

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: MANAGEMENT OF CHRONIC OTITIS MEDIA WITH EFFUSION IN CHILDREN

Initial HERC approval 10/11/2012
Reaffirmed 11/13/2014

This coverage guidance was created under HERC's 2012 coverage guidance process and does not include strength of recommendation, a GRADE-informed framework or coverage guidance development framework.

As a part of the normal evidence review process, the Evidence-based Guidelines Subcommittee reviewed new evidence in September, 2014 (see Appendix A) and found eight new systematic reviews from trusted sources. They determined that this guidance is supported by the updated literature. However, the guidance's recommendation language has been altered to be consistent with that of more recent guidances.

HERC Coverage Guidance

Antibiotic and other medication therapy (including antihistamines, decongestants, and nasal steroids) is not recommended for coverage for children with children with otitis media with effusion (OME) (without another appropriate diagnosis).

There should be a 3 to 6 month watchful waiting period after diagnosis of otitis media with effusion, and if documented persistent hearing loss is greater than or equal to 25dB in the better hearing ear, referral for tympanostomy surgery is recommended for coverage, given short, but not long-term, improvement in hearing.

Formal audiometry is indicated for children with chronic OME present for 3 months or longer. Children with language delay, learning problems, or significant hearing loss should have hearing testing initially upon diagnosis. Children with chronic OME who are not at risk for language or developmental delay should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.

Adenoidectomy is not recommended for coverage at the time of the first pressure equalization tube insertion.

Tympanostomy surgery is recommended for coverage for patients with craniofacial anomalies, Down's syndrome, cleft palate, and patients with speech and language delay along with hearing loss based on an individualized treatment plan.

Note: Coverage guidance for recurrent acute otitis media is addressed in a separate document.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Health Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE SOURCES

Effros, R., & Little, A. (2010). Pressure equalization tubes in children. (Produced for the Medicaid Evidence-based Decision Project). Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

Key Sources Cited in MED Report:

American Academy of Family Physicians, American Academy of Otolaryngology – Head and Neck Surgery, & American Academy of Pediatrics (AAFP/AAOHNS/AAP) Subcommittee on Otitis Media with Effusion. (2004). Clinical Practice Guideline: Otitis Media with Effusion. *Pediatrics*, 113(5), 1412-1429.

Griffin, G., Flynn, C.A., Bailey, R.E., & Schultz, J.K. (2006). Antihistamines and/or decongestants for otitis media with effusion (OME) in children. *Cochrane Database of Systematic Reviews*, 4(CD003423), 1-44.

Kay, D.J., Nelson, M., & Rosenfeld, R.M. (2001). Meta-analysis of tympanostomy tube sequelae. *Otolaryngology-Head and Neck Surgery*, 124, 374-380.

Leach, A.J., & Morris, P.S. (2006). Antibiotics for the prevention of acute and chronic suppurative otitis media in children. *Cochrane Database of Systematic Reviews*, 4(CD004401), 1-70.

Lous, J., Burton, M.J., Felding, J., Ovesen, T., Rovers, M., & Williamson, I. (2005). Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children. *Cochrane Database of Systematic Reviews*, 1 (CD001801), 1-58.

Mandel, E.M., & Casselbrant, M.L. (2006). Recent developments in the treatment of otitis media with effusion. *Drug*, 66(12), 1545-1576.

McDonald, S., Langton Hewer, C.D., & Nunez, D.A. (2008). Grommets (ventilation tubes) for recurrent acute otitis media in children. *Cochrane Database of Systematic Reviews*, 4(CD 004741), 1-14.

National Collaborating Centre for Women's and Children's Health. (2008). Surgical management of otitis media with effusion in children. London: National Institute for Health and Clinical Excellence (NICE). Retrieved July 6, 2012, from www.nice.org.uk/nicemedia/pdf/CG60NICEguideline.pdf

Perera, R., Haynes, J., Glasziou, P.P., & Heneghan, C.J. (2006). Autoinflation for hearing loss associated with otitis media with effusion. *Cochrane Database of Systematic Reviews*, 4(CD006285), 1-28.

