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THE SPANISH CONFEDERATION OF FAMILIES OF DEAF PEOPLE

CODEPEH
THE COMMISSION FOR THE EARLY DETECTION OF HEARING LOSS

Supplement

Diagnóstico y tratamiento de la otitis media secretora infantil: recomendaciones CODEPEH 2016

Diagnosis and treatment of otitis media with effusion in children: 2016 CODEPEH recommendations

Author: CODEPEH
(Faustino Núñez, Carmen Jáudenes, José Miguel Sequí, Ana Vivanco, José Zubicaray)

RESUMEN

La incidencia y prevalencia de la otitis media secretora infantil (OMS) son elevadas, sin embargo, existen evidencias de que sólo 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 para la Detección Precoz de la Hipoacusia (CODEPEH) ha realizado una amplia revisión de la literatura científica sobre la materia y ha elaborado un documento de recomendaciones para una correcta actitud clínica ante la OMS, abordando métodos diagnósticos y tratamiento médico y quirúrgico. Se aconseja no usar ninguna medicación, especialmente corticoides y antibióticos, siendo la espera vigilada la primera medida a tomar durante tres meses. Si persiste la OMS, el otorrinolaringólogo valorará el tratamiento quirúrgico. En niños que presentan comorbilidades de diversa entidad, el impacto de la OMS es superior por lo que hay que actuar de forma inmediata, sin espera vigilada.

PALABRAS CLAVE

Otitis media secretora, Tubos de drenaje, Adenoidectomía, Guía de práctica clínica.

ABSTRACT

The incidence and prevalence of otitis media with effusion in children (OME) are high. However, there is evidence that only a minority of professionals follow the recommendations provided in the clinical practice guidelines. With the purpose of improving the diagnosis and treatment of OME in children in order to prevent and/or reduce its impact upon development in children, the Commission for the Early Detection of Hearing Loss (CODEPEH) has reviewed the scientific literature on this field in depth, and has drafted a series of recommendations on the correct clinical response to OME, including its diagnosis and medical and surgical treatment. Medications, in particular antibiotics and corticosteroids, should not be prescribed, and three months of watchful waiting should be the first adopted measure. If OME persists, the ENT specialist should assess the possibility of surgical treatment. The impact of OME is greater in children with comorbidities, and immediate intervention is required in such cases, without watchful waiting.

KEY WORDS

Otitis media with effusion, Tympanostomy tubes, Adenoidectomy, Clinical practice guideline.

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The following are members of the CODEPEH:

Dr. Faustino Núñez-Batalla, Chair
ENT Department, Hospital Universitario Central de Asturias-Oviedo
Representing the Spanish Society of Otorhinolaryngology

Ms. Carmen Jáudenes-Casaubón, Member
Director of the FIAPAS
Representing the Spanish Confederation of Families of Deaf People

Dr. José Miguel Sequí-Canet, Member
Head of the Paediatrics Department, Hospital de Gandía-Valencia
Representing the Spanish Association of Paediatrics

Dr. Ana Vivanco-Allende, Member
Paediatrics Department, Hospital Universitario Central de Asturias-Oviedo
Representing the Spanish Association of Paediatrics

Dr. José Zubicaray-Ugarteche, Member
Paediatric ENT Department, Complejo Hospitalario de Navarra-Pamplona
Representing the Spanish Society of Otorhinolaryngology

Contact: codepeh@gmail.com

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1. INTRODUCTION

Otitis media with effusion (OME) is defined by the presence of fluid in the middle ear, without accompanying symptoms or signs of acute infection (Stool et al., 1994) (Antolí-Candela et al., 2013). Several synonyms can be found in the literature, such as "serous otitis media" or "seromucous otitis media". Following the literature review carried out, the term "otitis media with effusion" has been chosen in the present document, as it is the most frequent term used in reference to this clinical entity.

This type of otitis differs from acute otitis media (AOM), the manifestations of which are characterised by an acute onset, usually accompanied by pain, fever and sometimes suppuration.

The incidence in children is high. Up to 90% of all children develop OME before school age, with an average of four episodes per year (Mandel et al., 2008: 491-9).

OME usually occurs in two contexts: spontaneously due to abnormal functioning of the Eustachian tube; or after acute otitis media as an inflammatory reaction, especially in children between 6 months and 4 years of age (Paradise et al., 1997: 318-33). If in-school examinations for OME are made, fluid in the middle ear is found in 1 in 8 children between 5-6 years of age. However, the prevalence of OME in children with Down syndrome or a cleft palate is far higher, ranging from 60-85% (Maris et al., 2014: 1319-25). Most episodes resolve spontaneously within three months, but 30-40% of all affected children will have repeated episodes, and in 5-10% of the cases OME will last over a year (Williamson et al., 1994: 930-4).

OME is the most common cause of childhood deafness in developed countries. Permanent hearing loss related to the sequelae of otitis occurs in 2-35 cases per 10,000 patients (Qureishi et al., 2014: 15-24).

The persistence of fluid in the tympanic cavity results in decreased mobility of the tympanic membrane, producing an obstacle to the conduction of sound (Williamson, 2002: 469-76). At least a quarter of all Otitis media with effusion episodes persist for more than three months and may be associated with hearing loss, vestibular (balance) problems, poor school performance, behavioural problems, recurrent acute otitis media episodes, and worsening of patient quality of life. Structural damage to the tympanic membrane or middle ear ossicles may occur, less frequently, requiring future urgical intervention (Rosenfeld and Kay, 2003: 1645-57) (Rosenfeld et al., 2013: S1-S35) (Jung et al., 2013: E122-E143).

The incidence of AOM is 5-fold higher in children with Otitis media with effusion. In this scenario, and in addition to the symptoms of AOM, the patients also suffer otalgia with fever that causes physical suffering, emotional stress and parental concern (Rosenfeld et al., 2000: 585-92).

The impact of Otitis media with effusion in turn is greater in children with various comorbidities. There is also a greater risk of developmental delays or alterations in children when Otitis media with effusion is associated to a series of disorders such as sensory, cognitive or behavioural problems *(Table 1)*. It is therefore of great importance to identify such cases and to intervene therapeutically at an earlier stage.

Despite the high incidence and prevalence of OME, there is evidence that only a minority of professionals follow the recommendations of the clinical management guides. The limited use of pneumatic otoscopy in the diagnosis, the lack of audiometric examinations of children with Otitis media with effusion, or the inappropriate use of antibiotics to treat the disorder are the most frequent problems (Rosenfeld et al., 2016: S1-S41).

The CODEPEH considers it necessary to review the management of OME in children; establish a series of recommendations to try to counteract clinical variability in the attitudes towards the

disorder; and draw attention to the existence of a population of children with previous disorders who are particularly susceptible to suffer or experience worsening of developmental delays as a consequence of OME. This review is applicable for children with OME between 3 months and 12 years of age, with or without developmental disorders or comorbidities predisposing to them (Rosenfeld et al., 2004: S95-S118).

