or no treatment. The rest of the children (40/48; 83%) required ventilation tube insertion because of chronic OME and the intervention was usually carried out at between 6 and 18 months of age. Forty-two percent of the children received two sets of tubes, 7.5% received three sets and 5% received four sets, but at 2 years of follow-up none of the children had resolution of their chronic otitis media. The authors reported that prior to treatment, 81% of the 40 children requiring ventilation tube insertion had abnormal hearing levels and these improved dramatically after treatment with either ventilation tube insertion or with antibiotics. Almost 98% children had normal to borderline normal hearing while only 2.3% had mildly abnormal hearing.

In the retrospective review of case records, OME was diagnosed in 54/70 children (77%) with Down's syndrome and it was bilateral in 87% of them. The mean conductive hearing loss in children with OME tested with PTA was 46 dB (SD 11.4 dB; range 25 to 65 dB), while sensorineural hearing loss was found in five children with a mean hearing loss of 18 dB (range 10 to 30 dB). No hearing deficit was found in 23% of children. OME was treated with ventilation tube insertion in 29 cases (54%) and almost 60% of them required repeat insertion. The average number of repeat ventilation tube insertions was 2.4 and the average length of time for ventilation tubes staying *in situ* was 19.9 months (range 5 to 62 months). It was not possible to insert ventilation tubes bilaterally in four and unilaterally in two children. Tympanic membrane abnormalities were observed in almost two-thirds of children undergoing ventilation tube insertion, with tympanosclerosis being the most common complication. Hearing aids were used in 20 children with OME: 11 in combination with ventilation tube insertion and nine alone. Conservative treatment was given to 30% of the children and the condition resolved spontaneously in them. Adenoidectomy and tonsillectomy was carried out in 9/14 children with obstructive sleep apnoea and OME owing to the severity of the condition.

Evidence summary

Only limited studies have been published on OME in children with Down's syndrome and the studies evaluating effectiveness of treatment for OME in these children are of poor quality. Results from two comparative studies show that the cure rate and mean hearing levels of children with Down's syndrome after ventilation tube insertion are poorer than those of other children with OME, while the incidence of complications is higher. In one case series, aggressive medical and surgical treatment of chronic otitis media led to great improvement in the hearing levels but not in the resolution of disease, while the other case series indicated the difficulties associated with ventilation tube insertion and suggested hearing aids as an alternative.

Translation from evidence to recommendations

Children with Down's syndrome are highly susceptible to OME and present particular problems of assessment and management because of the earlier age of onset, prolonged course, greater risk of complications and potential diagnostic difficulties. A number will also have a co-existing

sensorineural hearing loss which must be identified. Children with Down's syndrome require specialist multidisciplinary assessment.

Evidence has shown that ventilation tube insertion in children with Down's syndrome is effective in correcting the hearing loss but the benefit may be more short lived. Insertion of ventilation tubes is made more difficult or even impossible by the often small size of the external auditory canal. As a result of this, early consideration of hearing aid provision is required.

The insertion of ventilation tubes is a less favourable option for children with Down's syndrome as they are more susceptible to subsequent otorrhoea and a higher extrusion rate. Chronic otorrhoea may prevent the wearing of hearing aids.

Recommendations on children with Down's syndrome

The care of children with Down's syndrome who are suspected of having OME should be undertaken by a multidisciplinary team with expertise in assessing and treating these children.

Hearing aids should normally be offered to children with Down's syndrome and OME with hearing loss.

Before ventilation tubes are offered as an alternative to hearing aids for treating OME in children with Down's syndrome, the following factors should be considered:

- the severity of hearing loss
- the age of the child
- the practicality of ventilation tube insertion
- the risks associated with ventilation tubes
- the likelihood of early extrusion of ventilation tubes.

See the end of Section 3.5 for a research recommendation on children with Down's syndrome and children with cleft palate.

3.5 Management of OME in children with cleft palate

Introduction

Cleft palate results in impaired Eustachian tube function and renders children with cleft palate particularly susceptible to middle ear disease, particularly OME. While the palatal cleft is now managed in the UK by specialist centres, the otological problems will be managed locally, in cooperation with the specialist centre. The routine and regular audiological surveillance of children with cleft palate will identify affected children at an early stage so that appropriate care can be instituted.

Description of included studies

A prospective survey carried out in Ireland⁷³ examined the incidence, natural history and outcome of middle ear disease in children with cleft lip and palate. The study population comprised 584 children with cleft lip and palate registered on the hospital's database, and a questionnaire was sent to parents asking for details of their child's history regarding middle ear disease. The response rate was 68.0% (397/584) and the medical records of these children were also reviewed to obtain more information.

A good-quality systematic review,⁸¹ which is yet to be published, was conducted to determine whether early routine ventilation tube insertion in children with OME and cleft palate has a beneficial effect on hearing and speech and language development compared with conservative management. Studies (both comparative and non-comparative) that included children diagnosed with unilateral or bilateral cleft lip and palate, cleft palate only or submucous cleft palate, and which separately reported results for these children, were considered for inclusion. Outcomes measured were degree of conductive hearing loss (primary) and general development, speech and language development, complications and quality of life. The methodology was described in detail and studies were appraised for their quality. Meta-analysis could not be performed owing to variability in the study designs or different outcomes analysed in studies with similar design. [EL = 2++]

A retrospective survey⁷⁴ was carried out in the UK to investigate parental opinion of ventilation tube insertion in children with cleft palate. A confidential questionnaire was posted to the parents of 53 children attending a multidisciplinary cleft palate clinic and who had ventilation tube insertion. Parents were asked to score in a scale of 0–10 with higher score indicating a greater improvement. Hospital notes of these children were reviewed and results expressed as median scores. [EL = 3]

Another retrospective study⁵⁹ from the UK looked at the results of a non-interventionist approach for the treatment of middle ear effusion in children with repaired cleft palate. The treatment included provision of hearing aids, and ventilation tubes were inserted only in limited clinical circumstances. This study was carried out in a special paediatric otology clinic and case reports of children with cleft palate or cleft lip and palate were reviewed. These children were followed up until they had a minimum of three visits over an 18 month period with normal audiogram, no otological symptoms and satisfaction expressed by the parents and teachers. [EL = 3]

