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International consensus

International consensus (ICON) on management of otitis media with effusion in children

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ABSTRACT

Otitis media with effusion (OME) is a common childhood disease defined as the presence of liquid in the middle ear without signs or symptoms of acute ear infection. Children can be impacted mainly with hearing impairment and/or co-occurring recurrent acute otitis media (AOM) thus requiring treatment. Although many meta-analyses and national guidelines have been issued, management remains difficult to standardize, and use of surgical and medical treatments continue to vary. We convened an international consensus conference as part of the 2017 International Federation of Oto-rhino-laryngological Societies Congress, to identify best practices in OME management. Overall, regional differences were minor and consensual management was obtained on several important issues. At initial assessment, although a thorough medical examination is necessary to seek reflux, allergy or nasal obstruction symptoms; an age-appropriate auditory test is the only assessment required in children without abnormal history. Non-surgical treatments poorly address the underlying problem of an age-dependent dysfunctional Eustachian tube; auto-inflation seems to be the only beneficial, low-risk and low-cost non-surgical therapy. There was a clear international recommendation against using steroids, antibiotics, decongestants or antihistamines to treat OME, because of side-effects, cost issues and no convincing evidence of long-term effectiveness. Decisions to insert tympanostomy ventilation tubes should be based on an auditory test but also take into account the child's context and overall hearing difficulties. Tubes significantly improve hearing and reduce the number of recurrent AOM with effusion while in place. Adjuvant adenoidectomy should be considered in children over four years of age, and in those with significant nasal obstruction or infection.

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1. Introduction

Otitis media with effusion (OME) is defined in recent international recommendations as the presence of liquid in the middle ear without any associated signs of ear infection [1–4]. It is different from acute otitis media (AOM), which gives highly symptomatic signs of the infection; recurrent AOM can overlap with OME history [1–3] and with fluid presence in the few weeks after an AOM the diagnostic decision may be slightly arbitrary. OME is a very frequent childhood disease and can be found in over 50% of children under the age of one and 60% of children under two [5]. A study with routine examination of the eardrum found OME in 15 to 40% of children between the age of one to five years old [6], and in a screening of 2097 Sicilian school children, 6.8% presented with OME lasting more than three months and notably 12.9% in the five-to-six year-old age group [7].

The Eustachian tube in the child is less effective than in the adult and hinders the ventilation of the middle ear contributing to the

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high incidence and prevalence of OME [1] in the early years; in the older child OME is more likely to spontaneously resolve and not re-occur. A study of 222 children (three to nine years of age) found that spontaneous resolution of OME occurred in 22% of cases at one year, 37% at two years, 50% at three years, 60% at four years, 70% at five years, 85% at seven years, and 95% at ten years [8]. Among the most enduring cases of OME, the tympanic membrane can suffer, leading to tympanic retraction pockets, atelectasis, and possibly cholesteatoma. Several studies have underlined the inflammatory mechanisms leading to the occurrence of OME: viral and bacterial traces have been found in the retro-tympanic liquid [9–14]. Risk factors such as pollution, allergy, gastroesophageal reflux disease (GERD) or genetics have been also clearly identified [12,15–18]. It is however difficult to draw strong causal inference from the associations in these results.

Despite its frequency, potential negative impact (mainly hearing loss and alteration of the eardrum) and four decades of attention, OME remains difficult to manage, and such consensus on the indications for medical or surgical intervention as has been achieved has been indirectly supported by evidence, couched in rather general terms and not always followed in practice. Various medical (mainly steroids or antibiotics) and surgical treatments (tympanostomy tubes or adenoidectomy) have been suggested, but their efficacy is debated. Also, the mandatory content of the initial assessment (for example hearing test and risk factor inventory) is undefined.