The purpose of this document is to establish a series of recommendations for all clinicians that diagnose and treat childhood Otitis media with effusion in any setting. Specifically, the aims are to improve diagnostic accuracy, identify the children most likely to suffer developmental sequelae secondary to the disease, and guide professionals in order to secure the greatest therapeutic benefits from the correct management of OME.

2. APPROACH TO OME IN CHILDREN

2.1. APPROACH TO RISK-FREE CHILDREN

The approach to risk-free children with Otitis media with effusion involves a three-month waiting period before deciding any further measures such as referral to an ENT specialist, audiological evaluation or surgery. This recommendation seeks to avoid unnecessary measures, and is based on the fact that Otitis media with effusion is self-limiting in most patients, especially in cases where the disorder is preceded by common triggering factors such as upper respiratory colds or acute otitis media (Bhutta, 2014: 210–23). It is known that 75-90% of all cases of Otitis media with effusion following acute otitis media will resolve within three months. This waiting strategy is safe in children who are not at risk. Parents should be informed that the child will experience a period of poorer hearing, until OME is resolved, and should be instructed in appropriate strategies to optimise hearing function (Roberts et al., 2000: 725-35) (FIAPAS, 2007).

This recommendation of the three-month observation period is based on clear dominance of benefit over risk, and is consistent with previous recommendations in this regard, with the clear aim of avoiding needless surgery (Stool et al., 1994).

2.2. APPROACH TO CHILDREN AT RISK

Although there are no firm study data, it is clear that Otitis media with effusion may prove more severe in children with comorbidities *(Table 1)* that place them at risk or make them more susceptible to developmental delays (Ruben, 2011: 707-12).

Developmental, behavioural and sensory disorders are not uncommon, and their association with Otitis media with effusion is therefore a frequent clinical problem. Hearing loss associated with OME can significantly worsen the outcomes of these children; the detection and treatment of such cases of otitis is therefore important. Frequent development of Otitis media with effusion can impair the auditory signals and cause difficulties in speech recognition, higher word processing, comprehension in noisy environments, and the spatial localisation of sounds (Khavarghazalani et al., 2016: 456-9).

Examples of this are patients with pre-existing permanent hearing loss, who will suffer increased hearing difficulties due to the consequences of OME - with a consequent negative impact upon speech and language development. Similarly, children with blindness or untreatable vision problems are more dependent on hearing, making them susceptible to imbalance, sound localisation difficulties, and speech and language delays (Ruben, 2003: 505-14).

Children with Down syndrome have more frequent and persistent OME, with narrow external auditory canals that may impede assessment of the tympanic membrane and

middle ear status. Prevalence is high in such patients, with 67% presenting OME at one year of age. At 6 or 7 years of age the incidence increases again, reaching 60%. From the age of 8 years onwards, the prevalence tends to decrease. The disorder is accompanied by mild to moderate hearing loss (Maris et al., 2014: 1319-25). In addition, the patients are also at risk of developing mixed or sensorineural hearing loss. These risks persist throughout childhood, and the repeated placement of drainage tubes may be necessary. In these cases, a 6-monthly audiological evaluation is recommended from birth to assess middle ear status and clean the canals. In addition, audiometric testing should be performed where appropriate (Iino et al., 1999: 143-9).

Cleft palate is a common malformation, with a prevalence of 1 case in every 700 newborn infants. OME is present in almost all these cases, because the insertions of the *tensor veli palatini* muscle are anomalous, causing difficulty in opening the Eustachian tube. Chronic OME in these patients results in conductive hearing loss, the severity of which should be monitored throughout childhood, even after surgical repair of the malformation, because its prevalence does not decrease after such treatment (Sheahan et al., 2002: 494-500) (Ponduri et ál, 2009: 30-8).

Tubal dysfunction not only affects children with cleft palate and Down syndrome, but is also associated with other craniofacial syndromes and malformations of the head and neck region (Marchisio et al., 2008: 426-32).

When OME is detected in a child at risk, early transtympanic drain (TTD) placement should be offered (Rosenfeld et al., 2013: S1-S35). In children where such treatment has not been prescribed, control visits should be programmed to monitor OME and hearing levels, depending on the individual needs. It is advisable to do this at intervals of less than three months, which is the interval recommended for children who are not at risk.

Considering the above, in children at risk it is advisable to rule out the presence of Otitis media with effusion at 12 and 18 months of age, as this is a particularly important period for the development of speech and language, balance and coordination (CODEPEH, 2014) (Núñez et al., 2016: 45-53).

Mild to moderate uni- or bilateral hearing loss can cause academic, social and behavioural difficulties; this is consequently a critical time period to identify and, if necessary, treat Otitis media with effusion. Therefore, in this population of children at risk, audiometric assessment is advised, using the appropriate method according to the age of the child, and with the periodicity needed to assess the effectiveness of surgical treatment when indicated (Rosenfeld et al., 2004: S95-S118).

This active search for the presence of OME in children at risk should not be extended to the population of risk-free children, where systematic OME screening is explicitly not advised (Simpson et al., 2007).

2.3. APPROACH TO ALTERED NEONATAL SCREENING ATTRIBUTABLE TO OME

If a child fails neonatal screening tests for hearing loss, and this result is attributed to the presence of Otitis media with effusion, periodic monitoring is advised in order to reduce the risk of missed or delayed detection of sensorineural hearing loss (Calderon and Naidu, 1999: 53-84).

OME is an important cause of transient moderate hearing loss in newborn infants that fail screening tests for hearing function. In this regard, a prospective study of screening failures found that 55% of the cases had Otitis media with effusion (Boudewyns et al., 2011: 799-804).

However, although most of these cases resolve spontaneously, some will be diagnosed with underlying sensorineural hearing loss. It has been reported that 11% of all patients with screening failure have both OME and

sensorineural hearing loss at the same time. However, in two-thirds of these cases screening failure was initially attributed to OME alone (Boone et al., 2005: 393-7).

3. IMPACT OF OME UPON CHILD BEHAVIOUR AND DEVELOPMENT

The impact of Otitis media with effusion upon patient quality of life is well-known. In effect, 64% of all affected patients have sleep disorders, 49% present behavioural disorders, 33-62% show delayed language development, and 15% suffer imbalance (Brouwer et al., 2005: 1031-41) (Karkanevatos and Lesser, 1998: 732-41).

In a child with OME, the latter causes a temporary decrease in hearing. This may occur repeatedly throughout the first years of life, with potential harmful effects on some areas of development (cognitive, communicative, socio-emotional), the educational process and learning. In fact, OME is associated with speech and reading difficulties, slow responses to auditory stimuli, poor vocabulary, and attention problems. This explains why, after identification and correct treatment of the disorder, patient school performance improves substantially (Rosenfeld et al., 2011: 190-5). This is even more manifest in the case of children at risk.

