Antibiotics Not Necessary or Helpful for Acute Sinusitis

February 14, 2012 — Most symptoms of acute sinusitis resolve just as quickly without antibiotics as they do with antibiotics, according to results of a new study in the February 15 issue of the Journal of the American Medical Association.

Jane M. Garbutt, MBChB, from the Division of General Medical Sciences at Washington University School of Medicine in St. Louis, Missouri, and colleagues conducted a randomized controlled trial in which they compared quality of life improvement in patients given a 10-day course of amoxicillin vs patients given a placebo.

“Considering the public health threat posed by increasing antibiotic resistance, strong evidence of symptom relief is needed to justify prescribing of antibiotics for this usually self-limiting disease,” the authors write.

Rhinosinusitis vs Common Cold

The study included 166 adult patients from 10 primary care offices in St. Louis, Missouri. Patients were eligible for the study if they met the diagnostic criteria for acute bacterial rhinosinusitis from the Centers for Disease Control and Prevention and if they rated their symptoms moderate, severe, or very severe.

Patients also had to have a history of maxillary pain or tenderness in the face or teeth, purulent nasal discharge, and rhinosinusitis symptoms for between 7 and 28 days that were neither improving nor worsening, or rhinosinusitis symptoms for 7 days or fewer that first improved and then worsened.

“A lot of the other studies are including people who just have a cold, instead of a real bacterial sinus infection. They used a more rigorous definition here that corresponds to guidelines from the American Academy of Family Physicians and the American College of Physicians,” said Richard M. Rosenfeld, MD, MPH, professor and chairman of otolaryngology at SUNY
Downstate Medical Center, Brooklyn, New York, in a telephone interview with Medscape Medical News. Dr. Rosenfeld was not involved with the study.

“The added twist on this study is they focused on quality of life,” said Dr. Rosenfeld.

Study Medications

Patients assigned to the treatment group (n = 85) received amoxicillin 1500 mg/day in 3 divided doses for 10 days. Patients assigned to the control group (n = 81) received a placebo.

All study participants were given a 5- to 7-day supply of symptomatic treatments, unless their physician felt the treatments were contraindicated. The treatments provided were acetaminophen 500 mg every 6 hours as needed for pain or fever; guaifenesin 600 mg every 12 hours as needed to thin secretions; dextromethorphan hydrobromide 10 mg/5 mL and guaifenesin 100 mg/5 mL every 4 to 6 hours as needed for cough; pseudoephedrine-sustained action 120 mg every 12 hours as needed for nasal congestion; and 0.65% saline spray, 2 puffs per nostril as needed.

The researchers assessed the effect of treatment on disease-specific quality of life at day 3 as the primary outcome. They used the modified Sinonasal Outcome Test-16 (SNOT-16) to measure severity and frequency of 16 sinus-related symptoms over the prior few days. Items assessed by the SNOT-16 tool included physical symptoms like runny nose, cough, and ear fullness, as well as quality-of-life factors including difficulty sleeping, trouble concentrating, and reduced productivity.

Both study groups reported high use of symptomatic treatments (92%; 95% confidence interval [CI], 88% - 96%).

Quality-of-Life Improvement

The mean change in SNOT-16 scores for quality of life was similar in both groups at day 3 (treatment group: 0.59 [95% CI, 0.47 to 0.71]; control group: 0.54 [95% CI, 0.41 to 0.67], \( P = .69 \); mean difference between groups, 0.03 [95% CI, −0.12 to 0.19]).
The mean improvement in quality-of-life scores was similar for both groups at day 10 as well (mean difference between groups, 0.01 [95% CI, −0.13 to 0.15]). The mean improvement in quality-of-life scores differed between the groups at day 7, with more improvement reported by the amoxicillin group (mean difference between groups, 0.19 [95% CI, 0.024 to 0.35]).

Symptom improvement was not significantly different between the 2 groups at day 3 (37% for the amoxicillin group vs 34% for the control group; \( P = .67 \)) or at day 10 (78% for the amoxicillin group vs 80% for the control group; \( P = .71 \)). More patients in the amoxicillin group reported symptom improvement at day 7 (74% for amoxicillin group vs 56% for control group, \( P = .02 \); number needed to treat = 6 [95% CI, 3 to 34]).

“In this study, retrospective assessment of change in sinus symptoms suggested that antibiotic treatment may provide more rapid resolution of symptoms for some patients by day 7. However, when improvement was assessed as the difference in SNOT-16 scores, the statistically significant benefit at day 7 was too small to represent any clinically important change,” the authors write.

### Resistant Organisms?

Dr. Rosenfeld suggested that the lack of an antibiotic effect may have been a result of antibiotic-resistant organisms. He pointed out that amoxicillin is a very common first-line antibiotic for treating bacterial infections. Two of the 3 main bacteria that cause sinus infections — *Haemophilus influenzae* and *Moraxella catarrhalis* — can be resistant to penicillin- and amoxicillin-type drugs. *Streptococcus pneumoniae* can also be resistant, he explained.

“In the discussion section [the authors] provide some data that in their community the resistance levels of *Streptococcus pneumoniae* to amoxicillin are low. They don't mention anything about resistance to the other bacteria,” Dr. Rosenfeld said.

“[If you] have a sinusitis caused by one of the penicillin- or amoxicillin-resistant germs, clearly you’re not going to see a benefit of treating with amoxicillin; that’s basically the same as giving a placebo,” he added.

If the investigators had used an antibiotic like amoxicillin clavulanate, which covers a broader spectrum of bacteria, they may have seen a bigger benefit. “Whether we can extrapolate this study outside of the St. Louis area or to
other antibiotics is very unclear, and they may have missed the benefit of using a broader spectrum of antibiotic,” he explained.

“Do I think they missed a dramatic benefit? No, but they may have missed some smaller benefit of using other antibiotics,” said Dr. Rosenfeld.

“Evidence from this study suggests that treatment with amoxicillin for 10 days offers little clinical benefit for most patients with clinically diagnosed uncomplicated acute rhinosinusitis,” the authors write. “It is important to note that patients with symptoms indicative of serious complications were excluded from this trial and likely need a different management strategy,” they conclude.

One of the study coauthors, Jay F. Piccirillo, MD, reports that he has grants pending with the National Institutes of Health, the Department of Defense, and the Federal Emergency Management Agency; has received honoraria from Emory University and New York University for invited speaker positions for grand rounds; has received royalties for the Sinonasal Outcome Test; and is chair of data and safety monitoring boards for Apnex Medical and the National Institutes of Health, National Institute on Deafness and Other Communication Disorders. No other author reported potential conflicts of interest. Dr. Rosenfeld has disclosed no relevant financial relationships.