Review findings

In the first prospective survey from Ireland, there were 178 children (49.6%) with cleft palate only, 62 (17.3%) with cleft lip only, and 119 (33.1%) with both. The median age of children in the sample was 7 years (range 5 months to 27 years) and 53.2% were male. There was a high incidence of ear problems (infections or hearing loss) in children with cleft palate (68%) or cleft lip and palate (76%), and the problems began in the first year of life in nearly half the children. These children had a higher incidence of current hearing loss than children whose problems began after the first year, but the difference was not statistically significant ($P = 0.094$). Ear problems in children with cleft palate or those with cleft lip and palate peaked at age 4–6 years, with 56% of parents reporting problems in the preceding year and 40% reporting current hearing loss, and the problems persisted at significant levels until the age of 12 years. However, the majority of parents did not consider ear problems in their children at less than 2 years of age. Forty-five percent of these children had a history of recurrent ear infections, and this group had significantly increased incidence of current hearing loss (45% versus 17%; $P < 0.001$ and surgery for chronic OME (16% versus 1%; $P < 0.001$) compared with children without a history of recurrent ear infections. Almost 60% of these children had also undergone ventilation tube insertion by the time the study was conducted, and the incidence of current hearing loss was much higher in them compared with children without ventilation tube insertion (42% versus 11%; $P < 0.001$). The median number of ventilation tube insertions was 2 and, by logistic regression analysis, the number of ventilation tube insertions was found to be related to current hearing loss and surgery for chronic OME. [EL = 3]

Eighteen studies with sample sizes ranging from 19 to 261 were included for the systematic review of which five were conducted in the UK or Ireland. Most of the studies were of poor quality, with either no comparator group or an inappropriate comparator group. The review included eight case series, six historical cohort studies, three prospective observational studies and one RCT. Hearing impairment was measured in ten studies, speech and language development in six studies, middle ear status in nine studies and complications in five studies.

Results from some case series and one prospective observational study suggested improvement in hearing with ventilation tube insertion, while the retrospective cohort studies did not show any improvement. Inconsistent results (some studies showing improvement while others showing no improvement) were also seen for speech and language development in retrospective cohort studies. The only RCT included in the review was of poor quality and this made it difficult to interpret its results.

The response rate in the postal survey was 68% (36/53) and 22 of these were boys and 14 girls. Cleft repair was carried out in all children at the age of 6 months except in five children with Pierre Robin syndrome. The mean age at the first ventilation tube insertion was 17 months. Nineteen children had two or more ventilation tube sets inserted and the average number of ventilation tube insertions was two sets. Overall, parents were pleased with the results of ventilation tube insertion (median score 8.25; range 0 to 10) and noticed an improvement in both hearing (median score 7.7; range 2 to 10) and speech (median score 5.5; range 2 to 10). They did not find any change in the number of ear infections or ear discharge. Audiology results were available for

17/36 children after ventilation tube insertion and 12 of them had normal hearing thresholds, but their preoperative audiology results were not available for comparison.

In the last study, case records of 70 children were reviewed retrospectively and 11 of these children had associated syndromes. Males accounted for 60% (43/70) of the study population. Hearing aids were used in 31 children, including 14 with both ventilation tubes and hearing aids, and the mean age of first usage was 3 years and 2 months (range 12 months to 8 years). Six of the 14 children with both interventions had hearing aids as the first line of treatment and ventilation tubes were inserted following decreased compliance or recurrence of suppurative otitis media, while the rest (eight) had ventilation tube insertion first followed by hearing aids later. Twelve children had only ventilation tube insertion and 27 children did not require any treatment. More than half of the children using hearing aids had good compliance. There was no statistically significant difference between the mean hearing thresholds of children treated with either hearing aids or ventilation tubes, both before starting treatment and during follow-up. A significantly greater number of children with ventilation tube insertion had otological complications compared with those without the tubes (38.4% versus 4.5%; $P < 0.005$).

Evidence summary

Results from a well-conducted systematic review shows that there is currently inadequate evidence of benefit from ventilation tube insertion for the treatment of OME in children with cleft palate. The other two studies did not use a comparison group. One study reporting parents' perception found ventilation tubes to be beneficial but there was no objective assessment. The other study showed children using hearing aids as the first line of treatment to have the same hearing thresholds and a reduced number of complications compared with children with ventilation tube insertion.

Translation from evidence to recommendations

Children with cleft palate are highly susceptible to OME and present particular problems because of the earlier age of onset, prolonged course, higher rate of recurrence, higher incidence of surgery and later complications, and potential diagnostic difficulties.

All children with cleft palate should be managed by a multidisciplinary group which includes local professionals and the core cleft palate team. The sharing of care between these groups should be arranged to maximise the benefit to individual patients.

There is a lack of evidence on the optimal treatment of OME in patients with cleft palate. Treatment should therefore be based on the needs of the individual child. While it may be convenient to insert ventilation tubes under the same anaesthetic as a lip or palate procedure, there is no evidence to support their automatic insertion on these occasions and the GDG does not recommend routine ventilation tube insertion at the time of palate repair.

Ventilation tube insertion has been shown to improve hearing in children with cleft palate but surgically treated children are more likely than the general population to require multiple operations with their attendant complications. There is some case-review evidence for the effectiveness of hearing aids in these children and the alternative of early aiding should therefore be considered. The GDG recognises that some children with cleft lip and palate (and/or their parents and carers) have concerns about the appearance that may make hearing aids unacceptable.

Recommendations on children with cleft palate

The care of children with cleft palate who are suspected of having OME should be undertaken by the local otological and audiological services with expertise in assessing and treating these children in liaison with the regional multidisciplinary cleft lip and palate team.

Insertion of ventilation tubes at primary closure of the cleft palate should be performed only after careful otological and audiological assessment.

Insertion of ventilation tubes should be offered as an alternative to hearing aids in children with cleft palate who have OME and persistent hearing loss.

Research recommendation on children with Down's syndrome and children with cleft palate

Studies and national audit should evaluate the acceptability, effectiveness and consequences of the various treatment strategies for OME in children with Down's syndrome and children with cleft palate.

Why this is important

The GDG noted particular difficulties in organising research with children with Down's syndrome and those with cleft palate, and this seems to contribute to the lack of high-quality evidence for the questions of this guideline. Randomised controlled trials may not necessarily be the most cost-effective investment, and if undertaken would need to be conducted on a multicentre basis. However, high-quality designed national audits with statistical control for baseline characteristics would enable a fuller understanding of natural histories and sub-types, particularly in cleft palate, and could provide an informative and unbiased account of the consequences of locally varying management practices.

4 Information for children, parents and carers

4.1 Information for children, parents and carers

Treatment and care should always take into account patients' individual needs and preferences and thus all patients should have the opportunity to make informed decisions about their care and treatment. Information about treatment, especially with regard to non-surgical intervention, should be explained clearly at every stage. It is good practice for healthcare professionals to involve the young person's parents or carers in the decision-making process.

Good communication between healthcare professionals and children with OME is essential. All healthcare professionals should have a high standard of consultation and communication skills and use a consulting style that enables people with OME to participate as partners in all decisions about their treatment. The verbal giving of information by health professionals is particularly important and it is this that will remain foremost in the patients' and parents' mind.

Clear information should be provided after diagnosis as to what happens next, and to whom they will be referred regarding treatment options. There should be a contact number for a *named person* for any queries that they may have later. Realistic time frames should be given as to when they are likely to receive a follow-up appointment or an appointment with someone else further down the treatment pathway.

Clinicians should be aware that there is a wealth of information available through charities, the internet and particularly NHS Direct. Patients should be signposted onto these for further information.