Rovers, M.M., Black, N., Browning, G.G., Maw, R., Zielhuis, G.A., & Haggard, M.P. (2005). Grommets in otitis media with effusion: an individual patient data meta-analysis. *Archives of Diseases of Childhood*, 90(5), 480-485.

Simpson, S.A., Thomas, C.L., van der Linden, M., MacMillan, H., van der Wouden, J.C., & Butler, C.C. (2007). Identification of children in the first four years of life for early treatment for otitis media with effusion. *Cochrane Database of Systemic Reviews*, 1(CD004163), 1-24.

Thomas, C.L., Simson, S., Butler, C., & van der Voort, J. (2006). Oral or topical nasal steroids for hearing loss associated with otitis media with effusion in children. *Cochrane Database of Systemic Reviews*, 3(CD001935), 1-26. Additional sources

The summary of evidence in this document is derived directly from this evidence source, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical background

Otitis media is one of the most frequent infections in children and is a leading cause of both visits to the physician and use of antibiotics in this population. The direct costs of otitis media are estimated at \$3 to 5 billion per year in the US. Recurrent infections or chronic fluid in the middle ear can cause hearing deficits, and there is concern that in a rapidly developing child, this could lead to language and other developmental problems.

Pressure equalization (PE) tubes are small plastic or metal tubes that are surgically inserted into the tympanic membrane to allow for drainage of the fluid from the middle ear with the goal of improved hearing. The hope is that if hearing is improved, then language and other developments can be optimized. One of the challenges of determining which children require PE tube placement is that not all middle ear disease is associated with hearing loss, and even the presence of a mild to moderate hearing loss from a middle ear effusion does not necessarily translate into later speech or language delays in children. Further, the high rates of spontaneous resolution of both acute otitis media and middle ear effusions, and the fact that most PE tubes

only remain in the ear drum for 6-12 months, may lessen the potential benefit of PE tube insertion.

Evidence review

There is evidence that PE tubes decrease the duration of otitis media with effusion (OME) over the first year. In addition, PE tubes provide short-term (three to six month) improvements in hearing, but this advantage dissipates by 12 months. Overall, there do not seem to be consistent benefits in language and development as a result of PE tube placement for OME. The most common complication of PE tubes appears to be otorrhea, which can result in increased use of oral or topical antibiotics. Tympanosclerosis and retraction pockets of the tympanic membrane are also complications of PE tubes, but their clinical significance remains uncertain. Limited evidence suggests that children with PE tubes sustain higher costs in follow-up, in addition to the costs of the procedure itself, without consistent, measurable benefits in language and development.

There are no clear risk factors that identify children who should have PE tubes placed. Some evidence suggests that children with poor baseline hearing (i.e., >25 dB) and those in daycare obtain more of a hearing benefit from PE tubes. In addition, there is limited evidence that children with baseline language or other developmental delays and hearing loss may benefit from earlier PE tube placement.

Overall, the literature suggests that watchful waiting for at least three months is an appropriate initial step in the management of OME. The literature is less clear on management following this initial three months, with some evidence suggesting that even waiting as long as six months may not have deleterious effects on language and development in many children. In terms of other treatment options, there is no evidence that antihistamines, decongestants or nasal steroids are effective treatments for OME.

Adenoidectomy may improve middle ear effusions at six months but does not lead to significant improvements in hearing or in recurrent acute otitis media. Autoinflation may have some benefits in terms of resolution of effusion but may be difficult to use in young patients who might not be cooperative with the treatment. Oral steroids show short-term benefits for OME but fail to sustain these improvements over the longer term. Oral antibiotics may also improve OME in the short term, but the low quality of the evidence does not allow for definitive conclusions. Prophylactic antibiotics are also modestly effective at decreasing the number of episodes of acute otitis media in children with recurrent disease. There is concern for the development of antibiotic resistance with their chronic use, and despite the modest benefits, their use for recurrent acute otitis media and OME has declined.

