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A comparison between intranasal budesonide aerosol and budesonide dry powder in the treatment of hay fever symptoms

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SUMMARY

Sixty patients with seasonal allergic rhinitis due to birch pollen were enrolled in an open, randomized parallel group study. Efficacy and side effects were studied after intranasal administration of budesonide given as a freon propellant aerosol or as dry powder with a sniff actuated inhalation device. Medication started a few days before the actual peak pollen season and lasted for three weeks. The dose was 400 µg once daily. Efficacy was assessed daily by patient-rated symptoms scores and by nasal peak inspiratory flow measurements at the visits to the clinic. Safety was assessed by monitoring clinical adverse events.

No clear changes in nasal symptom scores or nasal peak flow occurred during the pollen season in either treatment group as compared to the pretreatment period, although the pollen season was very difficult in Finland during the study, ad 12000 grains per m^3. Substantial or total control of symptoms was achieved in 93% of the patients in the aerosol group and in 79% in the powder group. Side effects were minimal in both groups. We conclude that dry powder administration of budesonide is as effective and well tolerated as the aerosol in the treatment of seasonal allergic rhinitis.

INTRODUCTION

Nasal inhalation of the topically active steroid budesonide for the treatment of allergic rhinitis has been shown to be effective and safe in many studies (Pipkorn et al., 1980; Clissold and Heel, 1984; Norman et al., 1984). Side effects are unusual and mild, and when such occur, propellant gases or solvents are usually blamed.

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Budesonide powder without any additives in a new sniff actuated inhalation device for intranasal administration has been developed. The aim of this study was to compare the efficacy and short-term side effects of budesonide given intranasally either as this dry powder or as the freon pressurized aerosol in patients suffering from seasonal allergic rhinitis.

MATERIAL AND METHODS

Sixty adult patients with positive skin test or RAST reaction to birch pollen and a history of earlier birch pollen induced rhinitis were included (Table 1). Active infections, polyps or anatomic nasal abnormalities were not allowed, nor other anti-allergic therapy a few weeks before the study.

Table 1. Patient demographics.

medication group	aerosol	dry powder
patients	30	30
male/female	14/16	17/13
age (yrs)	34.5 (20–62)	33.7 (17–59)
duration of rhinitis	14.9 (5–35)	15.2 (3–50)

Two randomized parallel patient groups were given intranasal budesonide either as a dry powder in a sniff actuated inhalation device or as a freon propellant aerosol. The dose was 400 μg once daily administered in the morning. All patients started the medication on the same day a few days before the anticipated peak pollen season, and used it for three weeks. If needed, concurrent therapy with terfenadine 60 mg tablets or antazoline–naphazoline eyedrops was permitted during the trial.

Efficacy was assessed daily by patient-rated symptom scores recorded in the mornings. Nasal symptoms itching, sneezing, running and stuffiness, eye symptoms and possible side effects were each rated using a scale from 0 to 3. Sneezes within five minutes from the intranasal inhalation of budesonide were counted. Nasal peak inspiratory flow (PIF) measurements at the three visits to the clinic were compared. Patients were first seen a few weeks before pollen season, and if admission criteria were fulfilled, they entered a preseasonal medication-free baseline period for one week. At the second visit, still before the peak pollen season the patients got their study medication. A third clinical check-up was at the end of the three weeks treatment period.

Wilcoxon's one and two-sample tests and Fishers's exact test were used in statistical considerations.

RESULTS

One patient in the dry powder group did not return after having received the study medication. Two patients in the aerosol group withdrew during the active treatment, one because of lack of effect on day 11 and the other on day 7 because of heavy allergic eye symptoms treated with steroids.

Some birch pollen occurred during the baseline period, but the real peak pollen season commenced two days after starting the medication and continued through the study period (Figure 1). Over 12000 pollen grains/m^3 were counted on one day, and daily values over 400 were recorded through the medication days.