The impact of OME varies in nature and severity depending on circumstances such as the degree of hearing loss it causes, the age of the patient, and the level of language already acquired by the child.

In the case of an OME episode in a normally hearing child, the observed hearing defect is on the borderline of mild-moderate hearing loss (25-40 dB). In contrast, in the case of a child who already has hearing loss, and depending on its degree, the loss will be compounded by that caused by OME itself; hearing impairment therefore will further worsen, both quantitatively and qualitatively. This situation will be more or less pronounced depending on whether OME affects only one ear or both.

As mentioned, another aspect that determines the greater or lesser impact of OME is the age range in which this clinical condition appears most often (0-8 years). The first years of life are critical for speech and language development, as well as for the acquisition of instrumental tools for learning, such as reading and writing. In addition, there are other consequences referred to attention and memory processes, as well as behaviour (Jáudenes, 2004: 205-8) (Torres, 2004: 231-44) (Torres, 2004: 337-49) (Villalba, 2004: 185-204).

It also should also be taken into account that if hearing fluctuates with the persistence of OME, it can lead to instability in the behaviour of the child, who will respond differently to the same sound and verbal stimuli, will pay less attention to these stimuli, or may prove restless, etc. (FIAPAS, 2006) (FIAPAS, 2007).

3.1. CONSEQUENCES ACCORDING TO THE DEGREE OF HEARING LOSS

In the case of OME in children with normal hearing, losses of the kind commented above (less than 40 dB) still allow the patients to hear most of what sounds and is said around them, but not everything, since there may be a defect in discrimination of the phonetic features of words. Dyslalia may also be observed, since the patients do not hear or do not discriminate some phonemes from others, and they omit or interchange them in speech. Likewise, there may be some delay in language development.

All this can affect school performance and behaviour, as it results in attention problems and communication difficulties in spaces contaminated by ambient noise, such as playgrounds and spaces with other school children.

In the case of children with established hearing impairments above 40 dB, the presence of OME results in hearing losses that not only affect phonetic discrimination but also the acquisition of the phonological awareness necessary for cognitive and language development. Difficulties also result in communication in noisy environments and in exchanges with several people at the same time. Attention problems, delays in learning, as well as problems referred to school performance are also observed (FIAPAS, 2006) (FIAPAS, 2007).

All of these situations are of greater magnitude and are more prolonged over time when the background hearing loss is greater or if there are additional risk situations *(Table 1).*

3.2. CONSEQUENCES ACCORDING TO AGE AND ACQUIRED LANGUAGE LEVEL

In the case of children who have not yet acquired language (0-3 years), a decrease or lack of hearing leads to disturbances and deficits in phonological awareness and listening habit. It also has an impact on balance and psychomotor skills, as well as on early childhood learning and acquisition processes, with the generation of behavioural disturbances.

In the case of children with acquired language (3-12 years), there are also alterations and defects in phonological awareness and in listening habit, effects on school and educational learning, behavioural alterations, balance disorders, as well as effects in terms of reading and writing and school performance.

Of all these effects caused by hearing impairment secondary to OME, there is one condition in particular that initially may go unnoticed, but if not adequately monitored and treated, can have permanent consequences that need to be highlighted. Indeed, it is important to point out the consequences of limitations in access to the phonetic features of language. The acquisition of phonological awareness contributes to the assimilation and development of high-level cognitive tools that will later emerge, such as inner language, reading and writing, verbal thinking, mental representation, phonetic symbolism, etc. (Torres, 2016: 14-7).

It is therefore necessary to be very attentive, both at home and at school, to any change in the response behaviour of the child to sounds and in the interest shown in the sources that produce them. Attention must be paid to any changes in communication, social and play habits and strategies, as well as to any alterations in speech and language development and behaviour.

4. METHODS FOR THE DIAGNOSIS OF OME IN CHILDREN

4.1. OTOSCOPY

Otoscopy is the most important technique in assessing the ear and thus in diagnosing OME (Karma et al., 1989: 37-49). The study can be carried out with a conventional otoscope, a videoendoscope (Shiao and Guo, 2005: 1497-502) or microscopy, which greatly improves the possibility of establishing an accurate diagnosis (Lee, 2010: 151-3), matching the reference standard of pneumatic otoscopy.

Otoscopy is a technique that requires training and experience for correct assessment of the ear (Kaleida and Stool, 1992: 433-5). In children, and especially in very small children, the size of the external auditory canal (EAC), the angle of the tympanic membrane (more open in more smaller children), crying, and lack of cooperation on the part of the patient, cause some ears with disease to be interpreted as normal.

The otoscopic signs that facilitate the diagnosis of OME are loss of transparency, thickening of the membrane, and changes in tone. An air-fluid level is sometimes seen. It is important to differentiate this condition from non-suppurative acute otitis media, where pain and inflammatory signs are the most important features.

4.2. PNEUMATIC OTOSCOPY

Pneumatic otoscopy is considered the gold standard technique (American Academy of Family Physicians, 2004: 1412-29). The procedure requires an otoscope, a speculum that fits the EAC perfectly, and a bulb for the insufflation manoeuvres.

It is performed by gently pressing on the bulb attached to the otoscope. If the ear is normal, the tympanic membrane is seen to displace inwards when the bulb is pressed, and then moves back into position when the pressure is released. If an effusion is present in the middle ear, the mobility of the membrane will be diminished or it will not move at all, depending on the amount and density of the fluid. If the membrane is immobile, movement of the walls of the EAC may even be seen.

Pneumatic otoscopy is the first technique indicated in the initial diagnosis of OME, with a sensitivity of 94% and a specificity of 80% compared to myringotomy (Shekelle et al., 2002: 1-5).

This technique, despite its numerous recommendations for the diagnosis of OME (Rosenfeld et al., 2016: S1-S41), is rarely used in primary care, due to the need for appropriate equipment - despite its low cost - and the difficulty of learning the procedure. The use of tympanometry is thus preferred in this setting (Abbott et al., 2014: 181).

As a subjective technique, the main drawback of pneumatic otoscopy is the variability of interpretation between observers. Furthermore, in cases of AOM, the procedure can cause pain.

4.3. TYMPANOMETRY

Tympanometry is an objective test that provides information on the dynamic characteristics of the middle ear and the tympanic membrane-ossicle complex. The technique measures middle ear acoustic admittance in relation to pressure changes in the external ear (Nozza et al., 1992: 442-53). This test does not measure hearing in the child (Group MRCM-cOMS, 2009: 21-42).

The procedure is easy to perform with a portable tympanometer or a clinical diagnostic tympanometer. The result of the test is a graphical display of the energy admitted by the tympanic membrane and middle ear in response to pressurised air introduced into the EAC. The acoustic energy is transmitted to the EAC and a microphone measures the sound reflection while the pressure varies between +200 and -400 / -600 mm H_2O.