Guidelines

Two guidelines that address the surgical management of OME (a joint guideline produced by the American Academy of Family Physicians, American Academy of Otolaryngology – Head and Neck Surgery, and American Academy of Pediatrics [AAFP/AAOHNS/AAP]; a National Institute for Health and Clinical Excellence [NICE] guideline produced by the National Collaborating

Centre for Women’s and Children’s Health) provide similar but slightly different recommendations regarding the management of children with OME. Both recommend monitoring children for the first three months of middle ear effusion and evaluating the child’s hearing if the effusion remains at three months. However, NICE recommends hearing testing both at the time of initial diagnosis, and after three months, while the AAFP/ AAOHNS/AAP guideline recommends hearing testing only after OME has been present for three months, unless there is language delay, learning problems or hearing loss is suspected. In addition, language testing is recommended for any child with a documented hearing loss by the AAFP/ AAOHNS/AAP guideline, but not mentioned by the NICE guideline. In addressing this, the text of the evidence review states the following: “A proportion of children referred with suspected OME will also have underlying sensorineural or permanent conductive hearing loss. The GDG [Guideline Development Group] wished to emphasize the need to identify any such component.”

Regarding surgical management, the NICE guideline suggests that any child with persistent OME at three months who has a hearing threshold worse than 25 dB should be referred for PE tubes, and if tubes are contraindicated or not desired, then the child should be offered hearing aids and other educational/behavioral interventions. They note that surgical intervention for some children at hearing loss less than 25 to 30 dB may be considered if hearing loss would be expected to significantly impact behavior or development. They specifically identify children with Down syndrome and cleft palate as needing comprehensive specialty care and hearing evaluation, but do not make specific recommendations regarding the timing or use of PE tubes. With regard to the hearing loss level, the text of the evidence review states the following: “Persistent and/or fluctuating OME, resulting in a hearing loss of 25–30 dBHL or greater may have adverse effects on a child’s speech and language development, behaviour, emotional development and school progress. This 25–30 dBHL value is of necessity somewhat notional. *(italics added)* Hearing levels fluctuate with time and would not predict the impact precisely even if the hearing history over time were known, because of differing susceptibilities.”

In contrast, the AAFP/ AAOHNS/AAP guideline recommends a risk-based approach, in which children at risk for or with language or other developmental delay should be referred more promptly for PE tubes. In children at low risk for delays, the guidelines recommend watchful waiting and monitoring every three to six months until the effusion disappears and referral if significant hearing loss develops or if language or other developmental delays appear. They divide hearing loss into three classes with different actions recommended for each level:

Table 1

Hearing level	Recommended action
≥ 40 dB (moderate hearing loss)	Comprehensive audiologic exam and if hearing loss persists at this level, surgery recommended.

21-39 dB (mild hearing loss)	Comprehensive audiologic exam. Individualize based on effusion duration, severity of hearing loss, parent/caregiver preference: can include optimizing listening and learning environment. Repeat hearing testing in 3-6 months if otitis media with effusion persists and tympanostomy tubes have not been placed.
≤ 20 dB (normal hearing)	Repeat hearing test in 3-6 months if otitis media with effusion persists.

The guideline states this recommendation is based on RCTs and observational studies, with a preponderance of benefit over harm. However, specific citations are not provided that pertain directly to the hearing levels noted above. The text of the guideline does provide citations for the following:

“Asymptomatic OME usually resolves spontaneously, but resolution rates decrease the longer the effusion has been present and relapse is common. Risk factors that make spontaneous resolution less likely include:

- Onset of OME in the summer or fall season,
- Hearing loss more than 30-dB HL in the better hearing ear,
- History of prior tympanostomy tubes, and
- Not having had an adenoidectomy.”

Overall summary

Pressure equalization tubes likely decrease the duration of middle ear effusion over the first year. They also provide short-term improvement in hearing that dissipates by 12 months, resulting in no long-term benefits in language and development as a result of PE tube placement for OME. There are no clear risk factors that identify children who should have PE tubes placed. Some evidence suggests that children with poor baseline hearing (i.e., >25 dB) obtain more of a hearing benefit from PE tubes. Watchful waiting for at least three months and possibly up to six is an appropriate initial step in the management of OME. There is no evidence that antihistamines, decongestants or nasal steroids are effective treatments for OME. Adenoidectomy may improve middle ear effusions at six months but does not lead to significant improvements in hearing or in recurrent acute otitis media. Autoinflation may have some benefits in terms of resolution of effusion, while oral steroids and antibiotics show short-term benefit for OME, but longer term improvement is either not sustained or is uncertain. Prophylactic antibiotics modestly decrease the number of episodes of acute otitis media in children with recurrent disease.

