REVIEW ARTICLE

Diagnosis and Treatment of Otitis Media With Effusion: CODEPEH Recommendations∗, ∗∗

Faustino Núñez-Batalla, a,* Carmen Jáudenes-Casaubón, b Jose Miguel Sequí-Canet, b Ana Vivanco-Allende, b Jose Zubicaray-Ugartecheb

a Presidente de la CODEPEH (Comisión para la detección precoz de la hipoacusia)
b Vocales de la CODEPEH

Received 5 July 2017; accepted 7 July 2017

Abstract The incidence and the prevalence rates of otitis media with effusion (OME) are high. However, there is evidence that only a minority of professionals follow the recommendations provided in clinical practice guidelines. For the purpose of improving diagnosis and treatment of OME in children to prevent and/or reduce its impact on children’s development, the Commission for the Early Detection of Deafness (CODEPEH) has deeply reviewed the scientific literature on this field and has drafted a document of recommendations for a correct clinical reaction to OME, including diagnosis and medical and surgical treatment methodology. Among others, medication, in particular antibiotics and corticoids, should not be prescribed and 3 months of watchful waiting should be the first adopted measure. If OME persists, an ENT doctor should assess the possibility of surgical treatment. The impact of OME in cases of children with a comorbitity is higher, so it requires immediate reaction, without watchful waiting.
© 2017 Sociedad Española de Otorrinolaringología y Cirugía de Cabeza y Cuello. Published by Elsevier España, S.L.U. All rights reserved.

PALABRAS CLAVE
Otitis media secretora; Tubos de drenajes; Adenoidectomía; Guía de práctica clínica

Diagnóstico y tratamiento de la otitis media secretora infantil: recomendaciones CODEPEH

Resumen La incidencia y prevalencia de la otitis media secretora infantil (OMS) son elevadas, sin embargo, existen evidencias de que solo una minoría de profesionales sigue las recomendaciones de las guías para su manejo clínico. Con objeto de mejorar el diagnóstico y el tratamiento de la OMS, para prevenir y/o reducir sus consecuencias sobre el desarrollo del niño, la Comisión

∗ Please cite this article as: Núñez-Batalla F, Jáudenes-Casaubón C, Sequí-Canet JM, Vivanco-Allende A, Zubicaray-Ugarteche J. Diagnóstico y tratamiento de la otitis media secretora infantil: recomendaciones CODEPEH. Acta Otorrinolaringol Esp. 2019;70:36-46.
∗∗ CODEPEH papers are undertaken within the framework of a collaboration agreement between the Real Patronato sobre Discapacidad (Royal Board on Disability) and FIAPAS (Spanish Federation of Associations of Parents and Friends of the Deaf).
∗ Corresponding author.
E-mail address: fnunezb@telefonica.net (F. Núñez-Batalla).

2173-5735/© 2017 Sociedad Española de Otorrinolaringología y Cirugía de Cabeza y Cuello. Published by Elsevier España, S.L.U. All rights reserved.
Introduction

Otitis media with effusion (OME) is defined as the presence of fluid in the middle ear, with no signs or symptoms of acute infection. Various synonyms can be found in the literature, such as “serous otitis media” or “seromucous otitis media”. Having completed our literature review, we chose the term “effusion” as it is the terminology used most often for this clinical entity.

There is a high incidence in the paediatric age group, up to 90% of children develop an OME before school age, and suffer an average of 4 episodes a year.

OME usually presents in 2 ways: spontaneously due to abnormal functioning of the Eustachian tube, or after acute otitis media (AOM), as an inflammatory reaction, particularly between the ages of 6 months and 4 years. At school check-ups fluid is found in the middle ears of every 8 children between the ages of 5 and 6. However the prevalence of OME in children with Down’s syndrome or cleft palate is much greater, from 60% to 85%. Most episodes resolve spontaneously after 3 months. However, between 30% and 40% of children will have repeated episodes, and OME will last longer than one year in 5%-10% of those affected.