Recommendations on information for children, parents and carers

Parents/carers and children should be given information on the nature and effects of OME, including its usual natural resolution.

Parents/carers and children should be given the opportunity to discuss options for treatment of OME, including their benefits and risks.

Verbal information about OME should be supplemented by written information appropriate to the stage of the child's management.

Appendix A

Declarations of interest

GDG member	Interest
Peter Bull	None, other than part-time medical practice.
Mark Haggard	Accepted fees (total approximately £2,500) in 2006 and 2007 from GlaxoSmithKline for acting as an advisory board member re pneumococcal and NTHI vaccination. ENT-UK (representative of provider profession) has agreed in June/July 2007 to provide funding of £3,070 to complete delivery of an audit tool relevant to OME/ventilation tubes – the overall aim is the same as that of the guideline, i.e. more uniform and more appropriate practice. ‘As a researcher in the area I would naturally wish maximal account to be taken of my insights and my group’s data and publications.’
Ewa Raglan	Wrote a chapter on otitis media with effusion in children (glue ear) in <i>Textbook of Audiological Medicine</i> , edited by Luxon L, Furman J, Martini A, Stephens D (Martin Dunitz, 2003).
Kenneth Pearman	‘As an ENT surgeon with a significant paediatric practice, I could be considered to have an interest in the outcome of a guideline which could affect clinical practice.’
Gareth Davies	[Chief Executive of the Cleft Lip and Palate Association] ‘The use of grommets is debated within the charity but we do not take a line on “yes” or “no”. We eagerly await the outcome of the deliberations of the GDG.’

Appendix B

Clinical questions

1. What is the clinical presentation or the symptoms that raise the suspicion/are suggestive of OME in children?
2. How should the diagnosis be confirmed in a child suspected of suffering from OME? What is the predictive accuracy of the various methods?
3. What is the clinical effectiveness and cost-effectiveness of various treatments of OME?
 - What is the appropriate time for intervening (medical or surgical treatment) in children with OME?
 - Which of the children with OME can be predicted to get high benefit from surgical intervention?
 - What is the effectiveness of various surgical procedures in children with OME?
 - What is the effectiveness of various non-surgical interventions in children with OME?

Appendix C

Economic evaluation of alternative management strategies for OME in children

Literature review of economic evidence

A literature review identified several economic evaluations addressing the cost-effectiveness of treatment options in the managements of OME.

The first study⁷⁶ was a randomised controlled trial which compared costs and effectiveness of treatment with ventilation tubes with watchful waiting in 187 young children (mean age 19 months) with persistent bilateral OME identified by a population-based screening programme. The study was conducted in the Netherlands and adopted a societal perspective with medical and non-medical costs included in the analysis. Patients were followed up for 1 year with time without effusion and language development used as outcomes, with the latter considered the most important. The authors concluded that ventilation tubes had higher costs and showed no significant improvement in language development and therefore were not recommended as standard treatment of OME in all children identified with persistent bilateral OME. It is important to note that about 50% of parents of children eligible for this trial refused randomisation, which may decrease the generalisability of the trial findings.

A second paper⁷⁷ used a quality of life approach in identifying a cost-effective treatment for otitis media in children younger than 18 years within a US setting. A retrospective chart review and a telephone survey were used to determine the quality of life changes for both affected children and their parents after the insertion of ventilation tubes. The study concluded that tube insertion was cost-effective in the treatment for otitis media. The authors recognised that there appeared to be a relatively high rate of complications with the insertion of ventilation tubes, but the costs of such complications were not factored into the analysis and may be important. However, the conclusions drawn from this study should be interpreted with caution as the willingness to pay per case of otitis media resolved was not considered.

A third study evaluated the cost-effectiveness of management options for children with persisting middle ear effusions,⁷⁸ again within a US setting. The study looked at options involving observation, surgery, antibiotics and other medical management strategies. The study mainly considered medically managed treatment within the first 12 weeks of middle ear effusion after which all children were automatically referred for surgical intervention. Only a short-term analysis was therefore considered.

The final study identified in the literature review⁷⁹ also attempted a quality of life analysis when considering cost-effectiveness in otitis media treatment. This was a US study and although it sought to incorporate QALY calculations within its analysis, no reference was made to how such QALYs were determined or the assumptions behind such numbers. The author of the study concluded that surgical therapy is cost-effective but only in children in whom medical therapy for OME has failed.

It was felt that none of the above studies sufficiently addressed the cost-effectiveness of treatment alternatives for bilateral OME persisting for a period of 3 months within a context generalisable to the NHS. Therefore, a health economic model was developed for the guideline in order to guide GDG recommendations on treatment.

Introduction

There is wide variation in practice both internationally and across the UK in the decision to insert ventilation tubes as a treatment for OME. For example, UK rates of 20 per 10 000 compared to 200 per 10 000 in the Netherlands have been cited.⁸⁰ If this variation cannot be explained by population characteristics then the possibility must be raised that insertion rates are not optimal. In a world of scarce resources this is not a trivial matter. In fact, the insertion rate of ventilation tubes in OME has reduced dramatically since these figures were arrived at, although there is still a high level of variability across the country. However, despite the reduction in the level of variability, it remains inexplicably high and this means that some surgeons are putting in tubes where others would not.

It is inevitable that, in a universally available but ultimately cash-limited system, treatment of any one condition may be at the expense of treating other conditions elsewhere. This applies to OME as to everything else, and it is essential to consider the cost-effectiveness of ventilation tubes as well as their clinical effectiveness.

It is hoped that these guidelines will help to reduce this level of variation in insertion rates.

A decision tree, illustrated in Figures C.1 to C.3, was developed in Microsoft Excel® to compare four alternative strategies for the treatment of OME persisting after 3 months of watchful waiting in a cohort of 10 000 hypothetical patients. The four strategies are:

- hearing aids
- ventilation tubes
- ventilation tubes plus adjuvant adenoidectomy
- 'do nothing'.

Neither costs nor benefits are discounted in the presentation of the results.* This is because, at baseline, all benefits and a majority of costs are incurred within 12 months of the intervention.