Procedure

Placement of pressure equalization tubes

Pharmacotherapy
Autoinsufflation

Diagnoses

Acute otitis media
Chronic otitis media with effusion

Applicable codes

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
381.1	Chronic serous otitis media
381.10	... simple or unspecified
381.19	Other chronic serous otitis media
381.2	Chronic mucoid otitis media
381.20	... simple or unspecified
381.29	Other chronic mucoid otitis media
381.3	Other and unspecified chronic nonsuppurative otitis media
381.4	Nonsuppurative otitis media, not specified as acute or chronic
382.1	Chronic tubotympanic suppurative otitis media
382.2	Chronic atticofacial suppurative otitis media
382.3	Unspecified chronic suppurative otitis media
382.4	Unspecified suppurative otitis media
382.9	Unspecified otitis media
315.34	Speech and language developmental delay due to hearing loss
389.00	Conductive hearing loss unspecified
389.03	Conductive hearing loss middle ear
389.05	Conductive hearing loss unilateral
389.06	Conductive hearing loss bilateral
389.08	Conductive hearing loss of combined types
389.2	Mixed conductive and sensorineural hearing loss
389.20	Mixed hearing loss, unspecified
389.21	Mixed hearing loss, unilateral
389.22	Mixed hearing loss, bilateral
389.9	Unspecified hearing loss
CD-9 Volume 3 (Procedure Codes)	
None	
CPT Codes	
42820	Tonsillectomy and adenoidectomy; younger than age 12
42821	Tonsillectomy and adenoidectomy; age 12 and over
42830	Adenoidectomy, primary; younger than age 12
42831	Adenoidectomy, primary; age 12 and over
42835	Adenoidectomy, secondary; younger than age 12
42836	Adenoidectomy, secondary; age 12 and over
69433	Tympanostomy (requiring insertion of ventilating tube, local or topical anesthesia)

CODES	DESCRIPTION
69436	Tympanostomy (requiring insertion of ventilating tube, general anesthesia)
69424	Ventilating tube removal requiring general anesthesia
HCPCS Level II Codes	
None	

APPENDIX A

Scanning results:

Eight reviews were identified in the core sources that were published after the date of the MED report (some were updates of Cochrane reviews included in the guidance document). Summary results and/or conclusions are presented below:

Williamson, I. (2011). Otitis media with effusion in children. *BMJ Clinical Evidence*, 01(502), 1-30.

- Oral antibiotics, antihistamines plus oral decongestants, or mucolytics may be of no benefit in OME, and can cause adverse effects.
- Oral corticosteroids are unlikely to improve symptoms in OME, and can cause growth retardation.
- Intranasal corticosteroids are unlikely to be of benefit in children with bilateral otitis media with effusion.
- Ventilation tubes may improve short-term outcomes, but the clinical effect size is small. They may also increase the risk of tympanic membrane abnormalities. Ventilation tubes improve hearing for the first 2 years, but have no longer-term benefit, and may not improve cognition or language development.
- Adenoidectomy may improve hearing when performed with tympanostomy, but the clinical relevance of the improvements is unclear.
- Combination treatment with ventilation tubes plus adenoidectomy may be more effective than adenoidectomy alone.

van den Aardweg MTA, Schilder AGM, Herkert E, Boonacker CWB, Rovers MM. Adenoidectomy for otitis media in children. (2010). *Cochrane Database of Systematic Reviews*. Issue 1. Art. No.: CD007810. DOI: 10.1002/14651858.CD007810.pub2.

Main results:

Fourteen randomised controlled trials (2712 children) studying the effectiveness of adenoidectomy in children with otitis media were evaluated. Most of these trials were too heterogeneous to pool in a meta-analysis. Loss to follow up varied from 0% to 63% after two years.