1.1. Setting of the Consensus conference

An International Consensus Conference (ICON) on OME was held at the International Federation of Oto-rhino-laryngological Societies (IFOS) congress in June 2017 in Paris, France. Members of the expert panel included Mark Haggard (United-Kingdom), Richard Rosenfeld (United States of America), Huan Jia (China), Shazia Peer (South Africa) and Marie-Noëlle Calmels (France) who had each participated in developing or elaborating their respective national guidelines for OME. The discussion was led by moderators Vincent Couloigner and Natacha Teissier (France). The main objective was to draw on existing national guidelines, in order to endorse international consensual policy statement on central issues in OME management. A secondary aim was to air possible region-specific epidemiology and its implications (eg local high prevalence of HIV or respiratory allergy) which could influence the emphasis of clinical policies in for OME in different parts of the world. Each issue was discussed considering up-to-date evidence-based literature, with the panellists' input reflecting their country's practice. Unless indicated otherwise, this article refers to management of persistent OME, with no specific treatment generally required prior to meeting the criterion of condition still present after a three months surveillance period (watchful waiting) [1–3].

2. Specific assessment related to OME diagnosis

2.1. GERD and allergy

The first step in OME management is a thorough clinical examination and assessment. OME can be well diagnosed using pneumatic otoscopy (enabling visualization of retro-tympanic fluid and check for tympanic membrane damage and mobility) or by a tympanogram (mechanical trace indicating the relation between trans-tympanic pressure and tympanic compliance hence ability to conduct sound through the middle ear to the cochlea. Chronic OME is confirmed by the persistence of liquid in the middle after a three-month surveillance period (Grade A level of evidence) [1–3,19,20]. Flexible nasal endoscopy can be used in cases of associated nasal obstruction or prolonged unilateral OME to confirm adenoid hypertrophy (Grade C) [21,22]. It should be used more routinely in areas with high HIV prevalence, due to the increased risk of nasopharyngeal anomalies (lymphoma) [23,24].

All panellists agreed that a very thorough probing within medical history taking, from the parents (and the child where of sufficient age), is important to reveal risk factors that are not spontaneously mentioned by the family. The two main risk factors for OME with possible direct medical implications are GERD and allergies. GERD has been associated with OME, and pepsin and *H. Pylori* have been found in middle ear fluid. However, the relative prevalence is not high enough to be a major cause of OME, no causation has been proved, nor have any studies demonstrated convincingly that treating GERD will improve, or resolve, OME. GERD assessment is appropriate only if clinical symptoms are present such as epigastric pain, recurrent laryngitis or sinusitis (Grade A) [1,3,25,26].

Studies have also shown an association between allergy and OME [27–30] and similarly assessment is appropriate if the child presents with clinical symptoms such as chronic rhinitis, enlarged turbinates, asthma or allergies (Grade B) [31,32]. Also, in certain areas with poor air quality and pollution issues, allergy assessment could be more systematic even for milder clinical symptoms (Grade C) [4,33,34]. Although there is proof of association between allergy and OME, there is, however, no evidence of causation in the literature; there is also no convincing evidence that directly treating allergy affects OME outcome (Grade B) [35,36].

All panellists agreed that no routine allergy or GERD (or any other) assessment was required for asymptomatic children, as shown in Appendix 1 (grade A) [1–4]. In the particular case of an older child with persistent OME (over seven years of age, when a dysfunctional Eustachian tube is less probable), assessment should be pushed further to explore the most frequent risk factors such as GERD and rare causes of nasopharyngeal obstruction [1,3].

2.2. Hearing testing

An audiogram is the only formal test routinely required in chronic OME [1–4]. On average at frequencies of 500, 1000, 2000 and 4000 Hz, about 50% of patients with a confirmed OME diagnosis present a hearing loss of 20 dB, 20% a hearing loss greater than 35 dB and 5-10% hearing loss of up to 50 dB [37,38]. Hearing loss greater than 50 dB is seldom due to OME alone and usually associated to other middle or inner ear pathologies [39,40]. In most countries, the hearing status is formally required before contemplating hearing surgery, in some instances for medicolegal reasons; also in children presenting with speech learning delays or syndromes associated with OME (Appendix 1). Such signs and symptoms should prompt a much earlier auditory assessment to help steer more pro-active management [38].