Tympanometry should be promoted as an objective tool for the diagnosis of OME, both to confirm the findings of pneumatic otoscopy and as an alternative to otoscopy when visualisation of the membrane is limited. There are precise recommendations to be followed *(Table 2)* in performing tympanometry (Rosenfeld et al., 2016: S1-S41).

In order to use the technique correctly, it is necessary to first perform otoscopy in order to rule out occlusions or infectious processes in the ear. The 226 Hz probe has been shown to be effective in identifying OME in pre-school and school children (specificity 82-89% and sensitivity 95-100%), though its reliability is lower in patients under 6-9 months of age. The use of a 1 kHz probe is recommended for screening in children under this age (CODEPEH, 2014) (Núñez et al., 2016: 45-53) (Mena et al., 2016: 306-14) (American Academy of Pediatrics JCoIH, 2007: 898-921). Interpretation of the result is made from the graphic representations

(tympanograms) produced by the equipment.

Based on the classification of Jerger *(Figure 1),* there are three basic curves (Jerger, 1970: 311-24):

a) Type A curve. This is the normal pattern and is characterised by a global "pagoda roof" shape, with a narrow peak; the maximum pressure point is between +50 and -100 mm H_2O, with a maximum amplitude between 1-2 ml.

b) Type B curve. This curve is an almost flat line indicating effusion within the middle ear.

c) Type C curve. This curve peaks at more than 150 mm H_2O, indicating a negative pressure gradient within the middle ear.

In children under 6-9 months of age it is advisable for tympanograms to be classified as normal or abnormal, using the Baldwin classification *(Figure 2)* (Baldwin, 2006: 417-27). A vertical line is drawn from the baseline to the peak of the curve, with normality being defined when the peak is above the baseline (peak +), while abnormality is defined when the peak is below the baseline (peak -). If there is a positive peak and a negative peak, the test result should be regarded as normal.

Another important element is the size of the EAC, which is usually between 0.6 cc to 1.5 cc in adults and 0.4 cc to 1.0 cc in children aged 3-5 years of age.

A type B curve in which the volume of the EAC is greater than these figures indicates tympanic perforation or the presence of a drain (TTD).

5. MEDICAL TREATMENT OF OME IN CHILDREN

The main objectives of OME treatment are to remove the secretions from inside the tympanic cavity, restore normal hearing and prevent future episodes, if possible (Klein and Pelton, 2016) (Rosenfeld et al., 2016: S1-S41).

Several drugs have been used for the treatment of OME, with the dual aim of improving patient quality of life and avoiding invasive surgical interventions. This section analyses their efficacy.

5.1. ORAL AND TOPICAL CORTICOSTEROIDS

The principle behind the use of corticosteroids is based on their antiinflammatory effect upon the rhinopharynx and middle ear. In addition, they up-regulate transepithelial sodium transport in the middle ear, promoting the removal of fluid from the middle ear cavity (Principi et al., 2016: 415-23).

- **Oral glucocorticoids**

As early as 2004, various medical associations and later the National Institute for Health and Care Excellence (NICE) guidelines advised against the use of oral glucocorticoids for the treatment of OME (American Academy of Family Physicians, 2004: 1412-29) (NICE, 2008).

More recently, the Agency for Healthcare Research and Quality (AHRQ) examined the efficacy of oral corticosteroids in the treatment of OME and demonstrated that they are neither helpful nor beneficial in resolving effusion or improving hearing loss (Berkman et al., 2013). Furthermore, adding antibiotics did not improve the outcomes compared to the controls, who were left untreated or treated with antibiotics alone (Thomas et al., 2006) (Simpson et al., 2007).

In a 2011 Cochrane systematic review that included a variety of studies on the use of glucocorticoids (with or without antibiotics) for the treatment of OME in children, these drugs were found to be associated with resolution of OME at two weeks of treatment, but not beyond that time (Simpson et al., 2011).

Furthermore, in the only study that assessed hearing, oral glucocorticoids did not improve hearing function (Macknin and Jones, 1985: 329).

Oral corticosteroids are known to be associated with adverse effects, especially in children. In fact, avoiding the use of these drugs is taken as a measure of quality in the care of children with OME (Lannon et al., 2011: e1490) (Patel et al., 2008: 490).

The use of oral glucocorticoids in the treatment of OME in children is therefore not recommended. The risk of adverse effects outweighs the potential short-term benefits (Rosenfeld et al., 2016: S1-S41) (Principi et al., 2016: 415-23) (O'Connor et al., 2016: 215-25).

- **Intranasal glucocorticoids**

As with oral glucocorticoids, several medical associations advise against the use of nasal glucocorticoids for the treatment of OME (American Academy of Family Physicians, 2004: 1412-29) (NICE, 2008).

Subsequent studies showed that in children between 4-11 years of age treated with nasal mometasone or placebo, no differences were noted in the resolution of effusion or hearing loss beyond three months (Williamson et al., 2009: 1-144). However, there was an economic disadvantage in the mometasone-treated group, considering the high rate of spontaneous resolution recorded in the placebo group.

Topical (intranasal) glucocorticoids have fewer side effects, especially when compared to systemic administration, but between 7-22% of the patients in the study group experienced minor side effects (Simpson et al., 2007).

There may be a short-term benefit of topical intranasal glucocorticoid administration in children with adenoid hypertrophy - though the effect is small and the dosage, in one supporting study, was higher than advisable (Bhargava and Chakravarti, 2014: 766-70) (Cengel and Akyol, 2006: 639-45) (El-Anwar et al., 2015: 298-301).

Likewise, a 2011 Cochrane systematic review of several studies on systemic and topical nasal glucocorticoids for the treatment of OME in children found that intranasal glucocorticoids were not helpful in resolving OME or in improving hearing in the short term (Simpson et al., 2011).

No evaluation of the long-term resolution capacity or of speech development was made.

The avoidance of intranasal glucocorticoids (unless justified) is also a measure of the quality of care of children with OME (Lannon et al., 2011: e1490) (Patel et al., 2008: 490).

With the data currently available, it is not possible to confirm the role of allergic rhinitis in the aetiology of OME. There has also been much speculation about the relationship between allergy in general and OME, though no conclusions have been drawn to date.

No prospective studies have been conducted in children with OME on the effects of immunotherapy in allergic subjects versus other options (American Academy of Family Physicians, 2004: 1412-29).

Therefore, intranasal glucocorticoids are not recommended for the treatment of OME (Klein and Pelton, 2016) (Rosenfeld et al., 2016: S1-S41) (Principi et al., 2016: 415-23) (O'Connor et al., 2016: 215-25).

5.2. ANTIBIOTICS

The rationale for antibiotic treatment in children with OME arose from the identification of at least one bacterial pathogen in middle ear fluid in one-third of these patients. In most cases, the bacteria isolated were the same as those normally found in acute otitis media: *Haemophilus influenzae, Moraxella catarrhalis* and *Streptococcus pneumoniae*. Treatment with the same drugs recommended for AOM was therefore suggested.

