Beclomethasone dipropionate aerosol in treatment of perennial allergic rhinitis in children

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SUMMARY Forty-four children with perennial allergic rhinitis who had failed to respond to conventional therapy, including sodium cromoglycate insufflation and hyposensitization, were treated with beclomethasone aerosol given intranasally. The study was conducted in a double-blind manner, the patients being allocated active drug or placebo for a 3-week period, followed by a 1-week rest period. The treatments were then crossed over for a period of 3 weeks. After this all children were put on active drug and followed-up at monthly intervals for a period of 3 months.

Results were graded as either success or failure, and success had to be an unequivocal vote for the active drug by the patient, parent, and doctor. An overall success rate of 77% was obtained and no untoward or toxic effect was noted in any child. Tetracosactrin tests in 5 children remained normal at the end of the study period. We found intranasal beclomethasone dipropionate to be the most effective drug we have used for treating perennial allergic rhinitis in children.

Beclomethasone dipropionate aerosol (Becotide) has been successfully used in the treatment of asthmatic children and its essentially topical action emphasized (Brown *et al.*, 1972; Lal *et al.*, 1972; Brown and Storey, 1973; Godfrey and König, 1974). It has also been shown that the local application of beclomethasone dipropionate (Beconase) is an effective form of treatment in adults with hay fever (Mygind, 1973) and perennial allergic rhinitis (Hansen and Mygind, 1974). This form of therapy has also been successful in children with hay fever (Prah *et al.*, 1975). The steroid did not cause any suppression of adrenal function in the dosage given.

Most children with perennial allergic rhinitis do not respond very well to standard or commonly used methods of treatment. In view of the absence of reported side effects, we felt justified in conducting a trial of the effect of intranasal beclomethasone dipropionate in children suffering from this disorder.

Patients

We selected 46 children (36 boys, 10 girls) for inclusion in the study. All had been fully investigated in the Allergy Clinic, Red Cross War Memorial Children's Hospital, Cape Town. Their ages ranged from 4 to 12 years, mean 8 years.

Criteria for selection. (1) History of perennial allergic rhinitis of more than one year's duration. (2) Pre-treatment observation period in the Allergy Clinic for a minimum of 6 months. The majority of patients had, in fact, been seen for 2 to 5 years. (3) Inadequate response to other treatment. Only those children who failed to respond satisfactorily to 3 of the following treatments were selected: (a) antihistamines and decongestants; (b) nose drops; (c) sodium cromoglycate insufflation (Rynacrom); (d) hyposensitization (34 had been hyposensitized). (4) Symptomatic on entering the trial. (5) Radiological studies to exclude airway obstruction due to adenoidal hypertrophy or deviated nasal septum. (6) Informed consent had to be obtained from the parents of each child participating in the trial.

Diagnosis of perennial allergic rhinitis. Diagnosis was based on a careful history, together with the clinical findings, including the frequent presence of a typical allergic facies, nasal mannerisms, an 'allergic crease', and the appearance of the nasal mucosa. In addition, nasal smears were examined for clumping of eosinophils, peripheral blood smears for raised eosinophil counts, and the serum IgE level was determined. All children had raised eosinophil counts and IgE levels. Skin tests using Bencard skin testing solutions (prick through drop method) were positive in all. Every child tested was

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found to be sensitive to the housedust mite, *Dermatophagoides pteronyssinus*. 15 (36%) were allergic to grass extract and 5 (12%) to a variety of animal danders, usually dog or cat, summer pollens, and mould species. Associated allergic disorders were very common; 36 of the 46 children had asthma, 10 eczema, and 9 ocular allergy.

Method

The trial was initially conducted over two 3-week periods separated by a rest period of one week. The nasal aerosol spray used was the commercially available preparation, Beconase, which delivers 50 µg beclomethasone dipropionate with each puff.

The children were allocated to two groups at random in a double-blind fashion, one group receiving the active drug and the other the placebo for 3 weeks. After the rest period the treatments were crossed over for a further 3 weeks. At the end of this time all the children were put on the active drug and followed-up monthly for 3 months.

The children and their parents were carefully instructed in the correct use of the nasal aerosol. The procedure in each case was 2 puffs (50 µg per puff) up each nostril three times a day for 2 days and then 1 puff in each nostril three times a day for the next 19 days. This was followed by a rest period during which all medication was stopped. After one week the alternative spray was used in the same manner for the succeeding 3 weeks. The children were then maintained on active drug 50 µg twice daily up each nostril for the 3-month follow-up period. Initially all children were allowed to continue with their usual antihistamine decongestant therapy, but were told to reduce the dose or even stop this form of treatment completely if this proved possible.

Both the patients who were old enough and their mothers completed separate diary cards labelled with the patient's name and code number. The occurrence of nasal obstruction, nasal discharge, sneezing, itching, sniffing, twitching, or rubbing the nose was recorded daily. All these parameters were graded separately on a scale of 0 to 3 (0 = nil, 1 = mild, 2 = moderate, 3 = severe). At the completion of the trial the patients were asked to state which of the two aerosol nasal sprays they preferred. In addition, the number and name of the antihistamines taken each day, the number of tissues or handkerchiefs used, and the presence or absence of a sense of smell were recorded.