Guidelines recommend that audiometry be done prior to ventilation tube insertion: firstly, it can help determine the need for indication by the surgeon, and even more so for the parents if an important hearing loss is confirmed with an accepted precise measurement; secondly, to detect associated sensorineural hearing loss [1–4]. The tests are age-appropriate and in children under about 3–4 years usually free-field, they include pure tone audiometry (PTA), speech audiometry and bone-conduction when possible. In cases where even free-field assessment is not possible (due to very young age for example), authorities recommend objective auditory measurements such as Auditory Brain Response (ABR) when possible, so as not to miss an associated sensorineural hearing loss (Grade C) [41,42]. The overheads of surgery entail that ABR testing would not be done prior to surgery and could be done during the general anaesthesia for tube insertion or later under light sedation, according to the availability of the test [1–4].

3. Non-surgical management

OME in the young child is due to a variety of factors in the anatomy (the Eustachian tube being short, floppy and horizontal) exacerbating the functional consequences of oedematous mucosal immune response; currently no medical or surgical treatment can directly address this dysfunction [1]. Therefore, the objective of non-surgical management of OME is to limit chronic inflammation of the middle ear and to be otherwise harmless and cost-effective, until the growth of the child enables correct Eustachian tube function. Many different treatments have been used from oral or nasal steroids, antibiotics, antihistaminics, decongestants or mucolytics to auto-inflation techniques. All of these have been studied and the results compared in meta-analyses; most lack any long-lasting effect on OME evolution or hearing.

3.1. Steroids

Oral and nasal steroids have been used in an attempt to decrease inflammatory factors in the Eustachian tube and middle ear. A review comparing 12 studies with 945 patients has shown no improvement of long-term OME clinical symptoms; these results were confirmed by other studies (Grade A) [36,43,44]. Although these studies showed some short-term improvement of OME using oral steroids, they also reported side effects such as diarrhoea, nausea, hyperactivity and nosebleeds. Similarly, topical steroids did not show any benefit in the resolution of OME symptoms including hearing loss even in the short-term (Grade A) [36,44,45]. Overall, the guidelines do not recommend steroid treatments due to their cost, possible side effects and lack of any long-term efficacy [1–4].

3.2. Antibiotics

Various different antibiotic treatments have been tested but none have proven long-term efficacy nor any effect on OME symptoms. A recent Cochrane review included 23 studies and 3027 patients, comparing continuous antibiotic treatment (mostly amoxicillin) ranging from 10 days to six months but showed no effect on hearing, rate of tympanostomy tube insertion or language development (Grade A) [44,46]. In the past, effusions were thought incorrectly to be sterile, but the biofilm hypothesis has since helped to explain why we should not expect the low concentrations of systemic antibiotics reaching the middle ear to eradicate infection in an especially resistant form. Antibiotics also raise a cost issue and contribute to the increase in antibiotic resistance. A recent study from China seemed to show efficacy of a two-month low-dose macrolide treatment on OME symptoms (Grade B) [47], but further studies would be required to confirm this finding as a basis of prescription, considering the number of recommendations against antibiotic use and the impact of extended therapy on antimicrobial resistance.

3.3. Other medical treatment

Other non-surgical treatments suggested have poor or no efficacy. OME and allergy can be frequently associated, but, there is no convincing evidence that treating allergy (by attempting to reduce mucosal oedema in the Eustachian tube for example) has any effect on OME. On the other hand, decongestants and antihistaminics can induce side-effects and have shown no clinical or statistical benefits in OME in a meta-analysis of 16 different studies including 1880 patients (Grade A) [35]. Several studies on OME patients with allergies show that antihistamines can have a positive effect on allergic rhinitis as expected, but that any effect on OME is probably due to natural course (Grade A) [44,48–50]. Mucolytics such as carbocisteine, which attempt to reduce mucus production in the middle ear, can have short term efficacy. A review of seven studies including 283 children during a one to three-month period showed a decrease in ear-tube indication. Although no long-term efficacy has been shown, mucolytics may be used as support to watchful waiting, ie to buy time, these molecules being relatively harmless and cheap (Grade B) [3,4,51].