Several meta-analyses have long found antibiotics to improve OME clearance in the first month after treatment, but with frequent

relapses and no benefits beyond the first month (Rosenfeld and Post, 1992: 378) (Williams et al., 1993: 1344).

A 2012 Cochrane systematic review also concluded that the evidence does not support the routine use of antibiotics in children with OME (Van Zon et al., 2012).

This analysis was performed on 23 studies with both short- and long-term antibiotic use in the treatment of OME, and evidenced a small benefit in terms of complete resolution of the effusion at some point in the course of the disorder, and as regards complication with AOM. However, antibiotic therapy had no significant impact on hearing loss or on the need for posterior tympanostomy and tube insertion. Moreover, the positive effect was observed with treatments lasting more than one month. The authors concluded that antibiotics should not be used to treat OME, since the small benefits obtained do not justify the adverse effects and increased bacterial resistances caused, and there is no impact on hearing loss or the need for future surgery.

Recently, in 2016, the Cochrane has published an update on these recommendations, confirming the need to weigh the moderate improvements which antibiotics can afford against the side effects they produce and the increase in bacterial resistances they cause (Venekamp et al., 2015 and 2016).

In conclusion, the generalised use of antibiotics is not recommended for the treatment of OME (Klein and Pelton, 2016) (Rosenfeld et al., 2016: S1-S41) (Principi et al., 2016: 415-23) (O'Connor et al., 2016: 215-25).

The avoidance of antibiotics is also an indicator of quality of care in children with OME (Lannon et al., 2011: e1490) (Patel et al., 2008: 490).

The inappropriate use of antibiotics can affect not only the individuals taking them, but also their families, the community, and society as a whole. Treating a non-bacterial disorder with an antibiotic is unhelpful and exposes the patient to unnecessary risks (allergic reactions and other adverse effects). In addition, the ecological impact upon the respiratory and intestinal flora is considerable, as the antibiotic will eliminate the majority population of sensitive bacteria and favour the growth of the resistant bacterial population, and its possible subsequent dissemination (Ministry of Health, Social Services and Equality of Spain, 2006).

These findings should not preclude the use of antibiotic therapy when there are associated conditions that would benefit from its use, such as acute bacterial sinusitis or group A streptococcal infection .

5.3. ANTIHISTAMINES AND DECONGESTANTS

Decongestants seek to reduce mucosal oedema and swelling, improving mucosal function, ensuring central ventilation and reducing fluids. Like corticosteroids, antihistamines are indicated for reducing the inflammatory response.

In 2004, several medical associations, and subsequently the NICE guidelines, recommended that antihistamines and decongestants should not be used in the treatment of OME in children (American Academy of Family Physicians, 2004: 1412-29) (NICE, 2008).

The best evidence in this regard comes from a 2007 Cochrane review that included 16 clinical trials involving 1516 children treated with these drugs, alone or in combination; the results showed no benefit in terms of the primary endpoint (persistence of OME after one month). Likewise, no decrease in recurrences was evidenced. In contrast, the adverse effects increased compared to placebo (Griffin et al., 2007).

This was confirmed in a subsequent systematic review on antihistamines and/or decongestants for the treatment of OME, which concluded

that there were no short- (<1 month) or long-term (>3 months) benefits in terms of the resolution of OME. Neither was the duration of complications reduced, nor was AOM prevented (Griffin and Flynn, 2011).

On the other hand, no evidence of beneficial effects upon hearing was found, though there could be some benefit in terms of improvement of the eye and nasal allergy symptoms.

The adverse effects of antihistamines and decongestants in children also tended to favour the placebo group over the treatment group in several studies. Treatment with antihistamines and/or decongestants was associated with an increased risk of side effects in 17% of the cases, compared to 6% among those receiving placebo. These drugs are therefore not recommended for use in the treatment of OME. There is no evidence of benefit, but there is evidence of the risk of possible adverse effects with the use of these drugs (Griffin et al., 2007) (Griffin and Flynn, 2011) (Klein and Pelton, 2016). Even in children with allergic rhinitis and OME, these medications are of no benefit in terms of the latter (Rosa-Olivares et al., 2015: 480-6).

5.4. LEUKOTRIENE INHIBITORS

Previous studies have not found montelukast to be effective in clearing middle ear secretions (Schoem et al., 2010: 434-7). However, a later study on the use of leukotriene inhibitors, with or without an antihistamine, demonstrated statistically significant improvement using both therapies, as evidenced by otoscopy. Such improvement was not found to be significant in the bilateral tympanometry tests, however (Ertugay et al., 2013: 1266-72).

5.5. MUCOLYTIC AGENTS

Evidence on the potential benefit of mucolytic agents in OME is very limited. The available information recommends against their use (Klein and Pelton, 2016) (Rosenfeld et al., 2016: S1-S41) (Principi et al., 2016: 415-23) (O'Connor et al., 2016: 215-25).

5.6. AUTO-INSUFFLATION

Auto-insufflation refers to opening of the Eustachian tube by raising the intranasal pressure (e.g., through forced expiration with the mouth and nose closed, blowing a balloon through each nostril, or using a customised nasal balloon or other similar device) (Perera et al., 2013) (Williamson et al., 2015: 961-9) (Banigo et al., 2016: 59-65).

Auto-insufflation in the context of watchful waiting may be beneficial if the child is able to perform the technique. Data from the available studies are controversial, and reviews or guidelines therefore can be found that do not recommend its use (Rovers et al., 2004: 465-73). Others with low-grade evidence affirm that it could be beneficial in some patients (SIGN, 2003), while other more recent reviews conclude that it is better to apply the technique while awaiting spontaneous resolution of OME, in view of the absence of adverse effects (Perera et al., 2013) (Principi et al., 2016: 415-23) (Williamson, 2011: 0502) (Williamson et al., 2015: 961-9).

In a Cochrane systematic review of three studies, auto-insufflation with a customised nasal balloon was seen to reduce middle ear secretion based on tympanometric and audiometric criteria within two weeks to three months, as compared with no treatment (Perera et al., 2013).

No adverse effects were observed with auto-insufflation. However, some children may experience difficulties in performing the technique, and this may limit its application in young children (Williamson, 2011: 0502) (Haggard, 1999: 1178). In fact, in one trial, 12% of the children (aged 3-12 years) were shown to be unable to use the balloon (Blanshard et al., 1993: 188).

More recent studies do support its use because it improves several clinical parameters and symptoms, as well as the quality of life of children with OME (Bidarian, 2016: 65) (Alper, 2016: 255) (Williamson, 2011: 0502) (Williamson et al., 2015: 1-150). In addition, auto-insufflation may reduce the need for venting tubes for final treatment (Banigo et al., 2016: 59-65).

In conclusion, auto-insufflation could be a useful treatment for OME. However, it is difficult to perform for young children, who precisely constitute the age group in which OME can prove most harmful. On the other hand, the most effective device, allowing for the highest degree of patient compliance, has not yet been determined.