OME is the most common cause of childhood deafness in developed countries. Permanent hearing loss related to post-otitis sequelae has a prevalence of 2–35 per 10 000. Persistent fluid on the eardrum reduces the mobility of the membrane, causing an obstacle to sound conduction. At least a quarter of episodes of otitis with effusion last more than 3 months and can be associated with hearing loss, vestibular problems (balance), poor performance at school, and reduced quality of life. Structural damage to the eardrum or the small bones of the middle ear is less common, and will require future surgical intervention.

The incidence of OME is 5 times higher in children with otitis media with effusion who, in addition to the symptoms of the condition itself, experience bouts of earache with fever that cause physical suffering, emotional stress and concern for parents.

The impact of OME is higher in children with diverse comorbidities. There is also a greater tendency for delayed development when otitis with effusion is associated with certain situations, such as sensory, cognitive or behavioural factors, which constitute a greater risk of delayed development or changes in children with the condition (Table 1). Therefore it is extremely important to identify these cases and take more prompt therapeutic action.

Despite the high incidence and prevalence of OME, there is evidence that only a minority of professionals are following the recommendations of the guidelines for the clinical management of the disease. The infrequent use of pneumatic otoscopy in diagnosing the condition, the lack of audiometric explorations for children with chronic otitis with effusion and the inappropriate use of antibiotics, are the most common issues.

The Commission for the early detection of hearing loss (CODEPEH) considers it necessary to review the management of childhood OME, make a series of recommendations to counteract the clinical variability in how it is approached, and draw attention to the population of children with previous conditions particularly susceptible to incurring or aggravating delayed development as a consequence of OME. This review applies to children with OME between the ages of 2 months and 12 years, with or without developmental disorders or predisposing comorbidities.

Table 1  Risk Situations, Where Otitis Media With Effusion Has Greater Impact.

<table>
<thead>
<tr>
<th>Other baseline deafness</th>
<th>Autistic spectrum</th>
<th>Delayed speech and language</th>
<th>General developmental disorder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Craniofacial malformations</td>
<td>Syndromes with cognitive impairment or impaired speech and language</td>
<td>Blindness</td>
<td></td>
</tr>
</tbody>
</table>

© 2017 Sociedad Española de Otorrinolaringología y Cirugía de Cabeza y Cuello. Publicado por Elsevier España, S.L.U. Todos los derechos reservados.
Attitude Towards Childhood Otitis Media With Effusion

Attitude Towards Children Not at Risk

For children who are not at risk presenting with an OME, a watchful waiting approach should be taken for 3 months before starting other measures such as referral to the ENT specialist, audiological assessment or surgery. The purpose of this recommendation is to avoid unnecessary measures and because otitis with effusion is self-limiting in most cases, especially if preceded by common triggers such as an upper airway infection or AOM. It is known that from 75% to 90% of cases of OME after AOM will resolve in 3 months. This watchful waiting approach is harmless for children not at risk. The parents should be informed that the child will go through a period of poorer hearing, until the OME resolves, and should be taught strategies to optimise their child’s hearing.

The recommendation for a 3-month observation period is based on the benefit clearly outweighing the risk and is consistent with other previous recommendations in this area, with the clear objective of avoiding unnecessary surgery.

Attitude Towards Children at Risk

Although there are no definitive studies, it is evident that OME can affect children with comorbidities more severely (Table 1), which places them at risk, or makes them more susceptible to delayed development.

Developmental, behavioural and sensory disorders are not rare; therefore their association with otitis media with effusion is a common clinical problem. Hearing loss associated with OME can significantly compromise the development of these children and therefore the detection and treatment of this otitis must be a major goal. If it occurs often it can degrade the hearing signal and cause difficulties in speech recognition, the superior processing of words, comprehension in noisy environments, and the spatial localisation of sounds.

Examples of the above are cases with pre-existing hearing loss whose hearing difficulty will increase as a consequence of OME with the resulting negative effect on speech and language development. Similarly, blind children or children with untreatable eye conditions will be more reliant on their hearing, which makes them vulnerable to imbalance, difficulties in locating sounds and delayed speech and language development.