3.4. Auto-inflation

As shown in Appendix 1, all panellists agreed that auto-inflation was an interesting non-surgical method to partially restore Eustachian tube function by enabling the child to directly insufflate the Eustachian tube when blowing into a balloon through the nose (Grade B) [52]. In the developed world, the price (about $15), is not a major drawback, although it is one for widespread use in the developing world. Children require motivation for long-term adherence to the treatment especially at a young age so effectiveness should not be expected in all families. One team has studied a simple system using a facemask and balloons with different opening pressures (also includes a teddy bear to increase motivation) and has found significant improvement of both middle-ear pressure and hearing after four weeks of treatment in children as young as two (Grade B) [53,54]. All panellists agreed that further studies are required to develop a standardized, cheap and easy-to-use device.

4. Ventilation tubes

4.1. When to choose ventilation tubes

Recurrent AOM and hearing impairment, which are the two main indications for tube insertion, were discussed during this ICON. Concerning recurrent AOM, panellists agreed that no formal evidence-based definition of qualifying severity or frequency had been agreed but that the traditional definition used in the guidelines of ≥ 3 AOM in six months or ≥ 4 AOM in a year worked well for clinical practice [1–4]. Concerning hearing impairment, the criterion audiometric threshold varies between countries from 25 dB (a few lower) to 40 dB hearing loss [1–4,55]. Panellists agreed in emphasising assessment of the child as a whole including hearing difficulties and not just air-conduction hearing levels. Indeed, even if the standardisation element in thresholds makes them necessary to include in guidelines, clinical application requires a case by case approach; for example, one child could experience difficulties with a 25 dB hearing loss while another could sustain a normal social and school life with a 40 dB hearing loss. Also a hearing test on a single occasion does not reflect possible hearing fluctuations; the recent history of auditory deprivation in a given child is contained in reported hearing difficulties, but should also be directly sought. Overall, the panellists agreed that a tailored approach was paramount for decisions on tube insertion. The focus should be put on determining the child's context and hearing difficulties over a period of time rather than determining a threshold during a single auditory examination.

4.2. Choice of ventilation tube type

When the decision for tube insertion has been made, different tube types are available to the surgeon (represented in Fig. 1) according to the required duration of ventilation. Panellists preferred the purposive physiological term "ventilation" to the anatomical/surgical term "tympanostomy" or the misleading term "pressure equalisation". The most commonly used short-term tube is the Shepard tube (fluoroplastic or titanium made), often used in Europe, China (similar Paparella type 1 tube) and South-Africa, which usually extrudes within six months (the Paparella tube can extrude within six to 12 months). One of the main types of tube

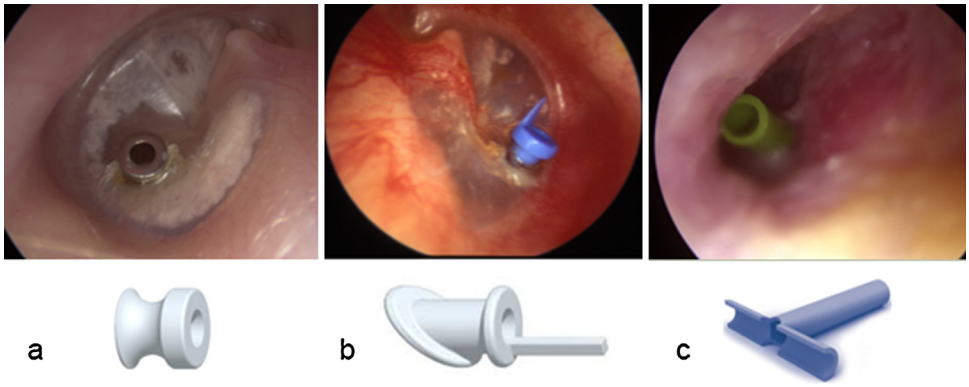


Fig. 1. Most common types of ventilation tubes (or grommets). Each tube is shown individually (bottom) and in position with a view of the eardrum (top). a: Shepard's grommets are short-term tubes which extrude within six months (Paparella type 1 are similar, although they can extrude over a 6-12 months period); b: Armstrong's grommets are intermediate tube which extrude between 9 and 14 months on average; c: T-tubes are long-term tubes and have to be manually removed and are generally kept up to two years.

used in North-America is the fluoroplastic Armstrong tube. This is considered an intermediate-stay tube as it spontaneously extrudes within nine to 14 months [38].