Adenoidectomy in combination with a unilateral tympanostomy tube has a beneficial effect on the resolution of OME (risk difference (RD) 22% (95% CI 12% to 32%) and 29% (95% CI 19% to 39%) for the non-operated ear at six and 12 months, respectively (n = 3 trials)) and a very small (< 5 dB) effect on hearing, compared to a unilateral tympanostomy tube only. The results of studies of adenoidectomy with or without myringotomy versus non-surgical treatment or myringotomy only, and those of adenoidectomy in combination with bilateral tympanostomy tubes versus bilateral tympanostomy tubes only, also showed a small beneficial effect of

adenoidectomy on the resolution of the effusion. The latter results could not be pooled due to large heterogeneity of the trials.

The effects of adenoidectomy on changes of the tympanic membrane or cholesteatoma have not been studied.

Authors' conclusions

Our review shows a significant benefit of adenoidectomy as far as the resolution of middle ear effusion in children with OME is concerned. However, the benefit to hearing is small and the effects on changes in the tympanic membrane are unknown. The risks of operating should be weighed against these potential benefits.

van Zon A, van der Heijden GJ, van Dongen TMA, Burton MJ, Schilder AGM. (2012). Antibiotics for otitis media with effusion in children. Cochrane Database of Systematic Reviews. Issue 9. Art. No.: CD009163. DOI: 10.1002/14651858.CD009163.pub2.

Main results:

We included 23 studies (3027 children) covering a range of antibiotics, participants, outcome measures and time points of evaluation. Overall, we assessed the studies as generally being at low risk of bias. Our primary outcome was complete resolution of OME at two to three months. The differences (improvement) in the proportion of children having such resolution (risk difference (RD)) in the five individual included studies ranged from 1% (RD 0.01, 95% CI -0.11 to 0.12; not significant) to 45% (RD 0.45, 95% CI 0.25 to 0.65). Results from these studies could not be pooled due to clinical and statistical heterogeneity. Pooled analysis of data for complete resolution at more than six months was possible, with an increase in resolution of 13% (RD 0.13, 95% CI 0.06 to 0.19). Pooled analysis was also possible for complete resolution at the end of treatment, with the following increases in resolution rates: 17% (RD 0.17, 95% CI 0.09 to 0.24) for treatment for 10 days to two weeks, 34% (RD 0.34, 95% CI 0.19 to 0.50) for treatment for four weeks, 32% (RD 0.32, 95% CI 0.17 to 0.47) for treatment for three months, and 14% (RD 0.14, 95% CI 0.03 to 0.24) for treatment continuously for at least six months.

We were unable to find evidence of a substantial improvement in hearing as a result of the use of antibiotics for otitis media with effusion; nor did we find an effect on the rate of ventilation tube insertion. We did not identify any trials that looked at speech, language and cognitive development or quality of life. Data on the adverse effects of antibiotic treatment reported in six studies could not be pooled due to high heterogeneity. Increases in the occurrence of adverse events varied from 3% (RD 0.03, 95% CI -0.01 to 0.07; not significant) to 33% (RD 0.33, 95% CI 0.22 to 0.44) in the individual studies.

Authors' conclusions:

The results of our review do not support the routine use of antibiotics for children up to 18 years with otitis media with effusion. The largest effects of antibiotics were seen in children treated continuously for four weeks and three months. Even when clear and relevant benefits of

antibiotics have been demonstrated, these must be balanced against the potential adverse effects when making treatment decisions. Immediate adverse effects of antibiotics are common and the emergence of bacterial resistance has been causally linked to the widespread use of antibiotics for common conditions such as otitis media.

Griffin G, Flynn CA. Antihistamines and/or decongestants for otitis media with effusion (OME) in children. (2011). Cochrane Database of Systematic Reviews. Issue 9. Art. No.: CD003423. DOI: 10.1002/14651858.CD003423.pub3.

Main results:

Sixteen studies (1880 participants) were included in the review. No statistical or clinical benefit was found for any of the interventions or outcomes studied. However, treated study subjects experienced 11% more side effects than untreated subjects (number needed to treat to harm = 9).

