

## Steroids for the Treatment of Otitis Media with Effusion in Children

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The Cochrane Abstract on the next page is a summary of a review from the Cochrane Library. It is accompanied by an interpretation that will help clinicians put evidence into practice. Drs. Seehusen and MacDonnell present a clinical scenario and question based on the Cochrane Abstract, followed by an evidence-based answer and a critique of the review. The practice recommendations in this activity are available at <http://www2.cochrane.org/reviews/en/ab001935.html>.



This clinical content conforms to AAFP criteria for evidence-based continuing medical education (EB CME). See CME Quiz on page 227.

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A collection of Cochrane for Clinicians published in *AFP* is available at <http://www.aafp.org/afp/cochrane>.

### Clinical Scenario

A mother brings her five-year-old son to your clinic because of several days of decreased hearing in his right ear following a mild upper respiratory tract infection. On examination, you find fluid behind a nonerythematous right tympanic membrane, and diagnose otitis media with effusion. You wonder if a course of steroids might help clear the effusion faster or improve his long-term hearing outcome.

### Clinical Question

Do oral or topical nasal steroids improve short- or long-term outcomes of children who have otitis media with effusion?

### Evidence-Based Answer

Oral steroid use, alone or in combination with antibiotics, speeds the resolution of otitis media with effusion. However, there is no evidence that oral steroids improve symptoms or affect long-term outcomes, such as hearing loss. Topical nasal steroids have no effect on otitis media with effusion. (Strength of Recommendation: A, based on consistent, good-quality patient-oriented evidence.)

### Practice Pointers

Otitis media with effusion, a noninflammatory condition characterized by fluid in the middle ear, is common in young children. About 50 percent of children will have at least one episode in the first year of life.<sup>1</sup> Otitis media with effusion is the most common cause of transient hearing loss in children and can impact the development of speech. Although it usually resolves spontaneously, physicians sometimes use medical treatment in an attempt to hasten the course.<sup>2</sup>

One potential etiologic factor for otitis

media with effusion is inflammation, which may be reduced with steroids. Other potential mechanisms of action include directly shrinking tissue around the eustachian tube, improving eustachian tube surfactant secretion, and reducing middle ear effusion viscosity.<sup>3</sup> Oral and topical nasal steroids have been used to treat otitis media with effusion. Use of oral steroids is associated with behavioral changes, increased appetite, weight gain, adrenal suppression, and avascular necrosis of the femoral head. Topical steroids have fewer adverse effects because of minimal systemic absorption.<sup>1</sup>

Twelve randomized controlled trials comparing oral or topical nasal steroids (with or without antibiotics) with placebo were included in this analysis.<sup>3</sup> Nine studies evaluated oral steroids, and three studies evaluated topical nasal steroids. Children up to 12 years of age were included. Hearing loss was the primary outcome of interest; secondary outcomes included time to resolution of effusion and symptoms.

Three studies reported audiometry data from follow-up visits. One study compared oral steroids with placebo, and another compared oral steroids plus antibiotics with placebo. Neither study showed statistically significant differences between groups with regard to hearing loss. A third study comparing topical steroids with placebo showed no significant difference in the median number of days of hearing loss.

All 12 studies evaluated resolution of effusion. Two studies comparing oral steroids with placebo did not show a significant effect at short-term or intermediate-term follow-up. In five of six studies evaluating oral steroids plus antibiotics versus antibiotics alone, the children in the steroid group

## Cochrane Abstract

**Background:** Otitis media with effusion is common and may cause hearing loss with associated developmental delay. Treatment remains controversial.

**Objectives:** To examine the evidence for treating children who have hearing loss associated with otitis media with effusion using systemic or topical intranasal steroids.

**Search Strategy:** We searched the Cochrane ENT Group Trials Register, CENTRAL, PubMed, EMBASE, CINAHL, Web of Science, BIOSIS Previews, Cambridge Scientific Abstracts, mRCT, and additional sources for published and unpublished trials. The date of the most recent search was August 26, 2010.

**Selection Criteria:** Randomized controlled trials of oral and topical intranasal steroids, alone or in combination with another agent, such as an oral antibiotic. We excluded publications in abstract form only; uncontrolled, nonrandomized, or retrospective studies; and studies reporting outcomes by ears (rather than by children).

**Data Collection and Analysis:** The authors independently extracted data from the published reports using standardized data extraction forms and methods. We assessed the quality of the included studies using the Cochrane "risk of bias" tool. We expressed dichotomous results as a risk ratio (RR) and continuous data as weighted mean difference, both with a 95% confidence interval (CI). Where feasible, we pooled studies using a random-effects model, and performed tests for heterogeneity between studies. In trials with a crossover design, we did not use post-crossover treatment data.