The choice between tube-types has to be made in the context of the overall treatment strategy for the individual. Indeed, on one hand, the longer effect of the Armstrong tube corresponds better to the natural duration of OME and could therefore be more beneficial for the child until the Eustachian tube functions properly. On the other hand, Shepard tubes are more appropriate to kick-start hearing restoration for seasonal OME, especially if associated with adenoidectomy (which has wider long-term effects, as will be discussed later).

Long-term tubes such as silicon T-tubes are not self-extruding and are usually kept for about two years in patients with recurrent OME after a first attempt using Shepard tubes (or equivalent) [56]. Although the need for extraction is a further healthcare counter, so cost, an advantage is that they can be extracted in the office at any given time, thereby permitting the surgeon to control the period of ventilation. T-tubes compared to short-term tubes increase the relative risk of perforation by 3.5 and cholesteatoma by 2.6 (Grade A) [57]; risk of otorrhea has been reported as higher or lower for other (Grade A) studies [56,57] with no strong reason to believe it should differ. The perforation risk from T-tubes is high, reaching 16% in one meta-analysis (Grade A) [57] and from one to 6% in other recent studies (Grade A) [38,57–59]. Also the risk of patients lost to follow-up consulting several years after the planned tube extraction has prompted some surgeons to prefer intermediate self-extruding Armstrong tubes in these indications. Choice of long-term or short-term tubes should therefore take into consideration the family context as well as the pathology, to correctly prognose not so much the likelihood of OME recurrence (slender evidence base for this) but the likelihood of the family coming back for follow-up.

In the case of OME with tympanic retraction, panellists agreed that short or intermediate tubes should be preferred in as many cases as possible to limit complications, but that in many cases of complete retraction, the lack of space behind the retraction required T-tube use.

4.3. Otorrhea management

Otorrhea is the most frequent complication of ventilation tubes and can arise in 3% to 50% of cases [58]. There is no significant evidence that it is prevented by precautions over water exposure, and is more likely linked either to nasal secretions during upper respiratory infection, reaching the middle ear through a possibly dysfunctional Eustachian tube (Grade A) [60,61] or from the ear canal (irrespective of water exposure). Oral systemic antibiotics are again not recommended to treat otorrhea in children with ventilation tubes for two main reasons other than cost and side-effects. Firstly, the main bacterium encountered in otorrhea, *Pseudomonas aeruginosa*, is resistant to common oral antibiotics prescribed in children and secondly the presence of ventilation tubes enables easy topical treatment using quinolone drops [1–4]. Quinolone eardrops can achieve local drug levels up to 1,000 times higher than orally-administered antibiotics, which greatly enhances efficacy and reduces contribution to bacterial resistance. Reassuring the parents is paramount and tube extraction for otorrhea should be restricted as it could lead back to OME.

4.4. Ventilation tube efficacy

Hearing impairment due to OME is the main reason to perform tube insertions, and the effect of the tubes on short-term and long-term hearing has largely been studied. A systematic review including 10 randomized trials found a short-term benefit of Shepard tubes on hearing (gain of 12 dB), which rapidly decreased after tube extrusion with an absence of long-term benefit on hearing loss (Grade A) [62,63]. Another literature review summarising 63 studies found that ventilation tubes increased auditory levels during the first nine months (Grade A) [64]. Tubes seem to have a clear benefit on hearing loss while in place, but to have however no enduring effect after extrusion (Grade A) [63,65,66]. Thus children who present with recurrent hearing loss after a first tube extrusion can require a further new tube insertion, either using longer-stay tubes or the broader approach of adjuvant adenoidectomy for a more prolonged effect [1–4].