Patients were examined on entering the trial, again after 3 weeks, after the one-week rest period, at the end of the second 3-week period, and then monthly for 3 months. The following observations were recorded at each visit. (1) The child's height

and weight. (2) The nasal mucous eosinophil grading. (3) The appearance of the nasal mucosa; the amount of obstruction and the amount of secretion in each nasal passage was graded numerically. Careful attention was paid to any clinical evidence of side effects of steroid therapy and in addition tetra-cosactrin studies were carried out in 5 of the older children selected at random. These tests were done at the end of each of the 3-weekly treatment periods and again at the end of the 3-month follow-up period. Plasma cortisol levels were estimated before each test.

The trial started in midsummer and was completed in early winter. Autumn, a time when we experience the most difficulty in controlling the symptoms of children who are housedust mite sensitive, fell within the trial period.

Results

Forty-four of the 46 children completed the trial. The method of treatment with both intranasal beclomethasone dipropionate and placebo proved acceptable in all but 2 of the children, both of whom dropped out. The results were graded as success or failure (Table 1). Success was an unequivocal vote for

Table 1 Results obtained on nasal beclomethasone aerosol therapy

	Patient	Mother	Doctor	Record card
Success	33 (75%)	32 (73%)	33 (75%)	38 (86%)
Failure (including equivocal results)	11	12	11	6
Total	44	44	44	44

Note: Overall success rate 77%.

the drug by the patient, parent, and doctor. Failures included all those with no preference or placebo preference. All doubtful cases were classified as failures.

Overall results showed that 75% of the children and 73% of the parents thought that the drug had been effective. The completed record cards showed an 86% success rate and the medical assessment was that 75% of the children had been successfully treated on intranasal beclomethasone dipropionate. Using all parameters, the overall success rate was 77%.

No excess weight gain or any evidence of growth retardation was noted over the nearly 5-month period of the study. No steroid-induced side effects were noted. The tetra-cosactrin studies were entirely normal (Table 2). The nasal mucous eosinophil

Table 2 *Tetracosactrin stimulation tests after 3 months' therapy of beclomethasone dipropionate for perennial allergic rhinitis*

Case No.	Age (years)	Plasma cortisol (μ g/100 ml)		
		Resting	30-min poststimulation	Rise
1	11	16	35	19
2	6	11	28	17
3	12	13	33	20
4	11	17	44	27
5	9	18	42	24

counts followed no particular pattern and were of little help in assessing success or failure. The appearance of the nasal mucosa was not always of much help and did not seem to correlate well with the recorded diary findings. There was a marked reduction in the need for associated antihistamine therapy. No untoward or toxic effect was noted in any child.

Discussion

The method of administering intranasal beclomethasone dipropionate was acceptable to the vast majority of children though some did complain of a temporary burning sensation after both placebo and active sprays. The children's subjective response and their mothers' recorded observations were so unequivocal that assessment was not difficult in this study. This agrees with the dramatic results recorded by Prahl *et al.* (1975) in children with hay fever.

We found intranasal beclomethasone dipropionate to be the most effective drug we have used for treating perennial allergic rhinitis in children. No side effects of any significance were noted. The drug appears to exert its beneficial effect regardless of the extent of antigen challenge. Many of our patients come from poor socioeconomic backgrounds where house-dust avoidance procedures are usually impossible to introduce and mite exposure is heavy.

No child showed any improvement in associated allergic disorders. This finding, as well as the fact

that the plasma cortisol levels remained unaltered and that there was a normal adrenal response to tetracosactrin stimulation, tend to confirm the belief that the action of beclomethasone dipropionate is essentially local. The duration of action could not be established during the trial, but subsequent experience indicates that in some children 1 puff (50 μ g) in each nostril once a day may control symptoms for 1, 2, or even 3 days.

We concluded that beclomethasone dipropionate nasal spray is very acceptable to children. It is effective in well over 70% of cases of perennial allergic rhinitis and in the short- to medium-term appears to be a safe form of therapy. Perennial allergic rhinitis needs prolonged therapy and further studies are necessary, perhaps even including nasal biopsies, to determine the long-term effect of this drug on the nasal mucosa.

References

- Brown, H. M., and Storey, G. (1973). Beclomethasone dipropionate steroid aerosol in treatment of perennial allergic asthma in children. *British Medical Journal*, **3**, 161-164.
- Brown, H. M., Storey, G., and George, W. H. S. (1972). Beclomethasone dipropionate: a new steroid aerosol for the treatment of allergic asthma. *British Medical Journal*, **1**, 585-590.
- Godfrey, S., and König, P. (1974). Asthma-treatment with the aerosol steroid beclomethasone dipropionate. *Annals of Allergy*, **33**, 150-154.
- Hansen, I., and Mygind, M. (1974). Local effect of intranasal beclomethasone dipropionate aerosol in perennial rhinitis. *Acta Allergologica*, **29**, 281-287.
- Lal, S., Harris, D. M., Bhalla, K. K., Singhal, S. N., and Butler, A. G. (1972). Comparison of beclomethasone dipropionate aerosol and prednisolone in reversible airways obstruction. *British Medical Journal*, **3**, 314-317.
- Mygind, N. (1973). Local effect of intra-nasal beclomethasone dipropionate aerosol in hay fever. *British Medical Journal*, **4**, 464-466.
- Prahl, P., Wilken-Jensen, K., and Mygind, M. (1975). Beclomethasone dipropionate aerosol in treatment of hay fever in children. *Archives of Disease in Childhood*, **50**, 875-878.

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