Children with Down’s syndrome experience more frequent and persistent otitis with effusion. They have narrow external auditory canals (EAC) that can make it difficult to assess the eardrum and the condition of the middle ear. The condition is highly prevalent in these children: 67% of cases present with OME in the first year of life. The incidence increases again at the age of 6 or 7, at 60%. From the age of 8 years, this prevalence tends to decrease. It is accompanied by mild or moderate hearing loss. These children are also at risk of developing mixed or sensorineural hearing loss. The risks remain throughout their childhood and drainage tubes may need to be placed repeatedly. It is recommended that these children’s hearing should be monitored weekly from birth, to assess the condition of the middle ear and clear the canals. Audiometric tests should also be undertaken as necessary.

Cleft palate is a common malformation, with a prevalence of 1 in every 700 newborn infants. It is associated with OME in almost all cases because the insertions of the tensor veli palatini muscle are abnormal, causing difficulty in opening the Eustachian tube. Chronic OME in these patients causes conductive hearing loss, which it is recommended should be monitored throughout their childhood, even after surgical repair of the malformation, because its prevalence does not decrease after this treatment.

Tube dysfunction does not only affect children with cleft palate and Down’s syndrome, it is also associated with other craniofacial syndromes and malformations of the head and neck.

If OME is detected in a child at risk, they should be offered prompt placement of tympanostomy tubes (TT). A regimen of check-ups should be established for children for whom this treatment is not indicated to monitor their OME and hearing levels, according to their individual needs. It is advisable to do this more often than the every 3 months recommended for children who are not at risk.

Due to all of the above, it is advisable to rule out otitis with effusion in children at risk at the ages of 12 and 18 months, since this is a particularly important period in the development of speech and language, balance and coordination.

Mild or moderate, uni or bilateral hearing loss can cause learning, social and behavioural difficulties making this time critical for identifying OME and treating it when necessary. Therefore, audiometric assessment is recommended for this population of at-risk children using the method appropriate to the age of the child and as frequently as necessary to assess the effectiveness of surgery when indicated.

This active search for OME in the population of children at risk should not extend to those not at risk, for whom systematic screening for OME is explicitly not recommended.

Attitude Towards Altered Newborn Screening Attributable to Otitis Media With Effusion

If a child does not pass the newborn hearing loss screening tests, and this is attributed to an OME, it is recommended that they should be monitored periodically to reduce the likelihood of a failure or delay in detecting sensorineural hearing loss. OME is a major cause of transient moderate hearing loss in newborn infants that fail newborn hearing loss screening: in a prospective study of screening failures it was found that 55% of cases had OME. However, although most cases will resolve spontaneously, some children will be diagnosed with underlying sensorineural hearing loss. Eleven
percent of screening failures have been found to have OME and sensorineural hearing loss simultaneously, however, failure in 2 thirds of these cases was initially put down to OME exclusively.  

**Impact of Otitis Media With Effusion on Children’s Behaviour and Development**

OME has a notorious impact on quality of life. Sixty-four per cent of sufferers have sleeping disorders, 49% behavioural disorders, between 33%–62% delayed language development and 15% imbalance.

OME temporarily impairs a child’s hearing. This can occur repeatedly through the first years of life, and can eventually have a harmful effect on some areas of their development (cognitive, communicative, and socio-emotional), their educational process and learning. In fact, OME is associated with speaking and reading difficulties, slow responses to auditory stimuli, poor vocabulary and problems with attention. This explains why, after it has been identified and correctly treated, learning achievement and performance substantially increase. This is even more evident in children at risk.

If a normal-hearing child suffers an episode of OME, hearing loss will be considered borderline mild to moderate (25–40 dB). In contrast, if the child’s deafness is already established, depending on its degree, the hearing loss caused by the OME will add to it; therefore their hearing loss will be quantitatively and qualitatively worsened. All of this will be more or less acute depending whether the OME affects only one or both ears. As we mentioned earlier, another aspect determining the effect of OME are the ages when clinical onset is most common (0–8 years). The first years of life are critical in speech and language development, and in acquiring instrumental learning tools, such as literacy. There are other consequences on the processes of attention and memory, and on behaviour. It should also be borne in mind that if hearing fluctuates with the persistence of OME, this can cause instability in the child’s behaviour. Children will respond differently to the same sound and verbal stimuli, will pay less attention to these stimuli, and may appear restless, etc.