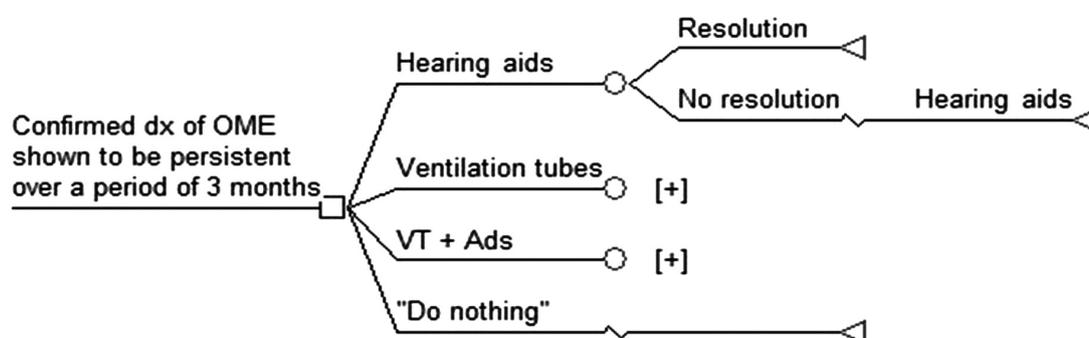


Figure C.1 The truncated version of the decision tree; the full sub-trees (+) for the ventilation tube and ventilation tube plus adjuvant adenoidectomy are shown separately; Ads = adenoidectomy, dx = diagnosis

Description of the four treatment strategies in the model

Hearing aid strategy and patient pathway assumptions

Based on GDG opinion, OME resolves in 75% of patients after 18–24 months[†]. In practice, many of these would resolve earlier but the model makes the simplifying assumption that all these patients resolve at the end of the specified period. This would lead to a slight overestimate of the 'downstream' costs[‡] associated with hearing aids in those who resolve earlier.

* The QALY loss associated with the very rare event of surgical death is an exception to this.

† The model uses the midpoint of this estimate – 21 months

‡ 'Downstream' costs are costs which arise subsequent to the intervention but as a consequence of it.

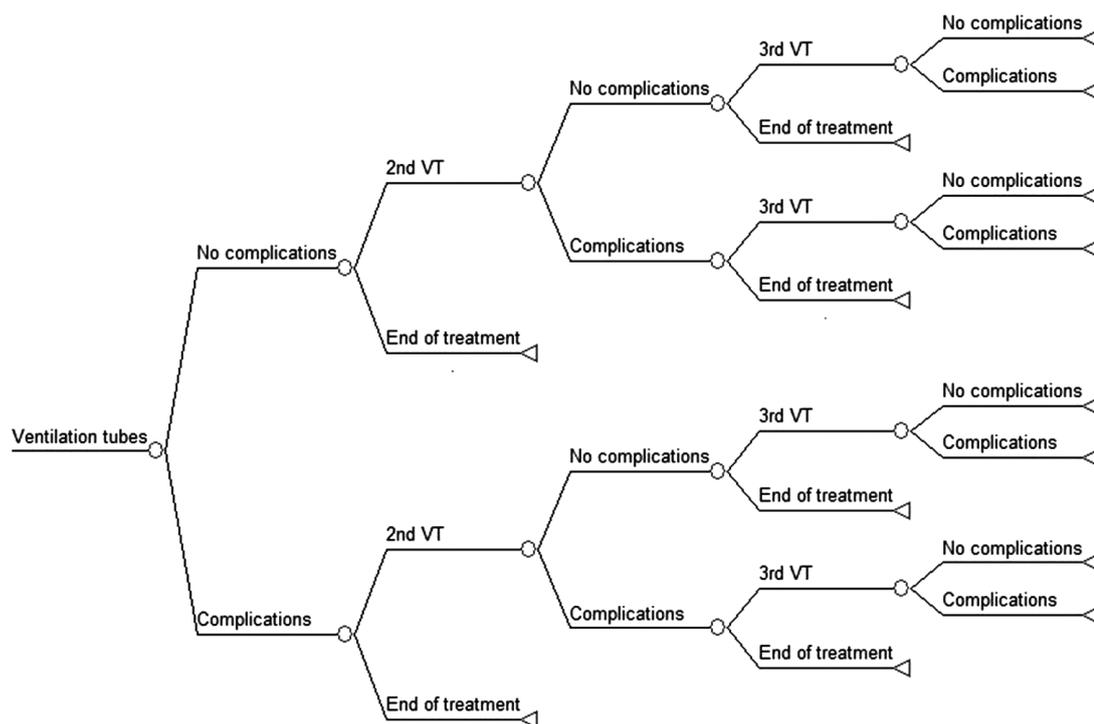


Figure C.2 The ventilation tubes sub-tree

In the 25% of patients where OME has not resolved at the end of 21 months, a number of alternative treatment strategies are available. The model assumes that they would continue with their hearing aids but an alternative strategy would be to offer children ventilation tubes at this stage in their care pathway. In this group it is assumed that OME resolves after a further 52 weeks of wearing aids. Again, this is a simplification as there will be some children whose OME resolves earlier and a small number in whom OME persists for longer.

Apart from the hearing aids themselves, the initial costs of this strategy include the moulds, a repair kit and the costs of fitting the hearing aid in an audiology department. It is assumed that there would be an audiological review after 13 weeks, with subsequent follow-up every 26 weeks thereafter. 'Downstream' costs also allow for mould replacement every 13 weeks, battery replacement every 4 weeks and hearing aid loss or breakage.

Hearing aids may not be acceptable to all parents and children and there is likely to be a concomitant effect on adherence. This is not explicitly addressed in the model owing to a lack of good-quality data on acceptability and use. It should be noted that non-adherence is likely to increase the costs associated with this strategy. This is because other treatment strategies are likely to be offered on top of the costs associated with the initial hearing aid provision.

Ventilation tubes strategy and patient pathway assumptions

The extrusion time is estimated to be 39 weeks (typically 6–12 months). It is estimated that a proportion of children will require a re-insertion after extrusion and that a proportion of these will require a third insertion. For each ventilation tube insertion, there are a number of complications that could occur that would result in 'downstream' costs additional to those arising from the surgery. These are otorrhoea, granulations, perforation of the eardrum and death. In addition, a proportion of inserted ventilation tubes will be surgically removed. A higher risk of perforation is estimated for re-insertions but other complication rates are as for the initial insertion. Patients are reviewed at an ENT outpatient clinic 6 weeks postoperatively, and every 26 weeks thereafter.

