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Rethinking antibiotics for sinusitis—again

Previous evidence rejected the need for antibiotics to treat acute rhinosinusitis, unless the symptoms were severe. A new study finds little reason to prescribe them even then.

PRACTICE CHANGER

Stop prescribing amoxicillin for acute rhinosinusitis. It's unlikely to provide a speedier recovery than over-the-counter (OTC) remedies alone.¹

STRENGTH OF RECOMMENDATION

B: Based on a single high-quality randomized controlled trial.

Garbutt J, Banister C, Spitznagel E, et al. Amoxicillin for acute rhinosinusitis: a randomized controlled trial. *JAMA*. 2012 ;307:685-692.

ILLUSTRATIVE CASE

A 28-year-old man comes to your clinic after suffering from fatigue, purulent nasal discharge, and unilateral facial pain for nearly 10 days. Overall, he appears healthy, and you diagnose acute rhinosinusitis. You suggest OTC remedies for supportive care and wonder if a course of amoxicillin would speed his recovery.

Each year, more than 30 million Americans—about one in 7 adults—are diagnosed with sinusitis.² No more than 2% of these cases are thought to be bacterial.³

Centers for Disease Control and Prevention (CDC) guidelines for the diagnosis of acute bacterial rhinosinusitis include symptoms that last 7 days or more, with maxillary pain or tenderness in the face or teeth and purulent nasal secretions.⁴ Patients with symptoms lasting less than 7 days are unlikely to have a bacterial infection. But the non-

specific signs and symptoms included in the CDC guidelines limit their usefulness in determining whether the cause of the sinusitis is bacterial or viral on clinical grounds alone.

Most cases of sinusitis spontaneously resolve

In patients with acute bacterial sinusitis, the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) guidelines advocate watchful waiting and symptom relief with nasal oxymetazoline, pseudoephedrine, and saline nasal irrigation.³ The rate of spontaneous resolution is high: 80% of patients with clinically diagnosed sinusitis improve without treatment within 2 weeks.^{1,5}

Traditional decongestants and mucolytics have not demonstrated efficacy in resolving sinusitis, although rigorous evaluation is lacking. Other treatments, such as saline irrigation and intranasal corticosteroids, are of unclear benefit and need further study.⁶⁻⁸

Lack of evidence has done little to curtail antibiotic use

An earlier PURL based on a meta-analysis of antibiotic treatment trials for sinusitis recommended that we stop prescribing antibiotics for adults with acute sinusitis unless their symptoms are severe.^{9,10} Yet antibiotics remain the mainstay of treatment.

Despite the AAO-HNS guidelines, evidence of spontaneous resolution, and ac-

cumulating data on the lack of efficacy of antimicrobials for sinusitis, 81% of patients diagnosed with acute sinusitis were given prescriptions for antibiotics, a study of primary care practices showed.¹¹ Frequent use of antibiotics contributes to high rates of drug resistance, and adverse events related to antibiotic use account for an estimated 142,500 emergency department visits annually.¹²

STUDY SUMMARY

Little benefit from amoxicillin, even for severe cases

Garbutt and colleagues revisited the issue, randomizing 166 patients from 10 primary care practices to amoxicillin plus symptomatic treatment or placebo plus symptomatic treatment for acute rhinosinusitis.¹ To be eligible for the study, patients had to be between the ages of 18 and 70 years, meet CDC diagnostic criteria for acute rhinosinusitis, and have moderate to very severe symptoms that were of 7- to 28-day duration and worsening or not improving or of <7-day duration but had worsened after an initial improvement. Exclusion criteria included complications from sinusitis, a history of allergy to penicillin or amoxicillin, antibiotic use in the past 4 weeks, comorbidities that impair immune function, cystic fibrosis, pregnancy, and mild symptoms.