**Consequences According to Degree of Hearing Loss**

In the event of OME supervening in a normal-hearing child, these types of hearing losses under 40 dB enable them to hear a large part of sounds and speech around them, but not all, since there can be a deficit in discriminating the phonetic features of words. There will also be dyslalia and some delay in language development. All of this can affect achievement at school and behaviour, because attention problems are generated and they will have difficulty in communicating in spaces with background noise. For children with established deafness, above 40 dB, the presence of OME causes hearing loss that not only affects better or poorer phonetic discrimination but also the acquisition of phonological awareness necessary for cognitive and linguistic development, and problems with attention and delayed learning. All of these situations are more far reaching and lasting the greater the baseline hearing loss or if there is added risk (Table 1).

**Consequences According to Age and Level of Acquired Language**

Hearing impairment or loss in children with no acquired language (0–3 years of age) cause alterations and shortfalls in phonological awareness and listening habits, affect balance and psychomotricity and learning and acquisitions specific to early childhood, and cause altered behaviour. Children with acquired language (3–12 years) also experience alterations and shortfalls in phonological awareness and listening habits, balance disorders, effects on access to literacy and academic achievement and performance. Of all these effects of hearing loss secondary to OME, there is one in particular that can pass unnoticed in the immediacy of the moment and yet, if not monitored and treated, will have permanent consequences that must be highlighted: limited access to the phonetic features of language. Acquiring phonological awareness helps in the deployment and development of high-level cognitive tools, which will flourish later, such as interior language, literacy, verbal thinking, mental representation, phonetic symbolism, etc.

**Methods for Diagnosing Childhood Otitis Media With Effusion**

**Otoscopy**

Otoscopy is the most important technique for assessing the ear and therefore for diagnosing OME. It can be performed with a conventional otoscope, videendoscope or microscope, which very much improve the likelihood of a precise diagnosis, matching the benchmark of pneumatic otoscopy. Otoscopy requires precise training and experience to correctly assess the ear. In children, particularly the smallest, the size of the EAC, the angle of the eardrum, the more open the younger the child, crying and the patient being unable to collaborate, can result in some ear diseases being interpreted as normal. Otoscopic signs that will enable a diagnosis of OME are loss of transparency, thickening of the membrane and change in colour. Air-fluid levels can occasionally be appreciated.

**Pneumatic Otoscopy**

This is considered the benchmark technique. An otoscope is required, a speculum that fits the EAC perfectly and a handle to perform the insufflation manoeuvres. The test is performed exerting gentle pressure on the handle connected to the otoscope. If the ear is normal, the membrane can be seen to move inwards on pressing the handle and return to the normal position when pressure is removed. If there is any effusion in the middle ear, the mobility of the membrane will reduce or it will not move, according to the amount and density of the fluid. If the membrane is immobile, movement of
the walls of the EAC might even be seen. Pneumatic otoscopy is the first technique indicated for initial diagnosis of OME; it has a sensitivity of 94% and specificity of 80% compared to myringotomy.7 This technique, despite numerous recommendations for the diagnosis of OME,12 is seldom used in primary care because of the need for appropriate material, despite its low cost, and due to the difficulty in learning it; tympanometry is preferred in this area. Since this is a subjective technique, its greatest disadvantage is the variability among various observers in interpretation, and it can be painful for cases of OME.