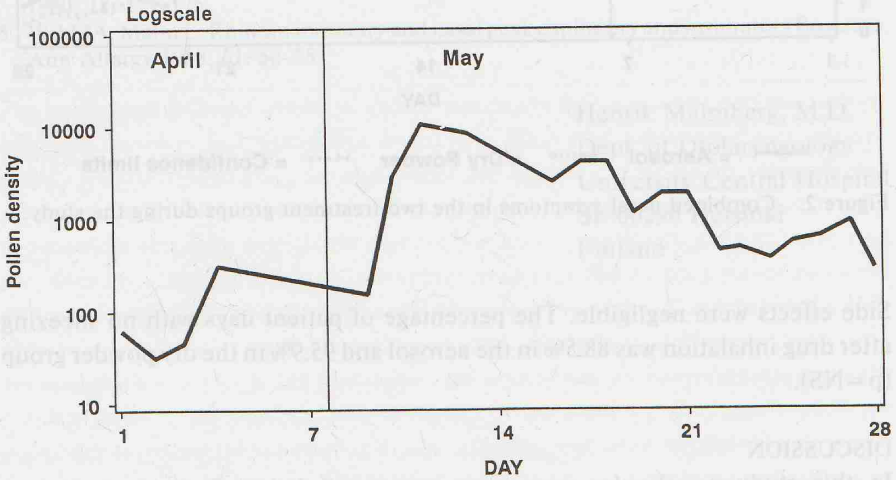

Figure 1. Birch pollen density in Helsinki during the study.

Some symptoms were seen in the patients during the baseline, and a slight initial increase in nasal and eye symptoms can be seen in mean daily symptom scores at the time of the peak pollination (Figure 2). But during the baseline and the treatment periods there were no statistical differences of any nasal symptoms between treatment groups nor between study periods. Mean nasal PIF of all patients increased from 119.3 l/min (SD 62) at visit 2 to 137.8 l/min (SD 48.5) at visit 3 ($p < 0.001$), but the difference between treatment groups was not significant. The mean weekly terfenadine tablet consumption during the medication period was 1.34 in the aerosol and 1.20 in the dry powder group (p = NS). The mean weekly eye-drop consumption during baseline was 1.8 in both groups, but increased to 3.7 in the aerosol and 5.8 in the dry powder group. The difference between groups is not significant. Substantial or total control of symptoms was achieved in 93% of the patients in the aerosol and 79% in the dry powder group.

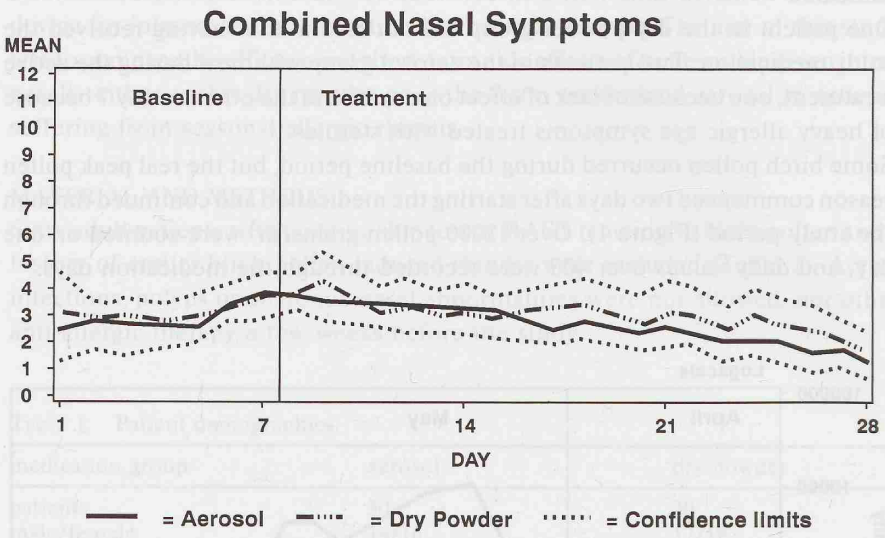

Figure 2. Combined nasal symptoms in the two treatment groups during the study.

Side effects were negligible. The percentage of patient days with no sneezing after drug inhalation was 88.5% in the aerosol and 95.9% in the dry powder group (p=NS).

DISCUSSION

In this study no placebo group was incorporated, but facilities for heavy symptoms were recognizable during the study. Patients had got symptoms for many years (Table 1) and they knew the symptoms. The pollen season was very heavy and long, and during the baseline when already some pollen existed, most patients got symptoms.

Daily symptom score cards are a simple but informative evaluation criterion, although it is subjective. Nasal inspiratory peak-flow is more objective and according to Wihl and Malm (1986) a rather reliable measurement of nasal patency. Neither criterion showed differences between the treatment groups in this small study, as could be expected. In both treatment groups, symptoms remained at the pretreatment level and nasal PIF even improved in spite of the heavy pollination. The medication was thus effective, and probably the "prophylactic" start of medication improved the effect.

Short-term side effect were negligible and the powder seemed to be well tolerated. The possible drying effect, which is disturbing at least in the nordic countries (Holopainen et al., 1982), should be studied in possible long-term trials.

Intranasal budesonide as a dry powder inhaled through the sniff actuated nasal applicator seems to be a good treatment alternative in allergic rhinitis.

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