

Amoxicillin did not improve the clinical course of acute maxillary sinusitis in primary care

van Buchem FL, Knottnerus JA, Schrijnemaekers VJ, Peeters MF. Primary-care-based randomised placebo-controlled trial of antibiotic treatment in acute maxillary sinusitis. *Lancet*. 1997 Mar 8;349:683-7.

Objective

To determine the efficacy and safety of amoxicillin for patients in a primary care setting who have suspected acute maxillary sinusitis and an abnormal radiograph.

Design

Randomised, double-blind, placebo-controlled trial with 1-year follow-up.

Setting

2 hospitals in the Netherlands in collaboration with 53 general practitioners.

Patients

214 patients (mean age 34 y, 63% women) with suspected acute maxillary sinusitis and for whom antibiotic therapy was considered by their general practitioner had radiographs of the maxillary and frontal sinuses done. Those with mucosal swelling > 5 mm, complete shadowing, or a fluid level were referred to an ear, nose, and throat specialist. Exclusion criteria were other nasal disorders; bronchitis; current episodes of > 3 months; recent antibiotic therapy; hypersensitivity to amoxicillin; hepatic, renal, or immunological disorders; or abnormal coagulation.

Commentary

Sinusitis is the fifth most common reason for office-based physicians to prescribe an antibiotic. This finding is supported in adults by a randomised trial showing a moderately large benefit of amoxicillin compared with placebo (86% cured or much improved vs 57%, respectively) (1). The study by van Buchem and colleagues was well designed but concluded that antibiotics did not benefit patients with suspected acute maxillary sinusitis. Why do these findings conflict?

First, did the study have adequate power to detect a clinically meaningful difference? The study showed a marginal antibiotic benefit at 2 weeks. 1-year outcomes did not differ, an outcome not examined in the previ-

Intervention

108 patients were allocated to amoxicillin (750 mg, 3 times daily for 7 d), and 106 received placebo. All patients were given 0.1% xylometazoline steam inhalation.

Main outcome measures

Primary outcomes were the rate of cure (absence of symptoms) after 2 weeks and symptom scores after 1 and 2 weeks. Additional outcomes were resolution of radiographic abnormalities (2 wk), side effects, and relapses and chronic symptoms (1 yr).

Main results

Analysis was by intention to treat. Amoxicillin compared with placebo

did not improve the cure rate ($P = 0.06$), the proportion of patients with greatly decreased symptoms ($P = 0.2$), or the rates of relapse or chronic symptoms (Table). More patients who received amoxicillin had side effects (28% vs 9%, $P < 0.001$).

Conclusion

Amoxicillin did not improve the clinical course of patients with suspected acute maxillary sinusitis.

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Amoxicillin vs placebo*

Outcomes at 2 weeks	Amoxicillin EER	Placebo CER	RBI (95% CI)	ABI EER - CER (CI)	NNT
Cured	65%	52%	23% (-2 to 57)	13% (-1 to 25)	NS
Greatly decreased symptoms	83%	77%	7% (-6.5 to 24)	6% (-5 to 17)	NS
Outcomes at 1 year	Amoxicillin EER	Placebo CER	RRI (CI)	ARI EER - CER (CI)	NNH
Relapse	21%	17%	25% (-27 to 118)	4% (-6 to 15)	NS
Chronic symptoms	2.8%	1.9%	47% (-70 to 627)	0.9% (-4 to 6)	NS

*NS = not significant. Other abbreviations defined in Glossary; RBI, RRI, ABI, ARI, NNT, NNH, and CI calculated from data in article.

ous study. Second, the current study used more liberal radiographic criteria to confirm sinusitis, which may have included patients with viral rhinosinusitis. Computed tomography studies have shown that most patients with viral rhinitis have maxillary sinus involvement that resolves without therapy. Inclusion of these patients would likely diminish the effectiveness of antibiotics. Finally, both studies had placebo responses > 50%. Given the high placebo response by 2 weeks, one clinically relevant question not addressed was whether antibiotics shorten the duration of the illness.

In summary, acute sinusitis is a self-limiting illness for most patients. Our chal-

lenge is to distinguish the > 50% of patients who will respond to decongestants alone from those who will benefit from antibiotics. Until then, physicians should prescribe a decongestant for adults with suspected sinusitis and weigh the slight-to-moderate benefit of antibiotics against the increased risk for gastrointestinal side effects.

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Reference

1. Lindbaek M, Hjordt Dahl P, Johnsen UL. *BMJ*. 1996;313:325-9.