Authors' conclusions:

The pooled data demonstrate no benefit and some harm from the use of antihistamines or decongestants alone or in combination in the management of OME, therefore we recommend against their use.

Perera R, Glasziou PP, Heneghan CJ, McLellan J, Williamson I. Autoinflation for hearing loss associated with otitis media with effusion. (2013). Cochrane Database of Systematic Reviews. Issue 5. Art. No.: CD006285. DOI: 10.1002/14651858.CD006285.pub2.

Main results:

Eight studies, with a total of 702 participants, met the inclusion criteria. Overall, the studies were predominantly assessed as being at low or unclear risk of bias; unclear risk was mainly due lack of information. There was no evidence of selective reporting.

Pooled estimates favoured the intervention, but did not show a significant effect on tympanometry (type C2 and B) at less than one month, nor at more than one month. Similarly, there were no significant changes for discrete pure-tone audiometry and non-discrete audiometry. Pooled estimates favoured, but not significantly, the intervention for the composite measure of tympanogram or audiometry at less than one month; at more than one month the result became significant (RRI 1.74, 95% CI 1.22 to 2.50).

Subgroup analysis based on the type of intervention showed a significant effect using a Politzer device under one month (RRI 7.07, 95% CI 3.70 to 13.51) and over one month (RRI 2.25, 95% CI 1.67 to 3.04). None of the studies demonstrated a significant difference in the incidence of side effects between interventions.

Authors' conclusions:

All of the studies were small, of limited treatment duration and had short follow-up. However, because of the low cost and absence of adverse effects it is reasonable to consider autoinflation whilst awaiting natural resolution of otitis media with effusion. Primary care could prove a beneficial place to evaluate such interventions and there is ongoing research in this area. Further research should also consider the duration of treatment, the long-term impact on developmental outcomes in children and additional quality of life outcome measures for children and families.

Browning GG, Rovers MM, Williamson I, Lous J, Burton MJ. Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children. (2010). Cochrane Database of Systematic Reviews. Issue 10. Art. No.: CD001801. DOI: 10.1002/14651858.CD001801.pub3.

Main results:

We included 10 trials (1728 participants). Some trials randomised children (grommets versus no grommets), others ears (grommet one ear only). The severity of OME in children varied between trials. Only one 'by child' study (MRC: TARGET) had particularly stringent audiometric entry criteria. No trial was identified that used long-term grommets.

Grommets were mainly beneficial in the first six months by which time natural resolution lead to improved hearing in the non-surgically treated children also. Only one high quality trial that randomised children (N = 211) reported results at three months; the mean hearing level was 12 dB better (95% CI 10 to 14 dB) in those treated with grommets as compared to the controls. Meta-analyses of three high quality trials (N = 523) showed a benefit of 4 dB (95% CI 2 to 6 dB) at six to nine months. At 12 and 18 months follow up no differences in mean hearing levels were found.

Data from three trials that randomised ears (N = 230 ears) showed similar effects to the trials that randomised children. At four to six months mean hearing level was 10 dB better in the grommet ear (95% CI 5 to 16 dB), and at 7 to 12 months and 18 to 24 months was 6 dB (95% CI 2 to 10 dB) and 5 dB (95% CI 3 to 8 dB) dB better. No effect was found on language or speech development or for behaviour, cognitive or quality of life outcomes.

Tympanosclerosis was seen in about a third of ears that received grommets. Otorrhoea was common in infants, but in older children (three to seven years) occurred in < 2% of grommet ears over two years of follow up.

Authors' conclusions:

In children with OME the effect of grommets on hearing, as measured by standard tests, appears small and diminishes after six to nine months by which time natural resolution also leads to improved hearing in the non-surgically treated children. No effect was found on other child outcomes but data on these were sparse. No study has been performed in children with

established speech, language, learning or developmental problems so no conclusions can be made regarding treatment of such children.

