



A Systematic Review of Management of Otitis Media with Effusion in Children

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Authors' contributions

This work was carried out in collaboration between all authors. All authors were involved in the study design, statistical analysis, writing the protocol, literature searches and the first draft. Author RP wrote the final draft of the paper. All authors read and approved the final manuscript.

Review Article

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ABSTRACT

Aim: Otitis media with effusion in children can result in impairment of speech and language development secondary to the effects of conductive hearing loss from the disease. The review was conducted as part of a clinical practice guideline to assist healthcare providers in the management of this condition.

Study Design: Systematic review.

Place and Duration of Study: Development Group on Otitis Media with Effusion in Children Clinical Practice Guidelines, Medical Development Division, Ministry of Health Malaysia, between 17 August 2010 and 21 February 2012

Methodology: Literature search was carried out on multiple electronic databases. In addition, the reference lists of all retrieved articles were searched to identify relevant studies. Experts in the field were also contacted to identify further studies. All searches were officially conducted between 17 August 2010 and 21 February 2012. All literature retrieved was appraised using Critical Appraisal Skills Programme (Oxford) by at least two members and presented in the form of evidence tables and discussed during development group meetings. The articles used in this review were graded using the

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US/Canadian Preventive Services Task Force Level of Evidence [7].

Results: A total of 356 relevant titles were identified and 147 abstracts were screened. Thirty one articles were used in the results. There was good evidence for non surgical intervention as the initial mode of management. It consists of active observation and medical therapy. Short term (less than six weeks) intranasal steroid can be used for otitis media with effusion (OME) with concurrent allergic rhinitis and adenoid hypertrophy ($p<0.001$). There was good evidence that oral steroids, prolonged intranasal steroids, antibiotics, antihistamines or decongestants, auto inflation, homeopathy and mucolytics are not beneficial. Surgical intervention should be considered after three months of persistent otitis media with effusion with in children with hearing loss >25 dB (at three frequency average). Myringotomy with ventilation tube (VT) insertion is the procedure of choice. Combined adenoidectomy should be considered in children with persistent OME and hypertrophied adenoids ($p<0.001$).

Conclusion: The initial management of OME in children consists of active observation. Short term (up to 6 weeks) use of intranasal steroids can be used in children with concurrent adenoid hypertrophy or allergic rhinitis. Surgical management is considered after three months of persistent OME. Myringotomy with VT insertion is the procedure of choice.

Keywords: Systematic review; otitis media with effusion; ventilation tube.

1. INTRODUCTION

Otitis media with effusion (OME) is a disease where there is a collection of 'glue like' fluid in the middle ear. Unlike acute otitis media there are no signs of acute inflammation such as pain and fever. It is common in the pediatric age group, with eighty percent having had one episode of OME by the age of 10 years [1]. In a survey from Malaysia, the overall prevalence is 2.9% with estimated cases of 761,962 [2]. These figures however may not reflect the actual disease burden as confirmatory testing could not be done in some children during that survey. Another study among preschoolers found that the prevalence rate of OME was 18.3% [3].

Medical therapy has been widely used to treat the condition. Surgical treatment options include myringotomy with or without VT insertion, adenoidectomy or both. Opinions regarding the risks and benefits of VT insertion vary and the management of OME therefore remains controversial [4,5].

This systematic review is part of a clinical practice guidelines (CPG) developed by the Ministry of health, Malaysia to address the variation in clinical practice, potential negative impact of OME on hearing and cognitive function and to assist healthcare providers in the management of this condition.