The effect of tubes on recurrent AOM, which is the other main indication for tube insertion, is more delicate to precisely evaluate, due to classificatory difficulties and the paucity of high-quality trials. Indeed, recurrent AOM can occur with or without effusion. It is also unclear whether and how chronic OME with superadded episodes of recurrent AOM should be differentiated from post AOM effusion that may simply take more time to clear the middle ear out before the next acute infection. At any rate, many prospective studies have shown that recurrent AOM episodes with persistence of fluid in the middle ear do benefit from tympanostomy tubes, with a significant decrease in the number of AOM when the ventilation tube is present (Grade A) [1,38,62,67–69]. On the other hand, children who have recurrent AOM, but who manage to return to a dry ear baseline between infections, do not seem to benefit much from ventilation tubes (Grade A) [1,38].

Consequences for tympanic retractions and cholesteatoma are difficult to interpret from available evidence as the ears with the most severe disease are usually those which require ventilation tubes, so it is difficult to dissociate disease from treatment as cause of complications. One study comparing children aged 8 to 18 showed that tympanic atrophy and pars flaccida retractions recede with age regardless of tubes whereas pars tensa retractions seem to stay stable regardless of tubes (Grade A) [70]. Another prospective study has shown that early tube insertion does not seem to prevent tympanic retraction in patients with OME (Grade A) [71]. Panellists agreed to distinguish full atelectasis (where tube insertion is seldom possible and moreover risks to worsen the situation), from retraction pockets, where tubes seem to help prevent adherence in certain cases. One must also bear in mind that in certain cases, after tube extraction, the tympanic membrane can heal without any fibrous layer and that some retraction pockets evolve in this way. Concerning cholesteatoma, there was insufficient literature to assess the possible benefit of tubes on cholesteatoma prevention. OME requiring ventilation tubes seems to be associated with a higher risk of cholesteatoma (Grade C) [69,72]; however, as with retractions the main difficulty in interpretation is lack of ability dissociate disease from treatment.

5. Adjuvant adenoidectomy

In addition to tympanostomy tube insertion, adenoidectomy can increase the efficacy of OME surgery, although rare complications such as bleeding or nasopharyngeal stenosis can also occur. Recent meta-analyses have concluded that adenoidectomy has a long-lasting beneficial clinical effect for at least two years (Grade A) [73,74]; this was confirmed by another prospective study, which showed that adenoidectomy prolonged the effect on audition of short-term tubes to two years after surgery (Grade A) [75]. A large prospective study also found that adenoidectomy reduced the risk of OME recurrence requiring renewed ventilation tubes, especially in children over four years of age (Grade A) [76]. Therefore, most guidelines recommend adenoidectomy in children with OME over the age of four (Appendix 1), generally as an adjunct to short-term ventilation tubes or even myringotomy [1–4]. Under that age, the issue is more complicated; clinical benefits for the child seem poor (for reasons yet unclear) and adenoidectomy is not recommended due to the, still rare, surgical risks entailed (Grade A) [1–4,76]. Given the long-term benefit of adenoidectomy, the procedure could also be performed along with ventilation tube insertion in recurrent OME [1–4]. In all children, adenoidectomy should, however, be considered in cases of symptomatic adenoid hypertrophy (nasal obstruction) accompanying OME [1–4]. More so, in areas with high HIV-positive prevalence such as South-Africa, antiretroviral treatment whilst primarily to increase CD4 count, can induce an increase adenoid volume, thus these children should be specifically examined for adenoid hypertrophy [77] but guidance on adenoidectomy for this is not yet available.