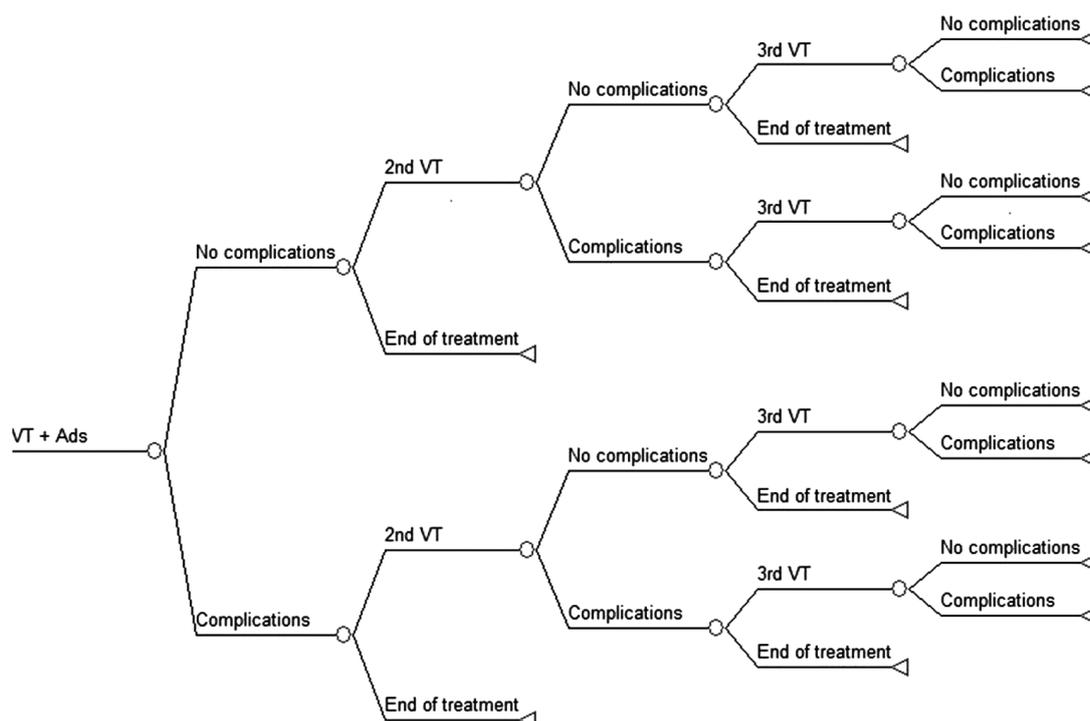


Figure C.3 The ventilation tubes plus adenoidectomy sub-tree

Ventilation tubes plus adjuvant adenoidectomy strategy and patient pathway assumptions

The patient pathway resembles that of the ventilation tubes strategy but the list of complications additionally includes severe bleeding* and palatal insufficiency.

'Do nothing' strategy and patient pathway assumptions

A trade-off exists by increasing the period of 'watchful waiting'. More cases would resolve spontaneously, lessening the need for surgery, but more children would suffer impaired hearing for longer periods. What the optimal or cost-effective period of 'watchful waiting' period would be is an interesting question but is not addressed here. This strategy is not meant to reflect simply a period of further 'watchful waiting' prior to active intervention. Rather, 'do nothing' is based on no active intervention on the basis that OME is usually self-limiting. Thus, this strategy serves as the benchmark against which to measure the cost-effectiveness of any strategy involving active intervention, surgical or otherwise.

However, 'do nothing' is unlikely to be cost-free. For many affected children, the condition will persist for a considerable time beyond the initial 3 month waiting period. In any children with a continuing health problem, there is likely to be ongoing contact with healthcare services and therefore the model suggests that these patients will require GP and audiological visits. The model also allows for an increase in 'downstream' costs arising from higher incidence of episodes of acute otitis media in patients whose OME is not treated.

* A 'severe bleed' is defined for the purposes of this model as a bleed significant enough to require a return to the operating theatre and/or an overnight hospital stay.

Model parameters

Table C.1 Treatment and consumable costs

Variable	Unit cost	Source	Notes
Ventilation tubes	£662	NHS Tariff 2006–07	From HRG code C55 (Minor Ear Procedure) which includes 'Insertion of VT through tympanic membrane'.
Ventilation tubes plus adjuvant adenoidectomy	£766	NHS Tariff 2006–07	From HRG code C58 (Intermediate Mouth/Throat Procedure) which includes 'Total adenoidectomy'.
Hearing aid	£70	GDG estimate	As the patients have bilateral OME, two are fitted per child.
Hearing aid mould	£15	GDG estimate	Two fitted per child, replaced every 13 weeks.
Hearing aid repair kit	£7	GDG estimate	
Hearing aid battery	£0.08	GDG estimate	Replaced in each hearing aid every 4 weeks.

Table C.2 Complication treatment costs

Treatment	Unit cost	Source	Notes
Medication	£10	GDG estimate	Approximate cost of a course of antibiotics/ear drops. A cost arising from otorrhoea/granulations.
Surgical arrest of bleeding from internal nose	£1,070	NHS Tariff 2006–07	From HRG code C22 (Intermediate Nose Procedure) which includes 'surgical arrest of bleeding'. A complication cost of bleeding.
Tympanoplasty	£1,549	NHS Tariff 2006–07	From HRG code C31 (Major Ear Procedure) which includes 'tympanoplasty using graft'. A complication cost of perforation of eardrum. ^a
Palatoplasty	£1,611	NHS Tariff 2006–07	From HRG code C57 (Major Mouth or Throat Procedure) which includes various palate repair procedures. A complication cost of palatal insufficiency.
Removal of ventilation tube	£662	NHS Tariff 2006–07	From HRG code C55 (Minor Ear Procedure) which includes 'Removal of VT through tympanic membrane'.

^a This may overestimate the costs of perforation as not all children will require tympanoplasty

Table C.3 Visit costs

Visit	Unit cost	Source	Notes
Hearing aid fitting	£66	NHS Reference Costs 2005–06	In patients who lose/break hearing aid this cost is incurred again.
GP	£31	PSSRU, Unit costs of health and social care 2006	A complication cost of otorrhoea and granulations. One visit assumed per case.
Audiology	£42	NHS Reference Costs 2005–06	This is used to cost hearing aid follow-up.
ENT	£60	NHS Tariff, 2006–07	This is used to cost surgical follow-up.

Table C.4 Critical care costs

Critical care	Unit cost	Source	Notes
HDU per day	£1,290	NHS Reference Costs 2005–06	It is assumed that patients who have severe bleeding as a complication of surgery will spend 2 days on a paediatric high dependency unit.
ICU per day	£2,067	NHS Reference Costs 2005–06	It is assumed that patients who die as a complication of surgery will spend 1 day on a paediatric intensive care unit.

Table C.5 Ventilation tubes complications

Complication	Probability	Source	Notes
Otorrhoea	0.26	Kay <i>et al.</i> (2001) ⁵⁴	'Transient otorrhoea occurred in 16% of patients in the postoperative period and later in 26%'. It is assumed that each patient affected will have one GP visit and one course of medication.
Granulations	0.05	Kay <i>et al.</i> (2001) ⁵⁴	It is assumed that each patient affected will have one GP visit and one course of medication.
Eardrum perforation (first tube insertion)	0.022	Kay <i>et al.</i> (2001) ⁵⁴	
Eardrum perforation (subsequent tube insertion)	0.10	GDG estimate	This higher estimate may be largely explained by a greater use of longer term tubes in re-insertion procedures. These have a higher rate of perforation (16% Kay <i>et al.</i> ⁵⁴).
Severe bleeding	0.00	GDG estimate	This baseline value can be varied in the model as part of a sensitivity analysis.
Surgical mortality	0.000005	www.netdoctor.co.uk/health_advice/facts/anaesthetic.htm	