Tympanometry

This is an objective test that will give us information about the dynamic features of the status of the middle ear and the tympano-ossicular complex. It measures the acoustic admittance of the middle ear in relation to the pressure changes of the outer ear.18 The result is a graph of the energy admitted by the eardrum and the middle ear in response to the pressure surised air inserted into the EAC (Figs. 1 and 2). The acoustic energy is transmitted to the EAC and a microphone measures the sound reflex while the pressure varies between +200 and –400/–600 mmHg. It is recommended that tympanometry should be promoted as an objective tool for diagnosing OME, both to confirm the findings of pneumatic otoscopy, and to serve as an alternative to otoscopy when there is limited visualisation of the membrane. There are precise recommendations to follow when performing tympanometry12; for it to be performed correctly, an otoscopy should be undertaken to avoid occulting or infectious processes of the ear. The probe with frequencies of 226 Hz has proved effective in identifying OME in pre-school and school-age children (specificity of 82%–89% and sensitivity of 95%–100%), but its reliability is less for children under the age of 6–9 months. A 1 kHz probe is recommended for explorations in children younger than this age.39

Medical Treatment of Childhood Otitis Media With Effusion

The main objectives in the treatment of OME are to eliminate the effusion from inside the eardrum, restore normal hearing, and prevent future episodes as far as possible.12,40 Various drugs have been used to treat OME, with the double objective of improving quality of life and avoiding invasive surgical interventions. The purpose of this section is to analyse their efficacy.

Oral and Topical Steroids

The idea of using corticosteroids is based on their anti-inflammatory effect on the rhinopharynx and the middle ear. In addition, they up-regulate transepithelial sodium transport in the middle ear, encouraging the elimination of fluid from the middle ear cavity.41

Oral Glucocorticoids

Already by 2004 various medical associations and subsequently, the directives of the National Institute for Clinical Excellence (NICE), were advising against the use of oral glucocorticoids for treating OME.36,42 More recently, the Agency for Health Research and Quality (AHRQ) examined the efficacy of oral steroids in treating OME and demonstrated them to be neither useful nor beneficial in resolving effusion or in improving hearing loss5 and that, adding antibiotics, they do not improve results compared to control patients left untreated or treated with antibiotics alone.44 In a 2011 Cochrane systematic review that included various studies on the use of glucocorticoids (with or without antibiotics) to treat OME in children, oral glucocorticoids were associated with resolution of OME after 2 weeks’ treatment, but not beyond this period.45 Moreover, in the only study that assessed hearing, oral glucocorticoids did not improve hearing. It is known that oral corticosteroids are associated with adverse effects, especially in children. In fact, avoiding the use of these drugs is taken as a quality measure in the care of children with OME.46 The use of oral glucocorticoids is not recommended, therefore, for the treatment of OME in children. The risk of adverse effects outweighs any possible short-term benefit.12,41

Intranasal Glucocorticoids

As with the oral glucocorticoids, several medical associations advise against using nasal glucocorticoids for the treatment of OME.36,42 Later studies have shown no difference in the resolution of effusion or hearing loss after 3 months in children from the ages of 4–11 treated with nasal mometasone or a placebo.47 Topical (nasal) steroids have fewer side effects, especially when compared with systemic administration, but between 7% and 22% of the patients in the study group experienced minor side effects.48 It is possible that there might be a short-term benefit in administering topical nasal steroids to children with adenoid hypertrophy, although the effect is small and the dose, in a study that supports this, was higher than that recommended.48 Similarly, a 2011 Cochrane systematic review with diverse studies on systemic and topical nasal glucocorticoids found that the nasal glucocorticoids were not useful in resolving OME or in improving hearing short term.49 The resolution capacity was not assessed long term either, neither was speech development. Not using nasal glucocorticoids (unless there is justified cause) is also a quality measure in the care of children with OME.46 With the currently available data it is not possible to confirm the role of allergic rhinitis in the aetiology of OME. Much has also been speculated about the relationship between allergies in general and OME, and no conclusions have been reached to date. Therefore nasal glucocorticoids are not recommended in the treatment of OME.12,40,41