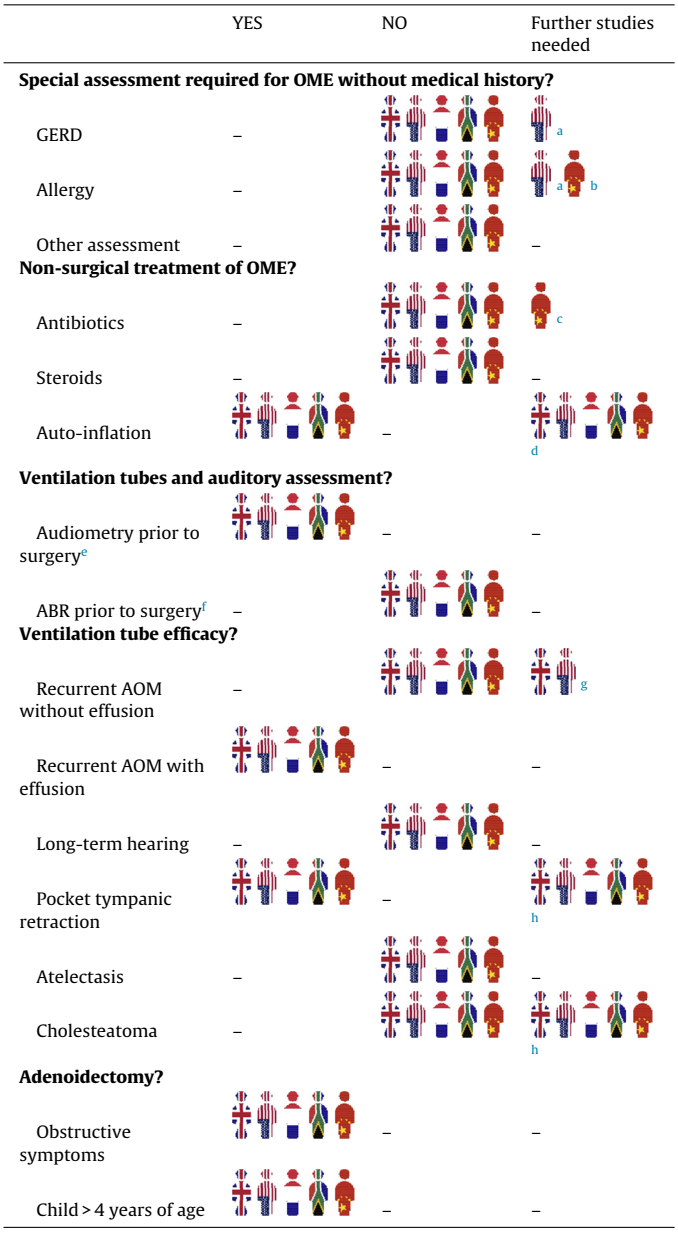
6. Summary conclusions

Overall, as shown in Appendix 1, the panellists expressed only minor regional differences and agreed on main OME management issues, regarding its initial assessment and medical or surgical treatment. Initially, a thorough medical examination of the child and his parents must be made in order to triage whether GERD and allergy need to be further assessed. In most cases, if the child does not have any abnormal medical history, the only recommended formal test is an age-appropriate auditory test, which should be done prior to any tube insertion. Other than auto-inflation, non-surgical treatment poorly addresses the underlying problem of an age-dependent dysfunctional Eustachian tube. There is a strong recommendation against treating OME with steroids (oral or intranasal), antibiotics, decongestants, or antihistamines, all of which have not convincingly demonstrated effect on OME resolution, but have side-effects and may be costly. Concerning surgery, decisions to insert tympanostomy ventilation tubes should be tailored to the child, taking into account hearing difficulties over the past months and the child's context as well as reproducible hearing tests. Ventilation tubes improve hearing by a worthwhile amount, and reduce recurrent AOM with effusion while in place, so seem to be an appropriate treatment for children who are impacted by their OME until the condition normalises. In the recurrent OME, for associated nasal obstruction, or in older children, additional adenoidectomy should be considered and seems to prolong the benefit of tube ventilation.

Disclosure of interest

The authors declare that they have no competing interest.

Appendix 1. Panellist's views on specific OME issues



ABR: Auditory Brainstem Response; AOM: Acute Otitis Media; GA: General Anaesthesia; GERD: Gastroesophageal Reflux Disease; OME: Otitis Media with Effusion.

[a] Further study of relationship between GERD/allergy and OME.

[b] Study of relationship between air quality and OME.

[c] Regarding the study on Macrolide use [47].

[d] Study of auto-inflation use, how to increase child motivation and reduce costs.

[e] Age-appropriate.

[f] If audiometry is unavailable, ABR could be considered on table or after surgery.

[g] To better understand difference between OME and recurrent AOM with and without effusion.

[h] To obtain studies with better level of evidence.

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