Table C.6 Ventilation tubes plus adjuvant adenoidectomy complications

Complication	Probability	Source	Notes
Otorrhoea	0.26	Kay <i>et al.</i> (2001) ⁵⁴	'Transient otorrhoea occurred in 16% of patients in the postoperative period and later in 26%'. It is assumed that each patient affected will have one GP visit and one course of medication.
Granulations	0.05	Kay <i>et al.</i> (2001) ⁵⁴	It is assumed that each patient affected will have one GP visit and one course of medication.
Eardrum perforation (first tube insertion)	0.022	Kay <i>et al.</i> (2001) ⁵⁴	
Eardrum perforation (subsequent tube insertion)	0.10	GDG estimate	This higher estimate may be largely explained by a greater use of longer term tubes in re-insertion procedures. These have a higher rate of perforation (16% Kay <i>et al.</i> ⁵⁴).
Severe bleeding	0.01	GDG estimate	www.emedicine.com/ent/topic316.htm suggests bleeding complications of 4 per 1000 requiring a return to the operating theatre. The definition of severe bleeding used in this model also includes that requiring an overnight hospital stay in addition to that requiring a return to the operating theatre.
Palatal insufficiency	0.0006	www.emedicine.com/ent/topic316.htm	
Surgical mortality	0.00005	Randall <i>et al.</i> (1998) ⁸²	The authors report a mortality rate of between 1 in 16 000 to 1 in 35 000.

Table C.7 Probabilities

Variable	Value	Source	Notes
Weekly breakage/ loss of hearing aid	0.0031	GDG estimate	Estimated that 25% would lose/break their hearing aid within initial resolution period (21 months). ^a
Re-insertion rate (second tube)	0.25	GDG estimate	At baseline this is assumed to be identical for both surgical procedures, but this assumption can be relaxed as part of a sensitivity analysis.
Re-insertion (third tube)	0.25	GDG estimate	At baseline this is assumed to be identical for both surgical procedures, but this assumption can be relaxed as part of a sensitivity analysis.
Removal of ventilation tubes	0.07	Hospital Episode Statistics, DH (2005–06)	Insertion procedures 31 818 Removal procedures 2149

^a The probability of weekly breakage/loss is calculated as an instantaneous event rate. The formula to derive an instantaneous event rate from a probability over a period of time is:

$$r = -[\ln(1-P)]/t$$

In our case, the instantaneous event rate (events per week) is:

$$r = -[\ln(0.75)]/91 = 0.0031$$

Table C.8 Resource consequences of the 'do-nothing' strategy

Resource use	Number	Source	Notes
GP visits	2	GDG estimate	
Audiology appointments	1	GDG estimate	
ENT visits	0	GDG estimate	
Episodes of acute otitis media	1	GDG estimate	This value is for cases of AOM above those which would be expected in a treated child.

Table C.9 QALY values

Outcome	Value	Source	Notes
QALY gain per unit increase in dB	0.00874	Individual-patient data set (Kubba 2004) ^{b3}	Analysis of this patient data was undertaken by Simon Dixon as part of an, as yet, unpublished economic evaluation of the TARGET trial. ^a
QALY loss per surgical death	27	Office of National Statistics, NICE Guidelines Methodology manual	It is assumed that children have a life expectancy of a further 71 years, and that each year will be lived in full health. The QALYs arising from this assumption are then discounted at a 3.5% annual rate.

^a Data were collected for 131 children, with a median age of 5 years. Estimates of Health Utility Index Mark III (HUI-III) existed for 105 children and a simple OLS regression of age and PTA on HUI-III was undertaken. The results of this regression produced a statistically significant coefficient for PTA with each unit increase in dB hearing loss resulting in a 0.00874 decrement in HUI-III score (95% CI –0.005 to –0.012).

There are potentially a number of limitations in this approach and the presumed relationship between PTA and utility. Therefore, a number of alternative model specifications were tested and these generally produced coefficients for PTA within these limits.

Table C.10 Hearing outcomes

Strategy	Hearing gain ^a (dB)	Source	Notes
Hearing aids	0.0	N/A	This is the baseline value and effectively omits hearing aids from the baseline incremental QALY analysis. The value reflects a lack of appropriate comparative evidence and not that the GDG considers hearing aids to be ineffective. The baseline assumption can be relaxed as part of a sensitivity analysis.
Ventilation tubes	7.3	Lous ⁵¹	
Ventilation tubes plus adjuvant adenoidectomy	2.9	Lous ⁵¹	The difference in the baseline estimates of effectiveness may reflect that the studies from which these values are obtained do not compare like with like.

^a The hearing gain is the average over 1 year and is estimated as a weighted average of hearing levels assessed at 1–3 months, 4–6 months and 7–12 months. The model facilitates sensitivity analyses where hearing gains may be experienced at 2 or 3 years.

Results

The results for the baseline analyses are described below.

To calculate incremental cost-effectiveness ratios (ICERs), QALYs were calculated as a linear function of hearing gain. The results of this analysis suggested that ventilation tubes are the optimal option with an ICER of £16,000 per QALY, which is below the £20,000 per QALY threshold used by NICE, as a willingness-to-pay benchmark for cost-effectiveness.

Table C.11 Cost and QALY gain of each strategy

Strategy	QALY	Cost	Incremental QALY	Incremental cost
Hearing aids	0	£752	0	£752
Do nothing	0	£187	0	–£565
Ventilation tubes plus adenoidectomy	0.024	£1,354	0.024	£1,157
Ventilation tubes	0.064	£1,208	0.040	–£147

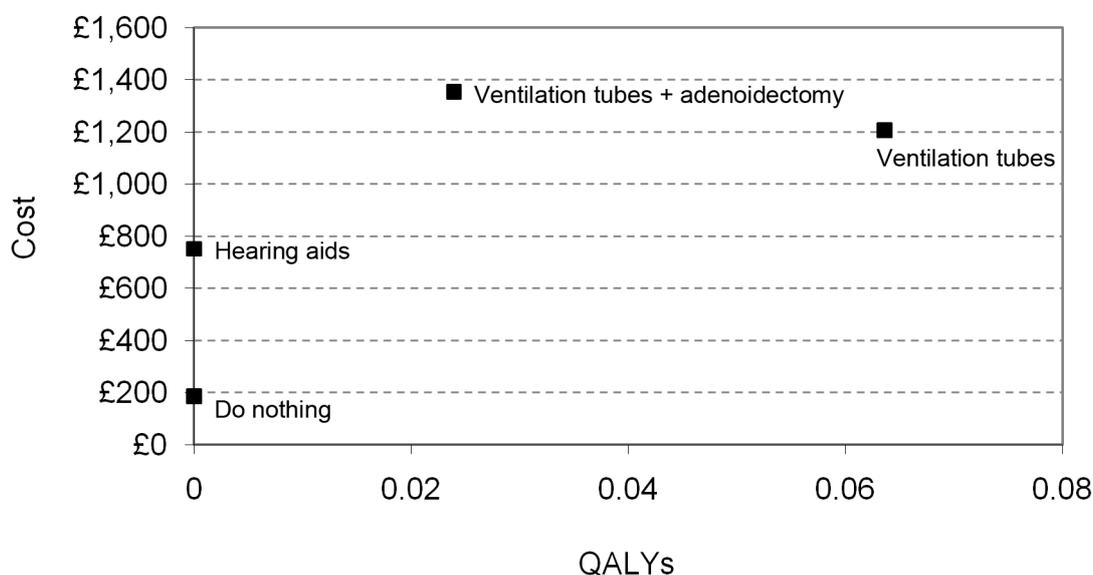
**Figure C.4** Cost and QALY gain of each strategy

Table C.11 shows that the hearing aid strategy is dominated by 'do nothing', being more expensive and no more effective (but note the caveat given in Table C.10). Similarly, ventilation tubes dominates the strategy with adjuvant adenoidectomy, being cheaper and generating greater QALY gains.