**Main Results:** We included 12 medium- to high-quality studies with a total of 945 participants. No study documented hearing loss associated with otitis media with effusion prior to randomization. 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 otitis media with effusion. Pooled data using a fixed-effect model for otitis media with effusion resolution at short-term follow-up (less than one month) showed a significant effect of oral steroids compared with control (RR = 4.48; 95% CI, 1.52 to 13.23;  $\text{Chi}^2$  2.75, degrees of freedom = 2,  $P$  = .25;  $I^2$  = 27 percent). Oral steroids plus antibiotic also resulted in an improvement in otitis media with effusion resolution compared with 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 ( $P$  < .01;  $I^2$  = 69 percent). There was no evidence of beneficial effect on otitis media with effusion resolution at greater than one month follow-up with oral steroids (used alone or with antibiotics) or with 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:** Although oral steroids, especially when used in combination with an oral antibiotic, lead to quicker resolution of otitis media with effusion 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 otitis media with effusion with topical intranasal steroids, alone or in combination with an antibiotic, at short- or longer-term follow-up.



These summaries have been derived from Cochrane reviews published in the Cochrane Database of Systematic Reviews in the Cochrane Library. Their content has, as far as possible, been checked with the authors of the original reviews, but the summaries should not be regarded as an official product of the Cochrane Collaboration; minor editing changes have been made to the text (<http://www.cochrane.org>).

showed significantly greater resolution of effusion at follow-up visits after seven to 28 days. Studies of topical nasal steroids showed no improvement in resolution of effusion versus the control group.

Adverse effects, including diarrhea, increased appetite, and hyperactivity, were reported in five of the oral steroid studies and three of the topical nasal steroid studies. In one study that compared oral steroids with antibiotics and placebo with antibiotics, five of 144 children dropped out of the study because of adverse effects; none of the adverse effects appeared to be related to steroid use.<sup>4</sup>

Oral steroids lead to faster resolution of otitis media with effusion but do not affect symptoms or hearing outcomes. Topical nasal steroids have no effect on otitis media with effusion. Given the cost and potential adverse effects of steroids, their use in otitis media with effusion is not warranted.

The views expressed in this article are those of the authors and do not reflect the official policy or position

of the U.S. government, the Department of the Army, or the Department of Defense.

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## Cochrane Briefs

### Exercise for Treatment of the Vasomotor Symptoms of Menopause

#### Clinical Question

Should exercise be prescribed to treat vasomotor symptoms of menopause?

#### Evidence-Based Answer

Although menopausal women who exercise are less likely to report vasomotor symptoms than those who do not, there is insufficient evidence that counseling women to exercise is more effective than no treatment or hormone therapy for vasomotor symptoms of menopause. (Strength of Recommendation: C, based on consensus, disease-oriented evidence, usual practice, expert opinion, or case series.)

#### Practice Pointers

Menopause is marked by a decline in estrogen levels, which can result in insomnia, fatigue, depression, and vasomotor symptoms, also known as hot flashes. Hormone therapy is more effective than placebo in alleviating hot flashes.<sup>1</sup> Because women who exercise regularly report fewer symptoms of menopause than those who do not exercise regularly,<sup>2</sup> increasing physical activity may reduce vasomotor symptoms.

To determine if an exercise prescription can improve vasomotor symptoms, the authors of this Cochrane review searched the literature for randomized controlled trials comparing exercise with no treatment, yoga, or hormone therapy. Six studies of 276 women from five countries were identified and combined in three meta-analyses. Exercise prescriptions were broadly defined, with most studies including two to three weekly sessions of low- to moderate-intensity aerobic activity, such as walking, biking, or aerobics.

Patients were encouraged to continue regular exercise for two to 18 months.

Exercise prescriptions were comparable with no treatment or nonexercise controls (e.g., dietary prescriptions), and also were no better than yoga. There was no statistically significant overall difference between exercise and hormone therapy, but all individual studies favored hormone therapy. The small number of participants and the heterogeneity of the studies led the authors to conclude that the data are insufficient to determine whether an exercise prescription can be used to treat hot flashes.

Although exercise has well-established cardiovascular benefits and relatively little risk, it remains uncertain if it effectively relieves the vasomotor symptoms of menopause. The Society of Obstetricians and Gynaecologists of Canada notes that exercise may be recommended for mild symptoms based on conflicting evidence.<sup>3</sup> The North American Menopause Society does not include exercise in its recommendations for management of vasomotor symptoms.<sup>4</sup>

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Author disclosure: No relevant financial affiliations to disclose.

SOURCE: Daley A, Stokes-Lampard H, MacArthur C. Exercise for vasomotor menopausal symptoms. *Cochrane Database Syst Rev.* 2011;(5):CD006108.

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