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The effect of carbocysteine on the healing rate of acute sinusitis

To the editor: Sinusitis is a condition with a high prevalence in all parts of the world.¹ It is often treated by means of an antibiotic, a mucolyticum and a decongestant to resolve the infection, facilitate the flow of mucus and open up the airways. However, little evidence exists to support this regimen. A clinical study was designed to explore the regime and to support or reject the practice. A decongestant was not added to the treatment regimen in order to investigate the contribution to the healing rate of the mucolyticum alone. Sinusitis can be acute or chronic. If it is present for fewer than seven to 14 days, it is an acute infection.^{1,2} Although sinus puncture is the gold standard for diagnosing bacterial sinusitis, it is painful and expensive. A well-performed clinical examination can be used to diagnose a bacterial or viral infection.³ A bacterial infection presents with a purulent rhinorrhoea, visible postnasal secretion, facial pain, headache and coughing. The organisms most commonly responsible for sinusitis are *Streptococcus pneumoniae*, *Haemophilus influenza* and *Moraxella catarrhalis*. They can be treated with any appropriate antibiotic for 10 to 14 days.³

A study group was selected from consenting male and female patients between the ages of 18 and 65 years in a private, primary health care setting who presented with acute bacterial sinusitis. Patients were selected randomly divided into two groups. One group of 20 subjects received 1g amoxicillin eight hourly, together with a suspension consisting of carbocysteine for 10 days (the carbocysteine group (C)). A second group of 20 subjects received 1g amoxicillin eight hourly, as well as a placebo suspension resembling the carbocysteine suspension in taste and colour (the placebo group (A)). All participants were given an evaluation sheet and coloured dots which would be used to represent the severity of their symptoms and were seen on days five and 10. In a two sample t-test, the test and standard treatments

were thus compared with time until relief. Statistical analysis was done using Fisher's exact test.⁴ A p value of less than 0.05 was considered statistically significant.

Forty subjects completed the trial. Two subjects received additional antibiotics after five days because of the deterioration of their clinical picture, and another one received a second course of antibiotics after 10 days. The only side effect was moniliasis, which occurred in two individuals. The sample size was determined according to the primary efficacy variable of time until relief. The mean standard deviation for amoxicillin was estimated to be 4(1) days. One subject reported a total absence of symptoms after five days. Twelve subjects were totally symptom free after 10 days, six from the carbocysteine group (C) and six from the placebo group (A). This represented no statistical significance and thus no indication for the addition of a suspension containing carbocysteine to the treatment schedule of sinusitis (p=1) (See table I).

Table I: Comparison of the two groups after 10 days

Symptoms after 10 days:	Group C	Group P	p-value
Headache cleared:	16	16	1.000
Facial pain cleared:	16	14	0.635
Postnasal drip cleared:	8	6	0.701
Cough cleared:	16	13	0.882

This study definitely shows that the addition of a mucolyticum such as carbocysteine to the treatment regimen of sinusitis does not influence the outcome more favourably and that treatment with high enough doses of amoxicillin for the prescribed length of time is effective and inexpensive.

Individual symptoms, such as coughing, were not influenced by the addition of carbocysteine and postnasal drip did not improve, even after the full course of antibiotics. The reason for this could be that the postnasal drip is due to an underlying allergy. It also seems as if a course of five days is too short to have a curative effect, because patients only really responded after 10 days. Compliance was found to be very good, but this could be due to the close monitoring in the form of the two follow-up visits. Mucolyticum does not increase the healing rate of sinusitis and has no beneficial effect on its symptoms.

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