Incremental analysis requires that all dominated treatment options be excluded so that the incremental cost-effectiveness ratio of individual strategies are calculated relative to an appropriate comparator. This is shown in Table C.12.

Table C.12 Incremental cost-effectiveness of treatment alternatives for OME

Strategy	QALY	Cost	Incremental QALY	Incremental cost	ICER
Do nothing	0	£187	0	£187	
Ventilation tubes	0.064	£1,208	0.064	£1,021	£16,041

However, it is important to note that the parameter values used in the baseline analysis reflect some of the limitations of the data both in terms of the measurement of hearing gain and the relationship between a relatively transient hearing gain and quality of life. It is possible to take the costs of the various strategies and undertake a form of 'what-if' or threshold analysis. If the calculated cost of the strategies accurately captures opportunity cost, then the incremental QALY gain necessary for the strategy to be considered cost-effective by NICE criteria can be calculated.

In Table C.13 the strategies are ranked in order of cost. If we assume that their effectiveness ranking in terms of QALYs is identical then there are no strategies that could be eliminated on the grounds of 'strict dominance'. The values in the final column indicate what incremental QALY gain would be needed for the incremental costs associated with a particular strategy to be considered as a more cost-effective option than the next cheapest strategy (i.e. if hearing aids provide at least 0.03 QALYs more than 'do nothing', hearing aids would be considered cost-effective relative to 'do nothing').

Table C.13 Cost of each strategy and QALY gain necessary for a strategy to be considered more cost-effective than the next cheapest alternative

Strategy	Cost	Incremental cost	Incremental QALY gain needed
Do nothing	£187		
Hearing aids	£752	£565	0.03
Ventilation tubes	£1,208	£456	0.02
Ventilation tubes plus adenoidectomy	£1,354	£147	0.01

However, the above analysis takes no account of the possibility of some strategies being ruled out on the grounds of 'strict' or 'extended' dominance. For example, if ventilation tubes represents a poor strategy in terms of cost-effectiveness then only comparing ventilation tubes plus adjuvant adenoidectomy with ventilation tubes provides very limited information about the cost-effectiveness of ventilation tubes plus adjuvant adenoidectomy. In other words the cost-effectiveness of a particular strategy will always be improved if it is compared only against a strategy which is not cost-effective. This is why strategies which are not cost-effective (on dominance grounds) are removed prior to the incremental analysis. Of course, in the absence of measures of incremental effectiveness it is not possible to remove strategies on this basis. However, the tables below (C.14 to C.16) show other pairwise comparisons between strategies to illustrate that the necessary incremental QALY gain from a particular strategy may be greater than that implied above.

Table C.14 A pairwise 'what-if' comparison of ventilation tubes versus 'do nothing'

Strategy	Cost	Incremental cost	Incremental QALY gain needed
Do nothing	£187		
Ventilation tubes	£1,208	£1,021	0.05

Table C.15 A pairwise 'what-if' comparison of ventilation tubes plus adjuvant adenoidectomy versus hearing aids

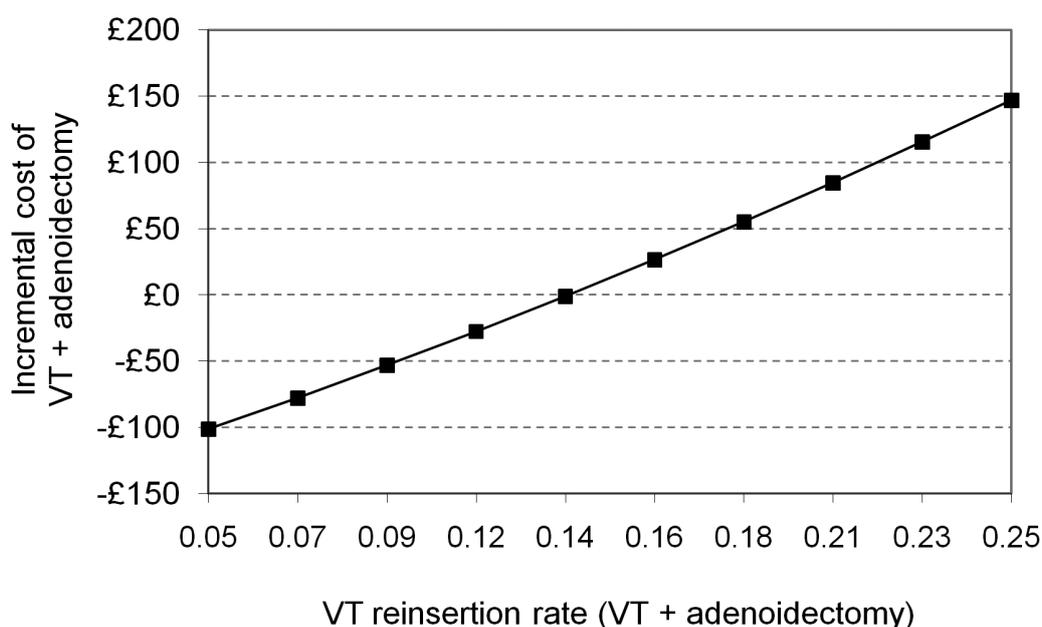
Strategy	Cost	Incremental cost	Incremental QALY gain needed
Hearing aids	£752		
Ventilation tubes plus adenoidectomy	£1,354	£602	0.03

Table C.16 A pairwise 'what-if' comparison of ventilation tubes plus adjuvant adenoidectomy versus 'do nothing'

Strategy	Cost	Incremental cost	Incremental QALY gain needed
Do nothing	£187		
Ventilation tubes plus adenoidectomy	£1,354	£1,167	0.06

Sensitivity analysis is used in economic evaluation to assess how sensitive the results of the model are to the assumptions made about the model parameters, particularly those parameters where considerable uncertainty exists as to their actual value. A number of one-way sensitivity analyses were undertaken to assess to what extent uncertainty over certain parameter values was likely to be important in interpreting the baseline results. In addition, threshold analyses were undertaken to determine scenarios in which decisions made on the basis of cost-effectiveness would change.