Antibiotics

The rationale behind treating children with OME with antibiotics arose from identifying at least one bacterial pathogen in the middle ear fluid in a third of these cases. In most cases, the bacteria cultivated were the same as those usually found in OME: Haemophilus influenzae, Moraxella catarrhalis and Streptococcus pneumoniae. Therefore it was suggested that they should be treated with the same drugs that are recommended for AOM. A while ago, several
meta-analyses found that antibiotics improved the elimination of OME in the first month after treatment, but that there were frequent recurrences and no benefit after the first month. A 2012 Cochrane systematic review also reached the conclusion that there is no evidence to support the routine use of antibiotics for children with OME. This review was of 23 studies, with the use of both short and long-term antibiotics for treating OME; showing a small benefit in completely resolving the effusion at any moment in its progression and complication with AOM. However, antibiotic therapy had no significant impact on hearing loss or the rate of subsequent tympanostomy and tube insertion. Furthermore, the positive effect took place using treatments over more than one month. The authors concluded that antibiotics should not be used to treat OME, since the small benefits do not justify their adverse effects and the increased bacterial resistance, and they have no impact on hearing loss or future surgery. Recently, in 2016, the Cochrane review published an update of these recommendations that confirm the need to assess the moderate improvement that antibiotics can offer compared to their side effects and the increased bacterial resistance they cause. In conclusion, the generalised use of antibiotics is not recommended in the treatment of OME. Not using antibiotics is also a quality indicator in the care of children with OME.

**Antihistamines and Decongestants**

The aim of decongestants is to reduce mucosal oedema and swelling, improve its functions, ensuring central ventilation and fluid reduction. Like steroids, antihistamines are indicated to dampen inflammatory response. In 2004, several medical associations and later the NICE directives recommended that antihistamines and decongestants should not be used to treat OME in children. The best evidence in this regard comes from a 2007 Cochrane review, which included 16 clinical trials with 1516 children treated using these drugs, alone or in combination, whose results showed no benefit in the principal variable (persistent OME at the
end of one month). Recurrence was not shown to reduce either. In contrast, more adverse effects were produced compared to the placebo.\textsuperscript{1} This was confirmed in a subsequent systemic review on the evaluation of antihistamines and/or decongestants for the treatment of OME, which concluded that they provided no short (<1 month), or long-term (>3 months) benefit in resolving OME. Neither was there a reduction in the duration of complications, and AOM was not prevented. Furthermore, no evidence was found of beneficial effects on hearing, although there might have been some benefit in terms of improved nasal and ocular allergy symptoms. Treatment with antihistamines and/or decongestants was associated with an increased risk of side effects in 17\% of cases, compared to 6\% of those receiving the placebo. Therefore these drugs are not recommended in the treatment of OME. There is no evidence of their benefit, and there is evidence of the risk of possible adverse effects from their use.\textsuperscript{40,52} Even for children with allergic rhinitis and OME, these drugs are not beneficial for the latter.

**Leukotriene Inhibitors**

Previous studies have not shown montelukast to be effective in clearing middle ear effusion,\textsuperscript{53} however, a later study on the use of leukotriene inhibitors, with or without antihistamine, demonstrated by otoscopy a statistically significant improvement using both therapies. Nonetheless, this improvement was not significant on bilateral tympanometry.

**Mucolytics**

The evidence is very limited on the potential benefit of mucolytics on OME. The available information recommends that they should not be used.\textsuperscript{12,40,41}

**Autoinsufflation**

Autoinsufflation refers to the process of opening the Eustachian tube, increasing intranasal pressure (for example by forced expiration with the mouth and nose closed, inflating a balloon through each nostril or using a nasal balloon manufactured for the purpose or another similar device).\textsuperscript{54} Autoinsufflation along with watchful waiting could be beneficial if the child is able to perform the technique. The available studies are controversial; reviews or guidelines can be found that do not recommend its use,\textsuperscript{55} and other more recent reviews conclude that it is better used while waiting for the OME to resolve spontaneously, because there are no adverse effects.\textsuperscript{47} In a systemic Cochrane review of 3 studies, autoinsufflation with a nasal balloon manufactured for the purpose reduced middle ear effusion according to tympanometric and audiometric criteria within 2 weeks to 3 months, compared to no treatment at all. No adverse effects have been observed with autoinsufflation. However, some children might have difficulties in performing it and this could limit its use for small children. In fact, in one trial 12\% of the children (aged from 3 to 12 years) proved unable to use the balloon. More recent studies support its use because it improves several clinical aspects and symptoms, as well as the quality of life of children with OME.\textsuperscript{47} In addition, it can reduce the need to place ventilation tubes for definitive treatment. In conclusion, autoinsufflation might be a useful treatment for OME. It is difficult for small children to perform, yet the OME itself might be more harmful. However it is difficult for small children to carry out.

