sicians switching to the use of clarithromycin over lower-cost alternatives?

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In reply

The aim of this study1 was to compare clarithromycin with another commonly used antibiotic in the treatment of acute maxillary sinusitis. Amoxicillin was chosen because amoxicillin (and ampicillin) are frequently used first-line antibiotics for the treatment of sinusitis. Gwaltney2 recommends several drugs, including ampicillin or amoxicillin, for initial treatment of uncomplicated community-acquired sinusitis. These drugs are not effective against \(\beta\)-lactamase-producing strains of bacteria, and other drugs are better choices in geographic areas where Haemophilus or Moraxella isolates are often \(\beta\)-lactam positive.

The sample size estimates were based on the 142 recruited patients. After the elimination of nonevaluable patients, 116 remained. It is true that with an infinite sample size, we could detect very small differences between groups; we were, however, limited to reporting on the data we obtained.

We have reanalyzed the numbers and the 2×2 table. A \(\chi^2\) analysis gave a \(\chi^2\) of 3.27, which has a \(P\) value of .07. With a sample size of 116, this test has a statistical power of only 0.6. Also, the 95% confidence intervals for the odds ratio included 1 (0.08 to 1.08), which is, again, an indication of no difference between the groups. We calculated this using two separate statistical packages, so we do not think our arithmetic is incorrect.

This study was industry funded, as are many studies done in the United States today. This human research was reviewed and approved by local human research committees. All research was carried out in a thoughtful and ethical fashion. The data were analyzed and the conclusions were reported in the medical literature. The funding company does have a right to review the papers generated as a result of the research it funded but has no right or ability to stop paper submission or publication even if the results do not support their products. The funding company had no editorial sway over any reported data, and either negative results or positive results (with respect to the usefulness of clarithromycin) would have been reported.

Although debates about the best antibiotic for the treatment of sinusitis, the meaning of \(\beta\)-lactam resistance, or the relationship of in vitro testing to in vivo antimicrobial activity could occupy many pages even among infectious disease specialists, none of those questions were asked or attempted to be answered by this study. They are, no doubt, fruitful questions for further research.

We thank the readers for their interest in this study.

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Editor's Note

We received several letters commenting on the cost difference between amoxicillin and clarithromycin. Of note, the abstract says, "clarithromycin twice daily is effective and well tolerated in patients with acute maxillary sinusitis." The final sentence of the report is "In conclusion, clarithromycin (500 mg twice daily) is an appropriate agent for the empiric treatment of acute maxillary sinusitis." Neither of these statements said that it was the drug of choice in all situations.

However, many patients have multiple drug allergies or have been receiving other agents recently. There are many times that drugs other than amoxicillin are used. Clarithromycin is another agent that can be used when clinically appropriate. Another recent ARCHIVES study has shown cefaclor and amoxicillin to be similarly effective.1