

Study finds two antibiotics for children with sinusitis equally effective, but one has fewer side effects

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In a new study published in [JAMA](#) and led by researchers at Brigham and Women's Hospital has found that patients prescribed amoxicillin-clavulanate had higher rates of gastrointestinal symptoms and yeast infections than those prescribed amoxicillin.

Acute sinusitis is one of the most common causes for children to be put on antibiotic medications, with patients in the United States filing nearly 5 million antibiotic prescriptions every year to treat the condition. The drugs [amoxicillin](#) and amoxicillin-clavulanate make up most of those prescriptions, but there is a lack of consensus on which should be first-line for children.

Scientists analyzed the treatment outcomes of over 300,000 children who were prescribed either of the two drugs. They found that there was no difference in the rates of treatment failure—that is, having to go on a new course of antibiotics or seek additional treatment for sinusitis or complications—between patients prescribed amoxicillin and amoxicillin-clavulanate.

Treatment failure was so rare, in fact, that the study's authors say that physicians should be confident that either medication will clear a case of [acute sinusitis](#) that requires antibiotics. But the risk of adverse events, especially [gastrointestinal symptoms](#) and yeast infections, were higher among those prescribed amoxicillin-clavulanate.

"This study adds recent, actionable data and evidence to inform what antibiotic a clinician should choose to treat a child with acute bacterial sinusitis," said lead author Timothy Savage, MD, MPH, MSc, an associate epidemiologist in the Brigham's Division of Pharmacoepidemiology and Pharmacoeconomics. "As seen from this study, there's no difference in the treatment failure rate regardless of which of these two antibiotics you choose."

Amoxicillin-clavulanate is believed to treat a wider range of bacteria than amoxicillin, but it is also associated with more gastrointestinal side effects. Scientists also worry that in the long-term, overprescribing amoxicillin-clavulanate may accelerate the rate at which infectious bacteria develop antimicrobial resistance. Doctors have therefore

wondered whether the benefits of prescribing amoxicillin-clavulanate to children with acute sinusitis outweigh the short- and long-term risks.

The researchers pulled data from 320,141 clinical cases of children diagnosed with acute sinusitis and compared whether children on amoxicillin or amoxicillin-clavulanate were more likely to undergo treatment failure. They discovered that there was no difference in the rates of treatment failures associated with either medication.

Treatment failure in general was exceedingly rare; less than 2% of prescriptions failed, most of which were corrected by an outpatient medication change. Only 0.1% of children had failures so severe that they required a visit to the emergency room or hospitalization.

The [clinical data](#) showed that adverse events were somewhat rare but more frequent among patients treated with amoxicillin-clavulanate, occurring in 2.3% of patients treated with amoxicillin-clavulanate and 2% of patients treated with amoxicillin. Patients treated with amoxicillin-clavulanate had a 15% increased risk of gastrointestinal side effects and 33% higher risk of [yeast infections](#) compared to patients treated with amoxicillin. The study's authors conclude that the more narrow-spectrum amoxicillin may be the best first-line choice to combat acute sinusitis.

"Our study shows that there are more adverse events when amoxicillin-clavulanate is used," Savage said. "Based on these data, physicians should seriously consider prescribing amoxicillin as a first line of defense against acute sinusitis."

Not all acute sinusitis cases are caused by bacterial infections; a previous study found that viruses may be responsible for up to 32% of instances. Still, because the symptoms of bacterial and viral sinusitis can be nearly indistinguishable, many doctors opt to first treat a patient with antibiotics and monitor whether the infection clears.

Around 85% of [children](#) that present with acute sinusitis receive an antibiotic, with amoxicillin and amoxicillin-clavulanate accounting for 65% of those prescriptions. The current study did not include microbiologic data and the authors could not discern whether acute sinusitis diagnoses were due to viral or bacterial infections.

As this was not a [randomized clinical trial](#), the study authors also acknowledge the possibility that residual bias could have impacted the results, although they re-analyzed the data several different ways to try to mitigate this, with no difference in the results.

Two previous studies that compared clinical outcomes of the two drugs were conducted more than 20 years ago. Those analyses showed that both medications alleviated symptoms at similar rates, but both studies were limited by a combined sample size of under 300 patients. Bacterial species have evolved significantly in the last twenty years, a fact that convinced Savage and his team to launch a new, larger study comparing treatment failure rates of both drugs.

"If a physician is trying to decide between these two drugs, they can look at these results and see that 98% of kids got better regardless of whether they were prescribed amoxicillin or amoxicillin-clavulanate," Savage said. "The chance that a child will end up in the hospital after using these drugs is less than one in a thousand. That should provide some reassurance that a child is going to do pretty well regardless of the antibiotic."

More information: Timothy J. Savage et al, Treatment Failure and Adverse Events After Amoxicillin-Clavulanate vs Amoxicillin for Pediatric Acute Sinusitis, *JAMA* (2023). [DOI: 10.1001/jama.2023.15503](https://doi.org/10.1001/jama.2023.15503)

Provided by Brigham and Women's Hospital

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