Both groups had similar baseline characteristics, with participants who were predominantly white (79%) and female (64%). All the participants received a supply of symptomatic treatments: acetaminophen, guaifenesin, dextromethorphan, and sustained-release pseudoephedrine. The treatment group also received amoxicillin 1500 mg/d, divided into 3 doses; the placebo group received identical-looking placebo pills.

Patients were assessed with the Sino-nasal Outcome Test-16 (SNOT-16), a validated measure that asks patients to assess both the severity and frequency of 16 sinus symptoms. SNOT-16 uses a 0-to-3 rating scale (0=no problem; 3=severe problem), with a clinically important difference of ≥ 0.5 on the mean score. The test was administered at enrollment and at Days 3, 7, and 10. The disease-specific quality of life at Day 3 was the primary outcome.

There was no statistically significant difference in SNOT-16 scores between the amoxicillin and placebo groups on Days 3 and 10. On Day 7, there was a small statistically significant improvement in the amoxicillin group, but it did not reach the level of clinical importance (≥ 0.5) based on SNOT-16's mean score.

The authors also asked participants to retrospectively assess symptom change since enrollment on a 6-point scale. Those who reported that their symptoms were "a lot better" or "absent" were characterized as significantly improved. The results correlated with the data from the SNOT-16, showing no difference between the amoxicillin and control group at Days 3 and 10. On Day 7, 74% of patients treated with amoxicillin self-reported significant improvement in symptoms since the start of the study, vs 56% in the control group. The number needed to treat was 6 (95% confidence interval, 3-34; $P=.02$) for a reduction in symptoms at Day 7.

Patients in both groups had similar rates of absenteeism, inability to perform usual activities, relapse and recurrence, and use of additional health care. Satisfaction with treatment was similar, as well.

No serious adverse effects occurred. Both groups reported similar frequencies (<10%) of nausea, diarrhea, abdominal pain, or vaginitis.

WHAT'S NEW

Even severe sinusitis resolves without antibiotics

Previous studies recommended foregoing antibiotics for acute sinusitis, except when symptoms are severe. This study—in which more than half (52%) of patients in each group had symptoms rated severe or very severe—found no benefit to adding amoxicillin to supportive treatments.¹ Antibiotics did not shorten the duration of illness, prevent relapse and recurrence, or improve satisfaction with treatment. The researchers found a statistically significant difference between groups on Day 7 of 0.19 points, but no clinically meaningful difference (≥ 0.5) based on the SNOT-16 mean score.

CONTINUED



INSTANT POLL

Do you prescribe antibiotics for acute rhinosinusitis:

- Often or always
- Only if the patient requests an antibiotic
- Only if the symptoms are severe or have persisted for >7 days
- Rarely or never
- Other (Please specify) _____

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CAVEATS

Guidelines, risk of complications may give reason to pause

The 2012 Infectious Diseases Society of America guidelines recommend amoxicillin with clavulanic acid as empiric therapy for acute bacterial rhinosinusitis.⁷ The findings of the study by Garbutt et al—conducted at a time when the incidence of beta-lactamase-producing organisms was low and amoxicillin was the treatment of choice—suggest otherwise.

Serious complications of sinusitis, such as brain abscess, periorbital cellulitis, and meningitis, can occur, however. Patients who deteriorate clinically or develop high fever or severe headache require close follow-up, which may include further diagnostic evaluation or consultation with an otolaryngologist. Evidence is lacking as to whether antibiotics prevent such complications.⁵

CHALLENGES TO IMPLEMENTATION

Managing patient expectations

Many patients with symptoms of acute

rhinosinusitis think they need an antibiotic. Managing their expectations and providing instructions about supportive treatments are time consuming and may be difficult.

Nonetheless, we're optimistic: We think that most patients today are aware of the problems associated with antibiotic resistance and wary of "superbugs," and will therefore be receptive to this practice change. Physicians can help by reminding patients of the adverse effects of antibiotics and the natural course of rhinosinusitis, as well as by offering symptomatic treatments. **JFP**

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