A comparison of beclomethasone dipropionate aqueous nasal spray and beclomethasone dipropionate pressurized nasal spray in the management of seasonal rhinitis

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Summary

Forty patients with seasonal rhinitis and a proven sensitivity to pollens were studied for 2 weeks during the pollen season of 1982. The study was carried out according to a double-blind, double-dummy design. All patients received 100 µg beclomethasone dipropionate (BDP) into each nostril twice daily (400 µg/day) on a randomized basis, from either the aqueous nasal spray or the pressurized nasal spray (Beconase Nasal Spray). Analysis of patients' symptom scores, additional symptomatic medication and physicians' assessment indicated that both treatments were equally effective in controlling the symptoms of seasonal rhinitis. Any adverse events reported were considered to be clinically insignificant.

BDP aqueous nasal spray was therefore found to be an effective and acceptable therapy in the management of seasonal rhinitis.

KEY WORDS: grass pollen sensitivity.

Introduction

Beclomethasone dipropionate (BDP) is a synthetic glucocorticosteroid which has potent, local, anti-inflammatory action within the respiratory tract. It is effective as a prophylactic inhalational medication in the management of asthma and rhinitis and is established as one of the major drugs for the treatment of these diseases.

For the treatment of rhinitis, BDP has been available for several years as a pressurized nasal spray which contains freon propellants (Beconase Nasal Spray). The pressurized spray has been found to be uniformly effective in alleviating or preventing the nasal symptoms of seasonal allergic rhinitis, with

a high success rate (Mygind, 1973; Brown and Storey, 1974; Prah, Wilken-Jensen and Mygind, 1975; Cockcroft *et al.*, 1976). However, some patients are unable to use the pressurized aerosol or find its use unpleasant. A nasal spray containing the steroid in a bland aqueous base has now been formulated (Beconase Aqueous Nasal Spray) and this provides an alternative method of administration for these patients.

The purpose of this study was, therefore, to compare the effectiveness and acceptability of BDP aqueous nasal spray with BDP pressurized spray in the management of seasonal rhinitis.

Patients and methods

The study was carried out during the hay fever season of 1982 according to a double-blind, double-dummy, parallel group design. Both adults and children suffering from seasonal rhinitis and requiring medication were considered for entry into the study. A proven sensitivity to grass pollens was required for all patients, as shown by a classical history and a positive skin prick test or a positive RAST to grass pollens. Patients with a marked septal deviation or large polyps and patients receiving medication which could affect the treatment of rhinitis, e.g. oral corticosteroids, were excluded from the study.

The patients were randomized into one of the two therapy groups and were provided with either active BDP aqueous nasal spray and placebo pressurized nasal spray, or active BDP pressurized nasal spray and placebo aqueous nasal spray, for administration of two puffs into each nostril from both sprays twice daily. Both active nasal sprays delivered 50 µg BDP per puff (equivalent to 400 µg BDP per day) and were

TABLE 1. Patient characteristics

Variable		Aqueous therapy group (n=20)	Pressurized therapy group (n=20)
Age (years)	Mean	27.8	25.6
	Range	14-53	12-51
Sex	Male	7	3
	Female	13	17
Duration of disease (years)	Mean	14.2	11.4
	Range	2-48	2-32
Severity of symptoms	Mild/moderate	8	7
	Severe	12	13

identical in appearance to the corresponding placebo. Any medication being taken for rhinitis before the start of the study was withdrawn.

If the symptoms of rhinitis were not adequately controlled during the study then the patients were allowed to take symptomatic antihistamine tablets for further control of nasal symptoms and eye drops for further control of eye symptoms. All patients were encouraged not to take these additional medications in the first 4 days of the study.

Medication for any other concurrent condition was kept constant as far as possible.

The patients were given a daily record card to complete and were asked to record on a daily basis, symptoms of sneezing, nasal irritation, nasal blockage, rhinorrhoea and eye symptoms, on a 0 to 4 scale (0 for no symptoms, 4 for very severe symptoms). Details of medication used for the treatment of rhinitis were also to be recorded on the daily record card.

On completion of the 2-week study period, an assessment of the control of the patient's symptoms was made by the physician.

Results

Forty patients, aged 12 to 53 years, entered the study. The two therapy groups each contained 20 patients and were well balanced with regards to age, sex and duration and severity of seasonal rhinitis. Details of the patients' characteristics are given in Table 1.

Thirteen patients, six in the aqueous group and seven in the pressurized group, were suffering from concurrent asthma of whom four in each group were receiving other medication.

Two patients in the aqueous group and three in the pressurized group had received pollen desensitization in 1982, which had been unsuccessful in allaying the symptoms of seasonal rhinitis. Seven patients in the aqueous group and six in the pressurized group were taking medication for the treatment of rhinitis in the period immediately before the study.

