Otitis media with effusion in under 12s: surgery

Clinical guideline
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www.nice.org.uk/guidance/cg60
Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.
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Overview

This guideline covers surgical treatment of children younger than 12 years who have fluid buildup behind their eardrum (otitis media, also known as 'glue ear'). It aims to improve hearing and quality of life in children with otitis media.

Who is it for?

- Healthcare professionals
- Commissioners and providers
- Children younger than 12 years with otitis media and their families and carers
Introduction

Otitis media with effusion (OME) is a common condition of early childhood in which an accumulation of fluid within the middle ear space causes hearing impairment. The hearing loss is usually transient and self-limiting over several weeks, but may be more persistent and lead to educational, language and behavioural problems.

OME may be overlooked because of the insidious nature of the condition, and suspicion of hearing loss in children must be acted upon effectively. In most instances of uncomplicated OME, no intervention is required because the fluid clears spontaneously and the hearing recovers.

A period of observation of the hearing loss over 3 months (with accurate audiometry), and its impact on the child’s development, is recommended in order to determine whether resolution occurs or if further treatment is needed. This may require better and more timely access to paediatric audiology services than is currently available in some areas.

Persistence of hearing loss with adverse effects on the child will require further action, which may include surgery. Once a decision is taken to offer surgery following the period of active observation, it is important that there is a minimum of delay in performing it. Similarly, it should be recognised that if surgery is not recommended, there is still a continuing need for expert review. However, there are also resource implications in the non-surgical management of OME, particularly if a hearing aid is fitted.

Children with Down's syndrome and those with cleft palate are particularly susceptible to OME and require special consideration. Middle ear effusions in these children are very common and are also likely to occur at an earlier age and be more persistent. Early and continuing specialist assessment is beneficial for these children.

This guideline makes recommendations specifically on the surgical management of OME in children under the age of 12 years, but also considers other forms of management. The recommendations are based on the best available published evidence and GDG consensus. Parents and carers often receive well meant but erroneous advice on a variety of non-surgical treatments for OME. This guideline explains the nature of the condition and when surgery is appropriate. The guidance may also allay anxieties over the use of active observation to allow natural resolution of OME to occur and thereby avoid the need for surgery.
The view has been expressed that surgery for OME is 'inessential'. This guideline provides a balanced, multidisciplinary opinion on the effects of hearing loss and the need for surgical management of OME based on current evidence. The guideline will also aid healthcare professionals, parents and carers in the practical management of the condition. It should also assist purchasers of healthcare to make cost-effective and unbiased arrangements for the management of this condition, thereby giving maximum benefit to children while minimising the risks of intervention.

Implementation of this guideline should not require a major change in what is already current practice in many areas. However, it will require acceptance on the part of purchasers of healthcare that the management of children with OME can be complex and long term and will also require specialist resources.
Key priorities for implementation

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.
Children who 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 to 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.

Surgical interventions

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

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.
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.

**Management of OME in children with Down's syndrome**

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

**Management of OME in children with cleft palate**

- 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.
Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in NICE's information on making decisions about your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

The following guidance is based on the best available evidence. The full guideline gives details of the methods and the evidence used to develop this guidance.

1.1 Clinical presentation

1.1.1 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 infections 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.
1.2 Diagnosis of OME

1.2.1 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.

1.2.2 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.
1.3 **Appropriate time for intervention**

1.3.1 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.

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

1.4 **Children who will benefit from surgical intervention**

1.4.1 Children with persistent bilateral OME documented over a period of 3 months with a hearing level in the better ear of 25 to 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.

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

1.5 **Surgical interventions**

1.5.1 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.

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

1.6 **Non-surgical interventions**

1.6.1 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.

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

1.6.3 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.

1.7 Management of OME in children with Down's syndrome

1.7.1 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.

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

1.7.3 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.

### 1.8 Management of OME in children with cleft palate

1.8.1 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.

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

1.8.3 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.

### 1.9 Information for children, parents and carers

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

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

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

The guideline development group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future. The guideline development group's full set of recommendations for research is detailed in the full guideline.

1 Effectiveness of surgical procedures for treating OME

There is a need for good-quality randomised controlled trials documenting the effect of adjuvant adenoidectomy with ventilation tubes compared to 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 subgroups that would particularly benefit from surgical intervention.

Why this is important

Despite a lack of robust scientific evidence, adjuvant adenoidectomy with ventilation tube insertion is routinely performed for recurrent or chronic persistent OME. There is, therefore, a need for good quality, randomised controlled trials with large samples which address the power deficit in measuring any additional difference derived from adjuvant adenoidectomy. In particular, the proportion of time spent with middle ear fluid and any corresponding benefit to hearing should be investigated. The trials need to follow up study participants beyond 6 to 12 months after ventilation tube insertion. This is because a high proportion of tubes would have fallen out during this period, and therefore any advantage that may exist for adjuvant adenoidectomy would become, in principle, demonstrable. Up to 2 years is a feasible follow-up period without high sample attrition. Further trials should also evaluate benefit to children's respiratory and general health, and additional benefits (for example, re-insertion of ventilation tubes) which would add precision to cost-effectiveness or cost-utility comparisons.
2 Presentation 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

Current studies are limited by the almost exclusive predominance of hearing level as an outcome measure. Developmental outcomes can be measured using various approaches (for example, validated questionnaires and objective reports) and incorporated into well-controlled longitudinal studies, which, to maximise their value, could form part of a larger population cohort study. One particular embedded trial (MRC Multicentre Otitis Media Study Group, 2004) used speech reception in noise as a measure of auditory disability, and reported a greater benefit in children with larger baseline deficits on the same test. Such a result is promising for linking sequelae with treatment, but needs to be generalised via a larger sample size and adequately powered stratification. Other markers of developmental impact between hearing (narrow, probably short-term) and speech, language and behaviour (broad, probably long-term) should also be considered.

3 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

There are particular difficulties in organising research of children with Down’s syndrome and those with cleft palate. These problems have contributed to the lack of high-quality evidence in these populations. Randomised controlled trials are not necessarily the most cost-effective investment, and would need to be conducted on a multicentre basis. In contrast, high-quality and well-designed national audits with appropriate statistical control for baseline characteristics would enable a fuller understanding of the natural history of these disorders and their subtypes, particularly in children with cleft palate. Such studies may also provide an informative and unbiased account of the consequences of different management practices that may vary by region.
Finding more information and committee details

To find NICE guidance on related topics, including guidance in development, see the NICE topic page on ear, nose and throat conditions.

For full details of the evidence and the guideline committee's discussions, see the full guideline, which includes care pathways for the surgical management of OME in children under 12 years, and in children with Down's syndrome and cleft palate. You can also find information about how the guideline was developed, including details of the committee.

NICE has produced tools and resources to help you put this guideline into practice. For general help and advice on putting our guidelines into practice, see resources to help you put NICE guidance into practice.

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