Simpson SA, Lewis R, van der Voort J, Butler CC. Oral or topical nasal steroids for hearing loss associated with otitis media with effusion in children. (2011). Cochrane Database of Systematic Reviews. Issue 5. Art. No.: CD001935. DOI: 10.1002/14651858.CD001935.pub3.

Main results:

We included 12 medium to high-quality studies with a total of 945 participants. No study documented hearing loss associated with OME prior to randomisation. The follow-up period was generally limited, with only one study of intranasal steroid reporting outcome data beyond six months.

There was no evidence of benefit from steroid treatment (oral or topical) in terms of hearing loss associated with OME. Pooled data using a fixed-effect model for OME resolution at short-term follow up (< 1 month) showed a significant effect of oral steroids compared to control (RR 4.48; 95% CI 1.52 to 13.23; Chi^2 2.75, $\text{df} = 2$, $P = 0.25$; $I^2 = 27\%$). Oral steroids plus antibiotic also resulted in an improvement in OME resolution compared to placebo plus antibiotic at less than one month follow up, using a random-effects model (RR 1.99; 95% CI 1.14 to 3.49; five trials, 409 children). However, there was significant heterogeneity between studies ($P < 0.01$, $I^2 = 69\%$). There was no evidence of beneficial effect on OME resolution at greater than one month follow up with oral steroids (used alone or with antibiotics) or intranasal steroids (used alone or with antibiotics) at any follow-up period. There was also no evidence of benefit from steroid treatment (oral or topical) in terms of symptoms.

Authors' conclusions:

While oral steroids, especially when used in combination with an oral antibiotic, lead to a quicker resolution of OME in the short term, there is no evidence of longer-term benefit and no evidence that they relieve symptoms of hearing loss. We found no evidence of benefit from treatment of OME with topical intranasal steroids, alone or in combination with an antibiotic, either at short or longer term follow up.

Berkman ND, Wallace IF, Steiner MJ, Harrison M, Greenblatt AM, Lohr KN, Kimple A, Yuen A. (2013). Otitis Media With Effusion: Comparative Effectiveness of Treatments. Comparative Effectiveness Review No. 101. (Prepared by the RTI-UNC Evidence-based Practice Center under Contract No. 290-2007-10056-I.) AHRQ Publication No. 13-EHC091-EF. Rockville, MD: Agency for Healthcare Research and Quality.

Results:

We identified 59 studies through the earlier reviews and our independent searches.

Generally, studies examined interventions in otherwise healthy, non-infant children. We did not find any eligible studies covering complementary and alternative medicine. Findings are

reported for clinical and functional outcomes, and harms. Variation in length of tympanostomy tube (TT) retention corresponded to whether TT were designed to be short versus long term, but variation in TT type was not related to improved OME and hearing outcomes. Tympanostomy tubes decreased OME for 2 years compared with watchful waiting (WW) or myringotomy, and improved hearing for 6 months compared with WW. OME resolution was more likely with adenoidectomy than no treatment at 12 months. Adenoidectomy and myringotomy were superior to myringotomy alone in relation to OME and hearing outcomes at 24 months. Adenoidectomy and TT were superior to WW for hearing outcomes at 24 months. Autoinflation was superior to standard treatment at improving OME at 1 month. We found no benefits from oral steroids at 2 months, or topical steroids at 9 months. In relation to functional outcomes, TT and WW did not differ in long-term language, cognitive or academic outcomes. Tympanosclerosis and otorrhea were more common in ears with TT. Adenoidectomy increased the risk of postsurgical hemorrhage. In one study of a subgroup, adults receiving autoinflation were more likely to recover from OME than those in the control group at one month. We found no studies examining the influence of any health care factors on treatment effectiveness.

Conclusions:

There is evidence that both TT and adenoidectomy reduce OME and improve hearing in the short term, but both treatments also have associated harms. Large, well-controlled studies could help resolve the risk-benefit ratio by measuring AOM recurrence, functional outcomes, quality of life measures, and long-term outcomes. Finally, additional research is needed to support treatment decisions in subpopulations, particularly those with comorbidities and those who have received a pneumococcal vaccine inoculation.

Summary:

The recently published evidence does not contradict the current coverage guidance recommendations.