bisoprolol reduces mortality when added to standard therapy with diuretics and ACE inhibitors. This is consistent with other published reports.2 There is still uncertainty as to which class of beta-blockers is most beneficial (beta-1–selective blockers, such as bisoprolol and metoprolol, or nonselective blockers, such as carvedilol), but upcoming trials may answer this question and further assess the impact on quality of life. Clinicians should begin to use beta-blockers for select patients with moderate to severe CHF and look for new studies to determine which specific agents are most beneficial.

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Intranasal Budesonide or Fluticasone for Allergic Rhinitis

Day J, Carrillo T. Comparison of the efficacy of budesonide and fluticasone propionate aqueous nasal spray for once daily treatment of perennial rhinitis. J Allergy Clin Immunol 1998; 102: 902-8.

Clinical question **Which intranasal steroid, budesonide or fluticasone, is more effective in controlling symptoms of perennial allergic rhinitis?**

Background Allergic rhinitis affects from 10% to 30% of the population of the United States. Intranasal corticosteroids have become more popular in the treatment of allergic rhinitis because of their ability to affect multiple steps of the inflammatory process while maintaining a large margin of safety. A study comparing the efficacy of aqueous formulations of budesonide and fluticasone had not been previously done.

Population studied A total of 375 subjects from Canada and Spain, aged 18 years and older, with at least a 1-year history of allergic perennial rhinitis were enrolled in this study. Participants were required to exhibit at least 2 of 3 symptoms of rhinitis (blocked nose, runny nose, or sneezing) during at least 8 days of an 8- to 14-day baseline period, and to have a positive skin prick response to 1 or more perennial allergens. Approximately 90% were allergic to dust mites. Exclusion criteria included systemic or intranasal corticosteroid treatment within 2 months before enrollment, inhaled steroids for asthma >1000 µg per day, nasal abnormalities that could interfere with efficacy assessment, pregnancy or breastfeeding, and not using effective contraception (for women of childbearing age).

Study design and validity The study was an adequately designed randomized placebo-controlled trial. Groups were given either budesonide (n = 111), fluticasone (n = 109), or placebo (n = 53). Treatment allocation was double-blind for budesonide and single-blind (to the healthcare provider) for fluticasone. During the 6-week treatment period, patients were instructed to administer 2 doses of the study medication to each nostril every morning (64 µg budesonide aqueous spray for a total of 256 µg; 50 µg fluticasone propionate spray for a total of 200 µg; or placebo using the same dosage vehicle as budesonide). Loratidine 10 mg was used as rescue medication throughout the study, when subjects considered symptoms intolerable. A high dropout rate of 27% (102 of the 375 randomized subjects) weakens the study somewhat, especially since explanation was lacking. The manufacturer of budesonide funded the study.

Outcomes measured The principal outcome measure was patient assessment of 3 symptoms: blocked nose, runny nose, and sneezing. Each symptom was self-scored on a 4-point scale, where 0 = no symptom and 3 = severe symptom. Secondary outcomes were patient assessment of overall treatment effectiveness (substantial/total control, minor control, aggravated/no control), nasal examination by rhinoscopy, use of rescue medication, and adverse events.

Results The reduction in the combined nasal symptom score was statistically significant for both budesonide and fluticasone when compared with placebo ($P < .001$ and $P = .001$, respectively). Of the 3 nasal symptoms assessed, nasal blockage was significantly more decreased with budesonide compared with fluticasone (0.75 vs 0.5 points, $P = .009$). Patient assessment of overall treatment efficacy was not statistically different between the 2 medications at 3 and 6 weeks after beginning treatment. Both were effective compared with placebo. The use of rescue medication was reduced in both active treatment groups with no difference between the 2 groups. Bloody nasal discharge was more common in the budesonide group (18%) versus the fluticasone group (7%).