2. MATERIALS AND METHODS

Literature search was carried out at the following electronic databases: Guidelines International Network (G-I-N), Pubmed/Medline, Cochrane Database of Systemic Reviews (CDSR), Database of Abstracts of Reviews of Effectiveness (DARE), Journal full text via OVID search engine, International Health Technology Assessment websites. In addition, the reference lists of all retrieved articles were searched to identify relevant studies. Experts in

the field were also contacted to identify further studies. All searches were officially conducted between 17 August 2010 and 11 August 2011. Literature searches were repeated allowing any relevant papers published up until 21 February 2012 to be considered. Details of the search terms and supporting evidence can be found in the CPG on Management of Otitis Media With Effusion In Children, available on the following websites: Ministry of Health Malaysia: <http://www.moh.gov.my> and Academy of Medicine: <http://www.acadmed.org.my>. A summary of the CPG can be found at the following website; <http://www.e-mfp.org/2013v8n2/otitis-media-with-effusion.pdf>.

All literature retrieved was appraised using Critical Appraisal Skills Programme (Oxford) by at least two members and presented in the form of evidence tables and discussed during development group meetings [6]. The articles used in this review were graded using the US/Canadian Preventive Services Task Force Level of Evidence [7].

3. RESULTS

A total of 356 relevant titles were identified and 147 abstracts were screened. After reading and appraising the full text articles, thirty-one articles were included in the results. The articles comprised two guidelines, three systematic reviews, two Meta analysis, 21 randomised controlled trials (RCT), two cohort studies and one narrative review. In two studies the distinction between recurrent AOM (acute otitis media) and OME is unclear and both are grouped together. (This distinction is mentioned when the articles are quoted below)

3.1 Active Observation (Watchful Waiting)

A systematic review (SR) examined the natural history and spontaneous resolution of OME in children. In children with newly diagnosed OME of unknown duration, the study found cumulative resolution rates of 56%, 72% and 81% at three, six and nine months respectively (using resolution criterion as change of tympanogram from type B to non-B). In contrast, children with documented chronic (defined as >3 months) bilateral OME had much lower resolution rates (19%, 25% and 31% at three, six and twelve months respectively) [8].

A few RCTs examined the role of early vs delayed VT insertion. Some of the trials involving children with persistent but uncomplicated OME found prompt insertion of ventilation tube (VT) as compared to delayed insertion (nine months) did not measurably improve speech, language, cognition and psychosocial developmental outcomes [9-13].

However, two trials conducted in more severely affected children (bilateral OME and significant hearing loss (25-75 dB) for >3 months) found some benefits from early VT insertion for expressive language, verbal comprehension and behavioral problems [14,15]. The subtle benefits appeared to persist up to age seven to eight years [16].

A period of continued observation will allow resolution of many cases of OME without the need for surgical intervention. During this period, parents and caregivers should be given advice on strategies to limit the effects of hearing loss in the child [5,17].

3.2 Steroids

Two studies report that topical intranasal steroid is beneficial either alone or with an antibiotic in treating OME at one month. However, the findings are not statistically significant [18,19].

In a RCT on patients with OME and adenoid hypertrophy, intranasal steroid spray was found to be effective at six weeks ($p < 0.001$) [20]. A Cochrane review showed faster resolution of OME when oral steroid was used alone (OR=0.22, 95% CI 0.08 to 0.63) or in combination with an antibiotic (OR=0.37, 95% CI 0.25 to 0.56) at two weeks when compared to control. No evidence of benefit beyond two weeks of treatment was noted [19].

In another RCT, no difference was demonstrated in the resolution rates of OME at three months follow-up between steroid, antihistamine and antibiotic alone or in combination ($p > 0.05$) [21].

No significant or lasting adverse events have been reported on topical intranasal or short term oral steroid use [18,19].

3.3 Antibiotics

Use of antibiotics leads to significantly lower rates in persistent OME in both ears and one or both ears in the antibiotic group (53% and 77%) compared to the controls (84% and 93%) after two weeks of follow-up [22].

However, a meta-analysis of 16 RCTs failed to support the continued use of antibiotics in the treatment of OME. Placebo-controlled trials did not show antibiotic efficacy (RD=0.043, 95% CI -0.001 to 0.086) [23].