**Gastro-oesophageal Antireflux Treatment**

This approach is based on the fact that pepsin and pepsinogen are found in the middle ear cavity of patients with OME, which might stem from a laryngopharyngeal reflux, indicating that this is associated with OME pathogenesis in children.\textsuperscript{56} There is a paper that recommends treatment of gastro-oesophageal reflux to improve otitis with effusion, however, a more recent systematic review did not confirm its usefulness. The prevalence of the disease due to gastro-oesophageal reflux in children with chronic otitis media with effusion and with recurring AOM might be higher than the global prevalence for other children, and the presence of pepsin/pepsinogen in the middle ear might be related to physiological reflux. However, the cause-effect relationship between pepsin/pepsinogen in the middle ear and OME has not been demonstrated. In conclusion, antireflux treatment for OME cannot be recommended on the basis of the existing research.

**Complementary and Alternative Therapies**

**Probiotics and Interleukins**

There are studies with probiotics for the treatment of OME that have had promising results, but they need to be replicated before this treatment can be recommended. In randomised trials, children with prolonged OME, who received *Streptococcus sanguinis* and other alpha streptococci (*mitis, oralis*) twice a day nasally, which interfere with the growth of other pathogenic bacteria, or *Lactobacillus rhamnosus*, had better clinical cure rates and fewer recurrences compared to those who received an intranasal placebo. No adverse effects were identified.\textsuperscript{59} This area of research is based on the existence of bacterial biofilms in the middle ear and, especially, the adenoids, which might be related to OME and AOM, acting as a pathogen reservoir, which could open the way to new therapeutic options. New approaches for treating this disease include the knowledge and regulation of inflammatory cytokines, such as IL-10, which are elevated in children with chronic OME.

**Homeopathy**

The few published studies on homeopathic remedies for middle ear infections or OME have study design defects, including small sample size, a lack of randomisation or blinding and a lack of diagnostic validation. A randomised and double-blinded article has recently been published that concludes that homeopathic treatment is not effective.\textsuperscript{58} Furthermore, there are no standardised homeopathic
regimens for otitis media and there are no data on dose or appropriate plans. The NICE guideline (2008) does not recommend homeopathy, cranial osteopathy, acupuncture, dietary changes (including probiotics), immunostimulants, or massage. The latest reviews have not changed this non-indication, and the possibility of side effects has been warned about, especially linked to the use of herbal remedies. In sum, the benchmark guidelines of recognised associations of various medical practices make no recommendations regarding complementary and alternative therapies for OME based on a lack of sufficient proof.\textsuperscript{12, 40, 41}

**Vaccinations**

Although it is logical to believe that flu vaccines and those that cover the usual pathogens in AOM might secondarily reduce the incidence of OME, which originate through respiratory infectious processes and other ENT disease,\textsuperscript{41} a systematic review and meta-analysis of the effect of antipneumococcal vaccination in OME prevention has recently been published which identified 3 studies that showed no direct beneficial effect.

**Surgical Treatment of Childhood Otitis Media With Effusion**

Surgical treatment of OME should be considered if the condition persists for more than 3 months. This approach will vary for at-risk children (Table 1).

Furthermore, it should be borne in mind that the condition might be more likely to become chronic in some children experiencing seasonal OME at the start of summer or in autumn, hearing loss greater than 30 dB in their best ear, a previous history with TT or who have not undergone adenoidectomy. The decision to operate must be agreed between the ENT specialist, the child’s parents and the paediatrician, and if there is no consensus it is best to provide more information, leave some time for consideration and arrange a return visit to the clinic to re-examine the decision.