Of the 40 patients entered into the study, four were excluded from the analysis of efficacy due to either missing daily record cards (three patients) or poor compliance (one patient). One of these patients was in the aqueous group and the other three in the pressurized therapy group. Another patient in the pressurized group withdrew from the study on day 9 due to ineffectiveness of the therapy but has been included in the analyses up until this date. All 40 patients were included in the assessment of adverse events.

The results of the mean daily total nasal symptom scores were significantly higher during the first 3 days of the study ($P < 0.05$, *t*-test for independent samples) for patients in the aqueous group than for those in the pressurized therapy group. However, this difference decreased during the first few days and during the second week the total nasal symptom scores were slightly lower for the aqueous than for the pressurized therapy group. There was no significant difference in the initial mean daily eye symptom scores for the two therapy groups. The results of the mean daily symptom scores were analyzed between days 7 and 13 inclusive to exclude any carry-over effects due to previous therapy. These indicated that there were no significant differences between the two therapy groups for any of the symptoms ($P > 0.05$, *t*-test for independent samples) (Table 2).

The physicians' assessment of efficacy of the treatments indicate that both treatments were equally effective with at least 70% of patients in each group with good or very effective control of their symptoms. Treatment was regarded as ineffective in one patient in the aqueous and 4 patients in the pressurized therapy group (Table 3).

No clinically significant adverse events were recorded. Transient stinging, experienced within 5 min of using the spray, was spontaneously reported by 11 patients after the active aqueous spray, four patients after the placebo aqueous spray and one patient after the placebo pressurized spray. This difference was statistically significant between the aqueous and pressurized sprays ($P < 0.05$, chi-square test with

TABLE 2. Mean symptom scores for days 7–13 inclusive

Symptom	Aqueous therapy group (n = 19)	Pressurized therapy group (n = 17)
Sneezing	0.83 (0.72)	1.06 (0.87)*
Nasal irritation	0.44 (0.53)	0.50 (0.68)
Nasal blockage	0.38 (0.52)	0.43 (0.68)
Rhinorrhoea	0.65 (0.70)	0.92 (0.97)
Overall nasal symptoms	2.29 (1.84)	2.90 (2.77)
Eye symptoms	1.00 (0.92)	1.39 (0.98)

A comparison between the two therapy groups indicated that there were no significant differences for any symptom ($P > 0.05$, t -test for independent samples).

*The figures in parenthesis represent one standard deviation.

TABLE 3. Physicians' assessment of the control of the patients' symptoms

Physicians' assessment	Aqueous therapy group (n = 19)	Pressurized therapy group (n = 17)
Very effective	5	3
Good	10	9
Satisfactory	3	1
Ineffective	1	4

Yates' correction). However, only one patient found the stinging of the aqueous spray sufficient to cause a temporary stoppage of the medication for a few days in the middle of the study and this patient had received the active pressurized spray. The incidence of adverse events spontaneously reported are given in Table 4.

TABLE 4. Spontaneously reported adverse events

Adverse events	BDP Aqueous spray	BDP Pressurized spray
Nose bleeding	0	3
Headache	2	1
Sore throat	1	1
Drying/crusting	0	1
Lethargy	0	1
Sneezing	3 + (2)*	2 + (1)
Stinging	11 + (4)	0 + (1)

*Figures in brackets refer to the numbers of patients reporting sneezing or transient stinging after the placebo nasal spray.

Discussion

BDP is used intranasally in the management of

rhinitis. The recommended dosage for the pressurized spray is 400 µg per day divided into two to four doses. Early studies with BDP pressurized nasal spray employed a dosage of 100 µg BDP four times daily. However, later studies including a multicentre one (Munch *et al.*, 1981), indicated that a dosage regimen of 200 µg twice daily was equally effective. A twice daily dosage has advantages over a four times daily dosage as compliance tends to be better, and patients do not need to carry the spray around with them during the day. The dosage regimen employed in this study was, therefore, 200 µg BDP twice daily, i.e. two puffs into each nostril twice daily.

The results of the mean symptom scores for the nasal symptoms indicated that there was no significant difference between the two treatment groups and the majority of patients required no additional symptomatic medication for further control of their nasal symptoms. The site of action of intranasal BDP is purely local and therefore as would be expected there was no marked benefit from therapy on eye symptoms. The physicians' assessment indicated that both treatments were very effective in controlling the symptoms of seasonal rhinitis.

The results of the study therefore, indicate that the new aqueous spray of BDP is very acceptable and equally as effective as the well-established BDP pressurized nasal spray. Some patients who are intolerant of one formulation find the other acceptable.

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