Short term use of antibiotics with oral steroid led to a faster resolution of OME as compared to antibiotic alone (OR=0.37, 95% CI 0.25 to 0.56) [19].

Both NICE and SIGN guidelines do not recommend the use of antibiotics in children with OME [1,17].

3.4 Antihistamine or Decongestant

As OME may occur with allergic rhinitis, antihistamine and decongestant are widely used as symptomatic treatment in children with OME in the local practice.

However, a Cochrane SR in 2006 on children with OME showed no benefit of its use [24]; Decongestant alone did not resolve OME at one month or less (RR=1.06, 95% CI 0.92 to 1.22). Antihistamine or combination with decongestant up to three months also did not resolve OME compared to placebo RR=0.94 (95% CI 0.65 to 1.36) and 0.97 (95% CI 0.89 to 1.04). Neither antihistamine, decongestant nor the combination treatment lessened hearing loss at one month (RR=1.08, 95% CI 0.93 to 1.27) or one year (RR=1.50, 95% CI 0.63 to 3.56). All the treatment groups reported more side effects at or before one month (RR=2.70, 95% CI 1.37 to 1.88).

An update of the above review in 2011 showed no statistical or clinical benefit on the use of antihistamine or decongestant [25]. Both NICE and SIGN guidelines do not recommend use of antihistamine and decongestant in children with OME [1,17].

3.5 Auto inflation

A SR on auto inflation in children with OME showed no improvement in tympanometry and audiometric outcomes [26].

3.6 Homeopathy and Mucolytics

There is no good quality evidence for homeopathy and bromhexine in children with OME.

3.7 Hearing Aid

Hearing aid is an option to amplify hearing in OME. It is generally acceptable to parents and children as it provides a non-invasive way of managing the problems associated with OME [27,28]. However, there is no evidence to support its use as the first line of treatment in children with OME.

Hearing aid should be offered to children with persistent bilateral OME and hearing loss as an alternative to surgical intervention where surgery is contraindicated or not acceptable [1]. However, potential noise trauma is the main concern associated with continuous use after resolution of OME [29].

3.8 Surgical Intervention

3.8.1 Timing of surgical intervention

Different guidelines and studies vary in their recommendations on timing of surgical intervention. Waiting time of three to six months before the intervention on persistent disease with hearing impairment of more than 25 dB or structural changes to the tympanic membrane is recommended [1,5,30,31].

3.8.2 Options of surgical intervention

3.8.2.1 Myringotomy

There is no retrievable evidence on myringotomy alone in the management of OME.

3.8.2.2 Myringotomy with VT

VT improves the hearing level in persistent bilateral OME. The effect of VT on hearing is significantly improved by 9 - 10 dB in the first six months compared to watchful waiting (WW) and diminishes but remains significant after this period [4,32,33]. The improvement in hearing is greater in those with hearing threshold of >25 dB compared to <25dB [34].

Patients with VT have shorter mean time with effusion ($p=0.0001$) [34] and fewer bilateral OME [33] up to 12 months of follow-up compared to WW group.

Improvement in hearing level in children with VT is better in those aged ≤ 3 years attending day-care and those aged ≥ 4 years with a hearing level of ≥ 25 dBHL in both ears persisting for at least 12 weeks [34].

Repeated VT insertion for recurrent AOM or OME early in life will not be detrimental in the long-term hearing outcome [35].

3.8.2.3 Myringotomy with VT plus adenoidectomy

Adjuvant adenoidectomy along with VT insertion is routinely performed in many countries including Malaysia for recurrent episodes of OME and chronic persistent OME.

The benefit of adenoidectomy in reducing the recurrent AOM or persistent OME was found in patients with hypertrophied adenoids abutting the torus tubarius ($p < 0.05$). However, adenoidectomy had no significant benefit in the non abutting group [36]. A cohort study showed that VT with adenoidectomy or adenotonsillectomy reduced risk of further VT surgery ($p < 0.001$) [37].