5.7. ANTI-GASTROESOPHAGEAL REFLUX TREATMENT

This approach is based on the fact that pepsin and pepsinogen are found in the middle ear cavity of patients with OME. These substances might be derived from laryngopharyngeal reflux, indicating that the latter is associated with the pathogenesis of OME in children (Luo et al., 2015: 1252-5).

There are some data recommending gastroesophageal reflux treatment for improving secretory otitis (McCoul et al., 2011: 35-41), though a more recent systematic review was unable to confirm its usefulness (Miura et al., 2012: 345-52).

The prevalence of gastroesophageal reflux disease (GERD) in children with chronic Otitis media with effusion and with recurrent acute otitis media may be greater than its overall prevalence in the rest of children. In turn, the presence of pepsin/pepsinogen in the middle ear may be related to physiological reflux, though the cause-effect relationship between pepsin/pepsinogen in the middle ear and OME has not been established.

In conclusion, antireflux treatment for OME cannot be recommended on the basis of the existing studies.

5.8. COMPLEMENTARY AND ALTERNATIVE THERAPIES

- **Probiotics and interleukins**

Studies with probiotics for the treatment of OME have yielded promising results, but need to be replicated before such treatment can be recommended. In randomised trials, children with prolonged OME who received twice-daily intranasal *Streptococcus sanguinis* and other *alpha streptococci (mitis, oralis),* which interfere with the growth of other pathogenic bacteria, or *Lactobacillus rhamnosus,* presented higher clinical healing rates and fewer recurrences compared to those who received intranasal placebo. No adverse effects were identified (Skovbjerg et al., 2009: 92) (Roos et al., 2001: 1-4) (Di Pierro et al., 2012: 991-7).

This area of research is based on the existence of bacterial biofilms in the middle ear and especially in the adenoids, which could be related to OME and AOM, acting as a pathogen reservoir - thus opening up new therapeutic options (Tawfik et al., 2016) (Van Hoecke et al., 2016) (Davcheva-Chakar et al., 2015: 71-6).

New approaches to the treatment of this disease also involve the understanding and regulation of inflammatory cytokines such as IL10, which are seen to be elevated in children with chronic OME (Zielnik and Stankiewicz, 2016: 104-8).

- **Homeopathy**

The few published studies on homeopathic remedies for middle ear infections or OME have flaws in study design, including small sample size, lack of randomisation or blinding, and lack of diagnostic validation (Harrison et al., 1999: 132) (Jacobs et al., 2001: 177).

Recently, a randomised, double-blind study has been published, concluding that homeopathic treatment is not effective (Pedrero et al., 2016: 217-23).

In addition, there are no standardised homeopathic regimens for otitis media and no data on appropriate dosages or schedules.

- **Immune modulators**

Another drug used in OME, AM3 (Immunoferon®) has likewise failed to demonstrate effectiveness (Ortega et al., 2005: 1-5), so this treatment cannot be recommended.

The NICE guide (2008) does not recommend homeopathy, cranial osteopathy, acupuncture, dietary modifications (including probiotics), immunostimulants, or massage.

Recent reviews have not modified such non-indication (Principi et al., 2016: 415-23), and have warned of the possibility of side effects, especially in connection with the use of herbal remedies.

In summary, the reference guides of recognised medical associations do not make any recommendations regarding complementary and alternative therapies for OME, based on a lack of sufficient evidence (Klein and Pelton, 2016) (Rosenfeld et al., 2016: S1-S41) (Principi et al., 2016: 415-23).

5.9. VACCINES

Although it stands to reason that influenza vaccines and vaccines covering common AOM pathogens may secondarily reduce the incidence of OME, which is caused by respiratory infectious processes or other ENT disorders (Principi et al., 2016: 415-23), a recent systematic review and meta-analysis involving three studies on the effect of pneumococcal vaccination upon the prevention of OME has not evidenced any direct beneficial effect (El-Makhzangy et al., 2012: 2021-6) (Antolí-Candela et al., 2013).

6. SURGICAL TREATMENT OF OME IN CHILDREN

The surgical treatment of OME should be considered when the disorder persists for more than three months. This approach will vary in children at risk *(Table 1).*

In addition, it should be borne in mind that in certain children the disease may be more likely to progress to chronicity in the presence of circumstances (Van Balen and de Melker, 2000: 605-11) such as the existence of seasonal OME with onset in summer or autumn, hearing loss greater than 30 dB in the better ear, a history of transtympanic drainage (TTD) and non-adenoidectomy status.

The decision regarding surgery should be made by consensus among the ENT specialist, the parents and the paediatrician. In the absence of consensus, it is better to expand the information, allow time to think, and arrange another visit in the clinic to address the decision again (Elwyn et al., 2013: 207-12).

Among children who have had OME for more than three months, it should be evaluated whether or not this type of treatment will be of benefit. For this purpose, an age-adjusted audiological test must be performed prior to surgery. If the test evidences thresholds better than or equal to 20 dB, re-evaluation should be made every three months until the complete resolution of OME. Tympanic membrane disorders should also be assessed at the same intervals (Heidemann et al., 2016: 154-63).

In the case of thresholds of more than 25 dB on average, in the frequencies 500, 1000, 2000 and 4000 Hz, in the better ear, surgery would be indicated. It also would be appropriate, where possible, to make an audiological assessment of intelligibility in language perception.

In children with hearing loss of less than 25 dB, surgery should be considered if they present language delays or any other type of risk situation.

When selecting the type of surgery to be performed, the age of the patient should be taken into account, with 4 years of age being taken as the reference age (Gates et al., 1987: 1444-51) (Boonacker et al., 2014: 1-118) (Mikals

and Brigger, 2014: 95-101). In children under 4 ears of age, only TTD placement is indicated, as there is no scientific evidence that simultaneous adenoidectomy offers greater benefit - unless it is indicated for some other reason.

In children aged 4 years and older, benefit has been found in performing adenoidectomy concurrent to TTD placement, with recurrence rates of only 7% as opposed to 20% in children not subjected to adenoidectomy. Therefore, from this age onwards, adenoidectomy should be offered (if it has not been performed before for some other reason) at the same time as TTD placement (Cervera et al., 2006: 59-65) (Wallace et al., 2014: 296-311).

The benefit of adenoidectomy is that it reduces relapses, irrespective of the size of the adenoids or whether OME is associated with bacteria forming biofilms at that level (Nguyen et al., 2004: 863-6).

At any age, TTD placement would be indicated in situations where there is a risk of tympanic membrane structural alteration or where such alteration has already occurred in the form of retraction of the membrane as a result of a negative pressure gradient in the tympanic cavity or atelectasis. The aim is to avoid further, more extensive surgeries, secondary to the above, or the first signs of cholesteatoma.