Recommendations for clinical practice **Intranasal budesonide and fluticasone propionate are both effective in relieving symptoms of perennial rhinitis. Although symptom reduction scores were better for budesonide, especially for nasal blockage, patients considered overall symptom control to be substantial or complete for both**

equally. For patients annoyed by bloody nasal discharge, fluticasone performs better. At the doses used in this study, the costs of the 2 treatments are comparable.

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Antibiotics for AOM in Children Younger than 2 Years

Damoiseaux RAM, Van Balen FAM, Hoes AW, De Melker RA. Antibiotic treatment of acute otitis media in children under two years of age: evidence based? Br J Gen Pract 1998; 48:1861-4.

Clinical question **Should we routinely use antibiotics to treat children with acute otitis media (AOM) who are younger than 2 years?**

Background The use of antibiotics for AOM is controversial because of the lack of consistent supporting data and the concerns about increasing antimicrobial resistance. Although many physicians in the United States routinely treat AOM with antibiotics, physicians in other countries do not. Meta-analysis of the treatment of otitis media in children of all ages found that from 7 to 17 children have to be treated with antibiotics for 1 to receive benefit (number needed to treat = 7 - 17).[1,2] Such a large range of effectiveness makes the decision to treat more difficult. One explanation for the variable results could be that antibiotic use is important for a particular subgroup, such as for children younger than 2 years, who may be more likely to follow an abnormal course of illness.[3] This systematic review and meta-analysis evaluated and combined the results of studies investigating antibiotic treatment in children of this age group.

Population studied Studies selected for inclusion in this review enrolled 832 children younger than 2 years of age along with older children with AOM. The data for children younger than 2 years were extracted for analysis.

Study design and validity Articles were located using the following key words on MEDLINE and EMBASE: otitis media, child, clinical trial, and placebo. References in those articles were also assessed. The meta-analysis included studies that used random allocation to different treatment groups, compared antibiotic therapy with nonantibiotic therapy, and provided specific data for children younger than 2 years. The quality of the studies was assessed by blinded reviewers using criteria in 4 categories: study protocol, blinding procedures, testing procedures, and statistical analysis.

This meta-analysis was limited by the small number of robust studies available for analysis. Only 6 studies met the main inclusion criteria. Their methodologic quality scores ranged from 27% to 73%. Only 4 studies provided quantitative data that could be separated for children younger than 2 years. Only 2 studies were truly placebo controlled. Of those, one included only recurrent AOM and the other only nonsevere episodes. No analysis of heterogeneity was reported.

Two other problems limit this analysis. Half of the included studies used myringotomy, either for therapeutic reasons or to identify the etiology of the infection. The maneuver might have improved outcomes, especially in children treated with placebo. Also, the diagnosis of AOM was likely variable across, and perhaps within, the studies. Although 3 studies assessed clinical signs of acute infection, the fundamental diagnosis of AOM was made by the subjective assessment of otoscopic appearance in at least 5 of the 6 studies. One study did not describe the diagnostic criteria.

Outcomes measured The primary outcome measured in all of the studies was symptomatic clinical improvement within 7 days of the start of treatment.

Results The authors found no statistically significant difference between treatment with antibiotic and placebo for children with AOM who were younger than 2 years, judged by clinical improvement within 7 days (common odds ratio [OR] = 1.31; 95% confidence interval [CI], 0.83-2.08). Restricting the quantitative analysis to studies with a methodologic quality of 60% or more did not change the results (OR = 1.42; 95% CI, 0.85-2.39).

Recommendations for clinical practice **Although this study does not support the use of antibiotics for children with AOM who are younger than 2 years, it is not robust enough to recommend changing a physician's current practice. However, there are other more compelling research data to discourage the automatic use of antibiotics: the financial cost and potential side effects of antibiotic treatment, the increase in antibiotic resistance, and the reports that 80% of untreated children with AOM are pain-free within 24 hours. The potential benefits of treatment with antibiotics rarely outweigh their cost. This study can be added to the literature that discourages the casual use of antibiotics for treatment of AOM.**

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