A meta-analysis showed that VT alone gave 6 to 9 dB hearing improvement compared to an additional of 1 to 4 dB in VT with adenoidectomy [32].

In another study, adenoidectomy in young children aged 24 - 47 months did not add any further benefit in the reduction of OME recurrence [38].

3.8.2.4 Long-term VT

Long-term VT may be indicated when short term VT and additional measures such as adenoidectomy to improve eustachian tube function fail. It should be used selectively as the rate of complications such as recurrent otorrhoea and persistent perforation is high [39,40]. A meta-analysis of cohort studies showed that long term tubes increased the risk of perforation (RR=3.5, 95% CI 1.5 to 7.1) and cholesteatoma (RR=2.6, 95% CI 1.5 to 4.4) compared to short term tubes [41].

3.8.2.5 Other options

Laser myringotomy is a safe method to treat chronic OME in children and can be performed under local anaesthesia. However, laser myringotomy alone is a less effective treatment than myringotomy with VT [42].

4. DISCUSSION

OME is a common ear disease among children especially those with craniofacial anomalies including cleft palate and Down syndrome (DS). Prevalence of OME varies from 6.5% to 10.9% among children in different countries [43–45]. A local study conducted in 1992 showed that the incidence of OME in children with cleft palate was 57.6% [46]. (The management of OME in Down syndrome and cleft palate is discussed in a separate paper) OME is a fluctuating condition with symptoms that vary with time and age. The disease may persist in some children. The main symptom of OME is impaired hearing [1,47]. This condition is often under diagnosed, leading to untreated hearing impairment, which can cause speech and language developmental delay and poor school performance [17].

While most cases of OME will resolve spontaneously, some children will need intervention in the form of educational and social action or the provision of hearing aids because of the effects of hearing loss [1]. Long-standing and untreated cases of OME may progress to serious conditions such as adhesive otitis media, ossicular chain disruption, retraction pockets and cholesteatoma.

The findings of this systematic review support the findings of previous guidelines and reviews on this condition [1,5,17]. As the disease usually resolves spontaneously, non-surgical management is the first line treatment. Active observation is recommended to offset the effects of conductive deafness which occurs as a result of the disease.

Active observation refers to educational and behavioral strategies to minimize impact of hearing loss before surgical intervention is considered. This includes; facing the child when speaking, getting the child's attention before starting to talk, reducing background noise to the minimal, speaking clearly with normal rhythm and volume using visual cues (such as hands and pictures) in addition to speech, reading to or with the child (explain pictures and ask questions), repeating words, phrases and questions when misunderstood and placing the child near the teacher in the classroom [5,17]

Medical therapy has a limited role in the management of OME. Two Cochrane Systematic Reviews showed no benefit of long term oral steroids used alone or in combination with an antibiotic or when antihistamines and decongestants were used [19,24]. In one RCT intranasal steroids for up to six weeks was found to be effective on patients with OME and adenoid hypertrophy [20].

The main reason for considering surgery in OME is persistence of hearing loss. It is performed to improve hearing and reduce OME recurrence. Due to the fluctuating nature of the disease, the decision for surgical intervention in OME is based on several factors such as duration of disease and presence of structural or functional complication.

A waiting time of at least three months is recommended before surgical intervention is considered in persistent disease with hearing impairment of more than 25 dB or structural changes to the tympanic membrane [1,5,30,31]. Myringotomy with ventilation tube (VT) insertion is the treatment of choice. Myringotomy with VT insertion combined with adenoidectomy should be considered in children with persistent OME and hypertrophied adenoids abutting the torus tubarius.

5. CONCLUSION

The initial management of OME in children consists of active observation. Short term (up to 6 weeks) use of intranasal steroids can be used in children with concurrent adenoid hypertrophy or allergic rhinitis. Surgical management is considered after three months of persistent OME. Myringotomy with VT insertion is the procedure of choice.

CONSENT

Not applicable.

ETHICAL APPROVAL

Not applicable.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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