Transtympanic drain placement would not be indicated in children presenting acute otitis media without coexisting chronic OME. Adenoidectomy likewise has not been found to be of benefit in preventing recurrent AOM.

6.1. COMPLICATIONS OF TTD PLACEMENT

Among other possible complications *(Table 3),* the most prevalent condition is otorrhoea, which occurs in 16% of all cases during the first four weeks, and in 26% throughout the duration of TTD placement (Vlastarakos et al., 2007: 385-91) (Kay et al., 2001: 374-80) (Rakover et al., 2000: 41-4).

Otorrhoea is related to the biofilm that is produced around the TTD (Idicula et al., 2016: 1946-51). In the case of otorrhoea through the TTD, only topical antibiotic drops should be prescribed, without oral antibiotics, except in the event of complicated infections.

Complications of adenoidectomy are rare (De Luca et al., 2015: 702-18). These include increased surgery time, the risk of postoperative bleeding, increased discomfort in the 2-3 days following surgery and, rarely, open rhinolalia or tubal dysfunction.

It should not be forgotten that children need long-term follow-up to ensure that hearing has been corrected and that intelligibility in language perception has improved. For this purpose, the necessary audiometric tests are performed. On the other hand, it should be taken into account that, following TTD extrusion, the recurrence rate of OME, which may require the fitting of new drains, is estimated to be 20-54%, according to different authors.

The benefits of TTD include improved quality of life for children and their caregivers in the short term, a 32% decrease in the prevalence of OME in the first year, and improved hearing levels (Browning et al., 2010), as well as improved speech and language, primarily in children with risk factors *(Table 1)* (Rosenfeld et al., 2011: 190-5).

7. INFORMATION AND GUIDANCE FOR THE FAMILY

It is important to inform the parents of the child diagnosed with Otitis media with effusion in order to improve the decision-making process shared with the professional. This can be done by providing a list of frequently asked questions, which should be complemented by an exchange of information accessible to the family and responsive to their needs. The information

provided by the family is very valuable, but it cannot be the only method for identifying whether or not hearing loss is present.

The most important aspects to be addressed in the process of informing the family are the predisposing factors, the natural history of the disease, the risk of middle ear damage, and the options available for minimising the effects of Otitis media with effusion (Rosenfeld et al., 2016: S1-S41).

7.1. OME PREDISPOSING FACTORS

Among the factors that cause the onset of OME (Casselbrant and Mandel, 2003), age stands out, as it is directly related to the angulation of the Eustachian tube.

Other factors include passive smoking, the male gender and nursery attendance (Todberg et al., 2014: e111732). There is also a family component.

In children under 18 months of age, it is important to limit the use of dummies, as this can reduce the incidence of acute otitis media by 30%, and consequently also reduce the incidence of Otitis media with effusion that routinely follows acute otitis media.

The risk is substantially reduced if the child has been breastfed, and the longer the breastfeeding period, the longer the protection against OME. Numerous studies show that breastfeeding reduces the risk of OME by transmitting antibodies from mother to infant, and by reducing environmental allergies (Schilder et al., 2004: 29-36).

Good hand hygiene is also a beneficial measure.

7.2. NATURAL HISTORY OF OME

OME evolves towards spontaneous healing in most cases, but this depends on the underlying cause and the time elapsed since onset of the condition. In 75% of all children, OME resolves within three months when caused by previous acute otitis media. If OME is spontaneous and it is not known when it appeared, the resolution rate at three months drops to 56%.

Resolution is less likely in children in whom the disorder occurs in the summer or autumn months; those with audiometric thresholds poorer than 30 dB; and/or patients a history of transtympanic drain placement (Van Balen and de Melker, 2000: 605-11).

7.3. RISK OF DAMAGE TO THE MIDDLE EAR

Although rare, the risk of sequelae such as tympanic membrane retraction or atelectasis, tympanic ossicle lesions, cholesteatoma or tympanic perforation must be taken into account.

7.4. MINIMISING THE EFFECTS OF OTITIS MEDIA WITH EFFUSION

There are different options for minimising the effects of Otitis media with effusion in terms of hearing loss, speech and language development, as well as school performance. Instruction should be given on strategies to optimise listening and learning while the otitis resolves *(Table 4).* The child should be spoken to by standing close and facing him/her, with clear but natural pronunciation. Additional communication strategies can also be used to increase attention on the part of the child, reducing ambient noise if possible, and repeating or clarifying the information we are trying to convey. The child should be placed in preferential places in the classroom, in the front rows and with the ear with the best hearing facing the teacher (Roberts et al., 2004: e238-e248) (FIAPAS, 2006) (FIAPAS, 2007).

Parents should be aware that medicines are of no use in the treatment of OME (Van Zon et al., 2012). Likewise, despite the popularity of alternative and complementary therapies, there is no evidence that they afford any benefit in Otitis media with effusion (Berkman et al., 2013).

8. CODEPEH RECOMMENDATIONS 2016

1. At the **diagnosis** of childhood otitis media with effusion, the presence of seromucous content in the tympanic cavity should be documented using pneumatic otoscopy, tympanometry or otomicroscopy.

2. In the case of otitis media with effusion in a **child with no risk factors**, a three-month watchful waiting period is recommended before therapeutic action is considered. Auto-insufflation is a measure that can help during this time.

3. Every **child with risk factors** should be screened for otitis media with effusion, both at the time of diagnosis of the risk factor and at 12-18 months of age.

4. **Screening for otitis media with effusion** is not recommended in children without risk factors or other symptoms attributable to otitis media such as hearing loss, balance problems, poor school performance, behavioural problems or otological symptoms.

5. In the event that **failure of neonatal screening for hearing loss** is attributed to otitis media with effusion, it is recommended that the child be monitored until hearing loss has completely resolved, and an audiological test should be performed to rule out underlying sensorineural hearing loss .

6. An age-adjusted **audiological test** should be performed if otitis media with effusion lasts longer than three months. In children with risk factors, this should be done at the time of the diagnosis.

7. It should be determined whether a child with otitis media with effusion has other concomitant sensory, physical, cognitive or behavioural factors that place him/her at **risk for language and/or speech development and learning alterations or delays.**

8. **The family should be informed** about the predisposing factors and the natural history of otitis media with effusion, including a warning about other sequelae that may occur, the possible development of secondary acute otitis media, and the need to monitor the progress of the child.

9. If **surgical treatment** is indicated for otitis media with effusion:

   a) in children under 4 years of age, the placement of **transtympanic drainage tubes is recommended, without adenoidectomy,** unless there are symptoms of adenoid hypertrophy.

   b) in children over 4 years of age, the placement of drainage **tubes and adenoidectomy is recommended.**

10. In the treatment of otitis media with effusion, **it is not advisable** to use systemic or intranasal corticosteroids, antibiotics, antihistamines, decongestants or other allergy treatments, antireflux treatment, immunomodulators or probiotics. The use of homeopathy or other alternative therapies is also not recommended.