We must consider whether this type of treatment will provide benefits for children who have had OME for more than 3 months. To that end we should perform an audiological test appropriate to the age of the child before surgery. If this test shows thresholds that are better than or equal to 20 dB, the child should be reassessed every 3 months until complete resolution of the OME. Changes to the eardrum must also be monitored with the same frequency.\textsuperscript{59}

Surgery would be indicated for thresholds over a mean 25 dB, at frequencies of 500, 1000, 2000 and 4000 Hz, in the best ear. It would also be appropriate, whenever possible, to perform a speech intelligibility and auditory speech perception test. For children with hearing loss under 25 dB, surgery should be considered if they have delayed language development or any other type of risk.

The age of the child is taken into consideration when selecting the type of surgery, taking the age of 4 as the benchmark.\textsuperscript{60} In children under the age of 4, only TT placement is indicated since no scientific evidence has been found that a simultaneous adenoidectomy provides greater benefit, unless another circumstance indicates it. In children aged 4 or older a benefit has been found in performing adenoidectomy simultaneously with TT placement with recurrence rates of only 7%, rather than the 20% of those who are not adenocectomised. Therefore from this age, if it has not been performed beforehand for any other cause, we should offer adenoidectomy at the same time as TT placement.\textsuperscript{51} The benefit of adenoidectomy is in reducing relapses, irrespective of the size of the adenoids, or if the OME is related with bacteria at this level forming biofilms. At any age, TT placement would be indicated in situations where there is a risk of alteration to the eardrum structure, or if this has already occurred as a retraction, the consequence of a negative pressure gradient in the eardrum or atelectasis, with the objective of avoiding other more extensive surgery, secondary to the abovementioned or the first signs of cholesteatoma. TT placement would not be indicated in children with AOM that does not coexist with chronic OME.

We should not forget that children require long-term monitoring to ensure that their hearing has been corrected and that their perception of intelligibility of language has improved. To that end we will perform the necessary audiometric tests. Furthermore, we should bear in mind that after extrusion of TT, the recurrence of an OME, which might require the placement of new TT, is estimated at between 20% and 54% of cases, according to different authors.

Outstanding among the benefits of TT placement is the improvement in the child’s quality of life and that of their caregivers in the short term, the reduction in the prevalence of OME by 32% in the first year and improved hearing levels,\textsuperscript{52} as well as improved speech and language, fundamentally in children with risk factors (Table 1).\textsuperscript{52}

**CODEPEH Recommendations for the Management of Childhood Otitis Media With Effusion**

1. In the diagnosis of childhood OME, the presence of seromucous content on the eardrum should be documented by means of pneumatic otoscopy, tympanometry or otomicroscopy.

2. In the event of an OME in a child with no risk factors, a watchful waiting approach should be taken for 3 months before planning therapeutic action. Autoinsufflation can help during this period.

3. All children with risk factors must be examined to rule out an OME; both at the time of diagnosis of the risk factor and at the age of 12–18 months.

4. Screening for OME is not recommended for children with no risk factors or other symptoms attributable to it such as hearing loss, balance problems, poor performance at school, behavioural problems or ontological symptoms.

5. If a newborn hearing loss screening test failure is attributed to OME, the child should be followed up until complete resolution of the OME and a hearing test performed to discount underlying sensorineural hearing loss.
6. An audiological test appropriate to the age of the child should be performed if the OME persists for more than 3 months. In children with risk factors this should be performed at the time of diagnosis.

7. It should be established whether a child with OME has other concomitant sensory, physical, cognitive or behavioural factors that place them at risk of impairment or delayed language and/or speech development, and learning.

8. The family should be informed of the predisposing factors and the natural history of the OME, including a warning about other sequelae that might present and the possible development of a secondary AOM, as well as the need for monitoring the child’s progress.

9. Surgical treatment of OME is indicated:
   a. For children under the age of 4, the placement of TT tubes is recommended, without adenoidectomy, unless there are symptoms of adenoid hypertrophy.
   b. In children over the age of 4, the placement of drainage tubes and adenoidectomy is recommended.

10. Systemic or nasal steroids, antibiotics, antihistamines, decongestants or other treatments for allergy, anti-reflux treatment, immunomodulators and probiotics are not recommended. Neither is the use of homeopathy or other alternative therapies recommended.

Conflict of Interests

The authors have no conflict of interests to declare.

References