At baseline, the model assumes that the re-insertion rate of ventilation tubes is identical for both surgical treatment alternatives. However, some studies^{58,59} have suggested that adjuvant adenoidectomy may substantially reduce the re-insertion rate of ventilation tubes. Figure C.5 shows the effect of varying the re-insertion rate of ventilation tubes in the adjuvant adenoidectomy

**Figure C.5** Incremental cost of ventilation tubes plus adjuvant adenoidectomy relative to ventilation tubes at various re-insertion rates

strategy, holding all other parameter values constant. The point at which the line crosses the x-axis illustrates the point of cost neutrality. If the strategy with adjuvant adenoidectomy reduced the re-insertion rate from 25% to 14% or less then it would no longer be a more expensive strategy than adenoidectomy alone.

Figure C.6 shows that the incremental costs of adjuvant adenoidectomy are not that sensitive to changes in the rate of bleeding within plausible ranges.

Many members of the GDG thought it likely that adjuvant adenoidectomy would, in practice, deliver improvement in hearing gain as good as with ventilation tubes in the model. If the model is changed so as to reflect this fact, then ventilation tubes still dominate because of the higher cost of adjuvant adenoidectomy and the greater loss arising from higher surgical mortality. However, if in addition to assuming an equal hearing gain with both strategies a lower re-insertion threshold for adjuvant adenoidectomy can be determined, it would become the optimal strategy.

Table C.17 shows that if adjuvant adenoidectomy reduced the re-insertion rate by 13.1 percentage points or more (from 25%) when compared with ventilation tubes then it would be the optimal strategy using a willingness-to-pay threshold of £20,000 per QALY.

Table C.17 Incremental cost-effectiveness of adjuvant adenoidectomy with re-insertion rates of 11.9% and with hearing improvement equal to that achieved with ventilation tubes alone

Strategy	QALY	Cost	Incremental QALY	Incremental cost	ICER
Do nothing	0	£187	0	£187	
Ventilation tubes plus adenoidectomy	0.062	£1,183	0.062	£996	£15,948
Ventilation tubes	0.064	£1,208	0.001	£25	£20,869

The final sensitivity analyses address scenarios in which hearing aids could be considered cost-effective. The GDG are of the opinion that hearing aids work but at baseline no value for hearing gain was assumed because of a lack of good-quality data comparing hearing aids with surgical treatment options for OME. If it is assumed that the surgical strategies have identical effects

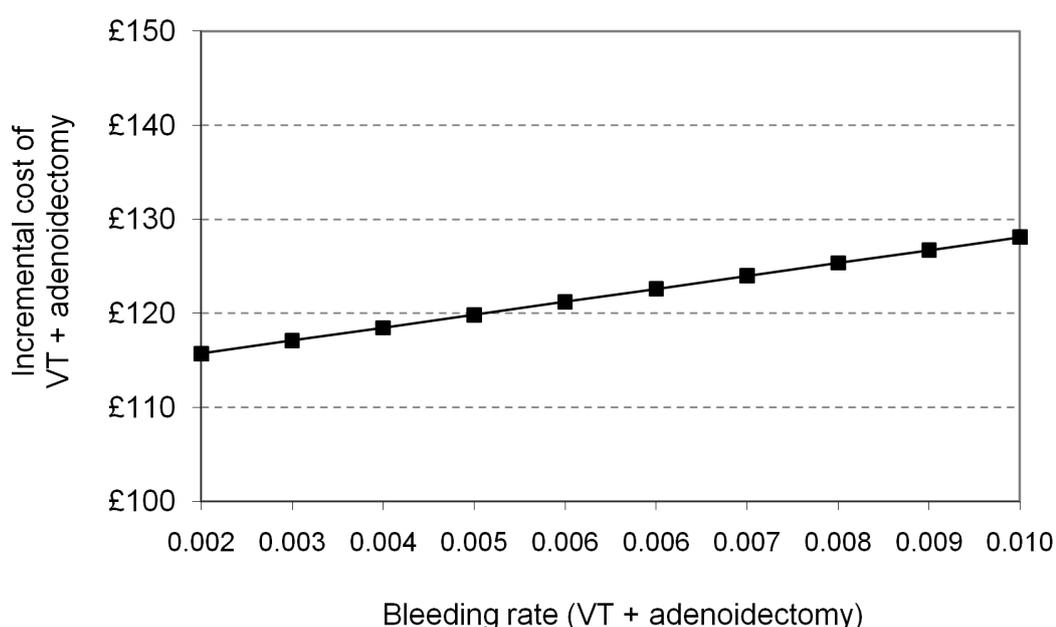


Figure C.6 Incremental cost of ventilation tubes plus adjuvant adenoidectomy relative to ventilation tubes at various bleeding rates

on hearing and have the same re-insertion rates, then hearing aids would be selected on cost-effectiveness grounds if they produced a QALY gain which is within at least 0.022 QALYs of that provided by the surgical strategies (Table C.18).

Table C.18 Incremental cost-effective analysis in which hearing aids achieve the minimum QALY gain threshold necessary for cost-effectiveness relative to surgical alternatives

Strategy	QALY	Cost	Incremental QALY	Incremental cost	ICER
Do nothing	0	£187	0	£187	
Hearing aids	0.042	£752	0.042	£565	£13,517
Ventilation tubes	0.064	£1,208	0.022	£455	£21,006

Finally, if we assume the parameter values for re-insertion at which adjuvant adenoidectomy becomes cost-effective this does not affect the threshold for hearing aids to be considered cost-effective (Table C.19).

Table C.19 Incremental cost-effective analysis in which hearing aids achieve the minimum QALY gain threshold necessary for cost-effectiveness relative to surgical alternatives and with re-insertion rates with adjuvant adenoidectomy of 11.9%

Strategy	QALY	Cost	Incremental QALY	Incremental cost	ICER
Do nothing	0	£187	0	£187	
Hearing aids	0.042	£752	0.042	£565	£13,762
Ventilation tubes plus adenoidectomy	0.062	£1,183	0.020	£430	£20,154
Ventilation tubes	0.064	£1,208	0.001	£25	£20,869

Discussion

The baseline cost-effectiveness ratios suggest that the surgical strategy of ventilation tubes is cost-effective according to a willingness-to-pay threshold of £20,000 per QALY. However, this baseline analysis needs to be interpreted with considerable caution. Sensitivity analysis suggested that there are plausible scenarios in which either hearing aids or adjuvant adenoidectomy could be preferred options on cost-effectiveness grounds. Nevertheless, given the concerns about the higher rate of surgical complications with adjuvant adenoidectomy and about acceptability and adherence with hearing aids, the baseline result is a reasonable one on which to base a recommendation.

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Enquiries regarding the above guidelines can be addressed to:

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A version of this guideline for parents/carers and the public is available from the NICE website (www.nice.org.uk/CG060) or from the NHS Response Line (0870 1555 455); quote reference number N1462.

ISBN 978-1-904752-45-5



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