9. TABLES AND FIGURES

Table 1.
Risk situations that compromise the development of the child due to the coexistence of otitis media with effusion

- Permanent hearing loss independent of otitis media with effusion
- Craniofacial syndromes or disorders resulting in cognitive, speech and/or language delays
- Blindness or untreatable vision problems
- Autism spectrum disorders and other neurodevelopmental disorders
- Speech and/or language delay or disorder (suspected or confirmed)

(Modified from Rosenfeld, 2016)

Table 2.
Recommendations for tympanometry

- Patient intolerance to pneumatic otoscopy
- Lack of experience in performing pneumatic otoscopy
- Difficulty in visualising the tympanic membrane due to partial wax blockage
- Difficulty in visualising the membrane due to a narrowed or stenotic EAC
- Doubts on the presence of OME due to equivocal pneumatic otoscopy findings
- Need to exclude OME in children at risk
- Need to confirm OME prior to surgery

(Modified from Rosenfeld, 2016)

Table 3.
Complications in transtympanic drain (TTD) placement

- Otorrhoea (16-26%)
- TTD obstructions (7%)
- Residual perforations (2-3%)
- Middle ear penetration (0.5%)
- Residual cholesteatoma (<1%), though there is evidence of a decrease in the latter when treating Otitis media with effusion with TTD
- Premature TTD extrusion (44%)
- Other types of membrane disorders (tympanosclerosis, atrophy, etc.) do not usually affect hearing

Table 4.
Guidelines and strategies for communicating with children with hearing loss

DRAW THEIR ATTENTION

- Before you start talking, draw their attention and wait for them to look at you before you start talking
- If there is more than one person or it is a group conversation, respect the turns of the speakers and indicate who speaks each time

SPEAK IN FRONT OF THE PATIENT

- Always be at the level of the child
- Speak facing the patient. Do not turn your back
- Speak without any object, candy or chewing gum in the mouth and without covering the mouth with the hands while talking
- Prevent the child from being dazzled by light

SPEAK NATURALLY

- Speak naturally, vocalising but without exaggeration, with a calm rhythm. Do not speak too slowly or too fast
- Speak without shouting, in a normal tone of voice
- Speak in complete sentences, contextualised and using familiar words

TALK CALMLY

- Repeat the message, making sure it has been understood, with simpler phrases
- Facilitate understanding with drawings, written words or natural gestures
- Answer his/her questions. Always listen. Give the patient time to speak and to respond
- Do not interrupt communicative interaction even if language errors occur

OTHER STRATEGIES

- Be attentive to the interests and communicative intentions of the child, to the objects and activities he/she likes, observing the reactions, the attitude in response to the stimulus, and the speech productions of the child in these contexts
- Avoid direct and frequent correction if he/she mispronounces something or confuses terms. In a natural manner, repeat the wrong word in new sentences that provide more information. It is important to provide correct language models
- Control the environment: well-lit and low-noise rooms, lowering the volume of television, music players, etc. while talking
- Place the patient where he/she can see the teacher and most of the classmates, in a circle, in the front rows... depending on the classroom activity and games

(Revised and updated from Jáudenes, 1984)

Figure 1.

Tympanometry curves, according to Jerger

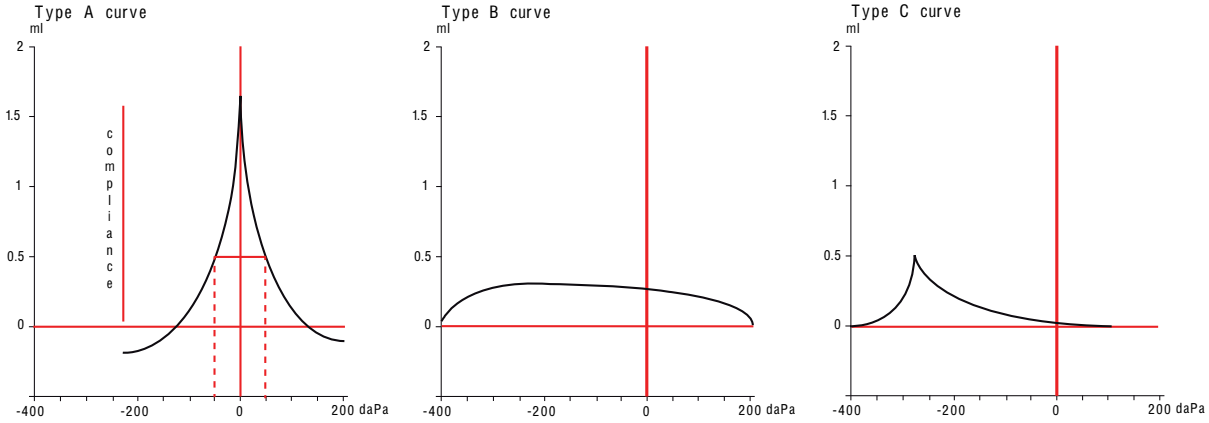
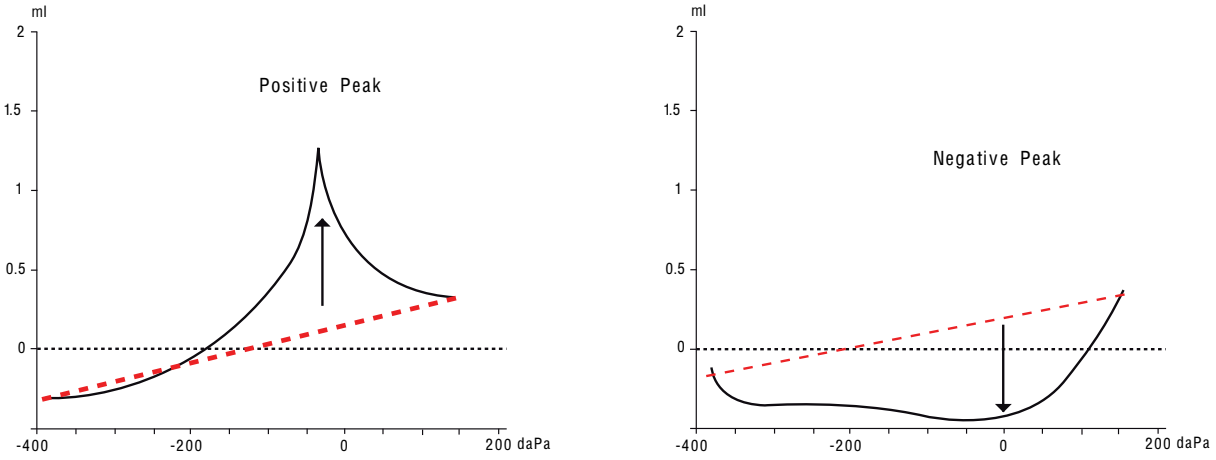


Figure 2.

Tympanogram with 1 kHz probe, according to the Baldwin classification



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