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FROM THE FAMILY PRACTICE INQUIRIES NETWORK

Are nasal steroid sprays effective for otitis media with effusion?

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EVIDENCE-BASED ANSWER

Treatment of otitis media with effusion (OME) with nasal steroids is not recommended (strength of recommendation [SOR]=**A**, based on systematic review).

Limited evidence exists that shows nasal steroids may increase the rate of resolution of OME in the short term, alone or in combination with antibiotics (SOR: **A**, based on randomized controlled trials). However, within 3 to 12 weeks, resolution of OME with nasal steroids is no better than placebo. No evidence exists that treatment with nasal steroids has any effect on decreasing potential complications of OME, such as hearing loss and delayed language development.

EVIDENCE SUMMARY

OME is diagnosed by visualization of an effusion on otoscopy, by limited tympanic membrane movement on insufflation, or by abnormal tympanometry, all in the absence of acute inflammation. OME is defined as chronic when the effusion has been present for at least 3 months.

The natural course of OME was observed in a longitudinal cohort study of 1439 children aged 2 years in the Netherlands. Single or recurrent flat screening tympanograms were noted in 20% and remitted spontaneously at a rate of 50% every 3 months.[1] This prevalence and spontaneous resolution rate is consistent with other studies.

Three randomized controlled trials published in English tested intranasal steroids for OME (**Table**).

The Lilholdt study enrolled children through a private ear, nose, and throat clinic over autumn, winter, and spring with a primary or new bout of OME.

The Shapiro study enrolled children who had documented allergic rhinitis and OME with failure to respond to 4

weeks of oral antihistamine and decongestant therapy at time of entry. This was the only study with short-term follow-up comparing intranasal steroids with control. The odds ratio for OME persisting after 3 weeks was 2.12 (95% confidence interval [CI], 0.65-6.90).[3]

The Tracy study enrolled children with chronic OME referred to a chronic ear clinic from October to June. Inclusion criteria included 3 episodes of acute otitis media in the prior 6 months or 4 episodes in the prior 12 months. This was a randomized comparison study with 3 treatment arms: an active nasal spray group and 2 control groups. The odds ratio for OME persisting after short-term follow-up was 0.79 (95% CI, 0.20-3.19); after intermediate follow-up the odds ratio was 0.72 (95% CI, 0.21-2.44).

This study, which included a symptom score after 3 months, favored treatment, with a weighted mean difference of -4.5, but with wide 95% CI of -10.28 to 1.28. An effect was demonstrated on clearing effusions in the short term, but the advantage appeared to vanish for the most part by 3 months. The study did not evaluate improvements in hearing.[4]

No adverse effects of intranasal steroid treatment were seen except for transient drops in cortisol levels in the Shapiro study, which tested dexamethasone. Approximately 8 randomized controlled trials using oral steroids with and without antibiotics for OME and chronic OME mirror a trend for short-term benefit of treatment, spontaneous resolution, and frequent recurrence.

In summary, limited evidence exists for short-term improvement of OME with intranasal steroids plus antibiotics, and no evidence exists for lasting beneficial effect on effusion or OME associated hearing loss.

Clinical trials: Intranasal steroids for otitis media with effusion

Study	Subjects	Groups	Duration	Outcome
Lilholdt 1982	n=70 (aged 4-14 yrs with OME)	Beclomethasone vs placebo	2 mo	No benefit at end of treatment month or after second month with no treatment by otoscopy, tympanometry, or audiometry.
				Spontaneous improvement in 25% and resolution in 25%.[1]
Shapiro 1982	n=45	Dexamethasone vs placebo	3 wk (aged 2-12 yrs with OME >1 mo)	Normalization of ear pressure and middle ear gradient at 1 and 2 weeks of treatment group over placebo (P<.05).

				No significant differences by third week.[2]
Tracy 1998	n=61 (aged 3-11 yrs with chronic OME)	Beclomethasone + amoxicillin vs placebo + amoxicillin vs amoxicillin alone	12 wk	Beclomethasone group showed a significantly greater frequency of resolution of chronic effusion at 4 and 8 weeks (P<.05) but not at 12 weeks, with improved middle ear pressures: left (P=.004) and right (P=.010) over the 12 weeks.[3]
OME, otitis media with effusion				

RECOMMENDATIONS FROM OTHERS

The Canadian Task Force on Preventative Health Care found insufficient evidence to recommend screening for OME to prevent delayed language development.[5]

The Cochrane Ear, Nose and Throat Disorders Group concludes that both oral and topical intranasal steroids alone or in combination with an antibiotic lead to a quicker resolution of OME in the short term, but no long-term benefit is seen from treating OME effusions or associated hearing loss with topical intranasal steroids.[6] They separately reviewed antibiotic treatment for OME, noting the short-term benefit above, but cited several drawbacks including cost and increased antibacterial resistance.[7]

The American Academy of Family Physicians Clinical Recommendation on Otitis Media with Effusion in Young Children does not recommend steroid medications for treatment of OME in a child of any age.[8]

CLINICAL COMMENTARY

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Management of OME can be challenging and expensive—annual costs are estimated at $5 billion. Antibiotics are often inappropriately prescribed for OME, which may promote bacterial resistance. Commonly, clinicians augment OME treatment with antihistamines, decongestants, and steroids. Yet studies such as those cited above confirm that these treatments offer limited or no benefit. We must avoid the kitchen-sink treatment of OME. Furthermore, randomized controlled trials have shown that 80% to 90% of cases of acute otitis media and OME resolve without any therapy.

However, children with chronic OME, especially those with bilateral disease or possible

hearing loss, may benefit from tympanostomy tube placement and adenoidectomy. If the OME doesn't clear within 3 months, refer to an ear, nose, and throat specialist.

Prevention efforts are valuable. Immunization of infants with pneumococcal conjugate vaccine reduced tympanostomy tube placement by 20% to 39%.[9,10] Since increased incidence of OME and recurrent acute otitis media are associated with secondhand smoke exposure, motivating parents to quit smoking may further reduce chronic OME.

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