Controlled trial of terfenadine and chlorpheniramine maleate in perennial rhinitis

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Summary

A double-blind clinical trial in 60 patients with perennial rhinitis was conducted to compare the efficacy and side effects of two antihistamines, terfenadine and chlorpheniramine maleate, and placebo. There was no statistically significant difference in response between active treatments and placebo. Although side effects were more frequent with chlorpheniramine this also was not statistically significant.

Introduction

Terfenadine is a newly developed antihistamine which has been shown to be devoid of central nervous system effects in animal (Kinsolving, Munro & Carr, 1973) and human pharmacological studies (Clarke & Nicholson, 1978; Kulshrestha *et al.*, 1978). Clinical trials have indicated that sedative side effects do not occur more often with terfenadine than with placebo and that its efficacy in hay fever is similar to that achieved by other antihistamines (Dugué *et al.*, 1978; Brandon & Weiner, 1980).

This trial was conducted in order to compare the effects of terfenadine, chlorpheniramine maleate and placebo in patients with perennial or non-seasonal allergic rhinitis.

Materials & methods

A double-blind, double-dummy technique was used. Suitable patients over 12 years old with moderate to severe symptoms of perennial rhinitis were first withdrawn from other treatments and then randomly allocated to receive for 2 weeks either terfenadine 60 mg twice daily, chlorpheniramine maleate 8 mg twice daily or placebo tablets twice daily. Severity of the clinical condition was determined before and after the trial by scoring nine symptoms, 3 for severe, 2 for moderate, one for mild and nil for absent. The symptoms were rhinorrhoea,

FIG. 1. Percentage reduction of mean symptom scores. T, Terfenadine; C, chlorpheniramine; P, placebo.

nasal congestion, nasal irritation, sneezing, post-nasal discharge, irritation of throat and watery, red or irritated eyes. Adverse effects were sought by direct questioning at the end of the trial.

Results

Sixty patients entered (20 on each treatment) and 12 either did not return or were unsuitable for

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evaluation (3 on chlorpheniramine, 5 on placebo, 4 on terfenadine). Three patients did not complete the treatment because of adverse effects—one with stomach upset on chlorpheniramine and 2 on terfenadine, one drowsy and one with headache. Mean symptom scores were improved from 7.6 before treatment to 5.1 after treatment with terfenadine, from 8.0 to 4.6 with chlorpheniramine and from 7.8 to 5.8 with placebo (Fig. 1). The differences between the clinical response of the treatments were not statistically significant. Side effects, including the 3 withdrawals, were reported by 6 (38%) patients on terfenadine, 9 (53%) on chlorpheniramine and 3 (20%) on placebo. Sedation occurred in 2, 5 and one patient respectively. The difference between these incidences was not statistically significant.

Discussion

In contrast to the marked beneficial effects of systemic antihistamines in controlling the symptoms of hay fever their use in perennial rhinitis usually provides only relatively modest benefit and the results of our small study tend to confirm this for

terfenadine and chlorpheniramine. Our results also indicate that by virtue of its low incidence of side effects, particularly sedation, terfenadine may possess an advantage in clinical use.

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