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Perennial rhinitis treated with a new steroid: Fluocortin butylester (FCB)

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SUMMARY

The effect of fluocortin butylester (FCB) in the topical treatment of perennial rhinitis was investigated in a double-blind study using a cross-over technique. The daily dose was 4 mg.

Of the 30 patients who completed the trial, 26 had either allergy or nasal eosinophilia.

20 of the 30 patients preferred FCB to placebo. Moreover, there was a positive, but not statistically significant, therapeutic effect according to the patient score cards ($0.1 < p < 0.2$). In other words, the results are positive, but not definite. It is concluded that possibly the dose ought to be increased to obtain a more reliable effect.

INTRODUCTION

Corticosteroids, which have proved beneficial in the topical treatment of seasonal allergic rhinitis, are usually also effective against the nasal symptoms of perennial rhinitis, although the success rate is somewhat lower (Gibson et al., 1974; Bloom et al., 1977; Balle et al., 1980). These agents are particularly effective when nasal eosinophilia or allergy is demonstrable (Mygind, 1979).

Fluocortin butylester (FCB) is a new corticosteroid which has proved effective in the treatment of seasonal allergic rhinitis (Moesgaard Nielsen et al., 1983). It is inhaled in the form of a fine powder, without the use of a propellant gas. Even after extreme doses applied intranasally, it has not been possible to demonstrate systemic corticoid effects. The explanation is that after absorption the substance is rapidly degraded to the inactive fluocortolone-21-acid.

The object of the present investigation, performed double-blind with a cross-over technique, was to record the effects and side effects of 4 mg FCB or placebo daily upon the nasal symptoms of perennial rhinitis.

MATERIAL AND METHODS

The trial comprised patients who had had typical symptoms of perennial rhinitis through at least one year. Patients under 15 years of age and pregnant women were excluded. So were patients with symptomatic nasal polyps, septum deviation, active sinusitis, asthma requiring treatment, and patients treated, within the

past year, with steroids or desensitization. A total of 36 patients entered the trial, 17 males and 19 females. Mean age 36.2 years, range 17–62.

The investigation was carried out in winter time. It lasted for eight weeks and was done as a double-blind cross-over trial, all patients starting on February 1th. After a run-in period of one week the patients received, through three weeks, either FCB or placebo (lactose). The dose was 1/2 mg four times daily into each nostril. The agent was inhaled as a fine powder through a specially designed inhalator, the Rhinolator®, without the use of a propellant gas. After a wash-out period of another week, the patients were given, by the cross-over technique, during the last three weeks placebo or FCB in the same dosage as during the former treatment period. All other medication for the perennial rhinitis was withdrawn during the trial. However, the patients were permitted to supplement with clemastine (Tavegyl®) tablets, if the symptoms grew too severe during the trial period.

Each parient was examined three times. At the first examination, immediately before the run-in period, they were informed of the nature of the trial. They were subjected to an ENT examination and given score cards on which they were to record daily their general condition, nasal symptoms, blockage, discharge, and sneezing. The scale was from 0 to 3 according to the severity of the symptoms. At the same time they were to record the use of supplementary medicine, in particular the number of clemastine tablets. The second examination was performed during the wash-out period and the third one at the termination of the second treatment period. Allergy testing was done by prick test for pollen, animal hairs, house dust mites, and mould fungus. Besides, the nasal secretion was examined for eosinophilia on each occasion.

At all three visits, furthermore, posterior bilateral rhinomanometry without decongestion was performed. The results were calculated as advocated by Broms (1980). At the final examination the patients were asked whether they felt that the treatment had been effective during the former or the latter period. In addition, any side effects during the two treatment periods were recorded.

RESULTS

During the former treatment period 18 patients received FCB/(FCB/P) and 18 placebo (P/FCB). The two groups were comparable as regards sex, age, seasonal fluctuation of symptoms, the occurrence of asthma, allergy, previous steroid therapy or desensitization, and previous severity of the symptoms. There were also no differences in the objective findings at the first examination or the symptom scores during the run-in period. Six patients dropped out, three from each group. Three failed to turn up after the first treatment period – two of those on FCB – and it was not possible to get into touch with them later. In the other three cases the patients left the trial for weighty private reasons. There was no instance in which side effects were stated as the cause of stopping.

Thus, 30 patients completed the trial. Of them 15 received FCB/P and 15 P/FCB. The occurrence of nasal eosinophilia and/or allergy, demonstrated at prick tests among these 30 patients, is shown in Table 1. It will be seen that 26 of the 30 patients had either nasal eosinophilia or allergy.

Table 1. Presence of allergy and nasal eosinophilia in 30 patients with perennial rhinitis.

no allergy, no nasal eosinophilia	4 patients
allergy	17 patients
nasal eosinophilia	22 patients
allergy and/or nasal eosinophilia	26 patients

In Table 2 it is shown during which of the treatment periods the patients themselves felt that the medication was effective. It discloses a definite preference in favour of FCB ($p < 0.01$ by x^2), 20 out of the 30 patients feeling that the treatment was effective while they were on FCB, while 5 preferred placebo.

Table 2. 30 patients subjective evaluation concerning the treatment period during which the agent was more effective against symptoms of rhinitis.

	FCB	placebo	no preference	total
FCB/placebo	9	4	2	15
placebo/FCB	11	1	3	15
total				30 patients

In contrast, the results from the patients score cards did not reveal a statistically significant effect of FCB. From Table 3 it is apparent that the mean scores in the FCB/P group were almost identical during both treatment periods, while those from the P/FCB group indicate a positive effect of FCB, especially upon blockage and discharge. However, a statistical analysis by Student's two-sided test did not show statistical significance, either for individual symptoms or for the total nasal symptoms calculated as the mean of the named symptoms ($0.1 < p < 0.2$). There was no difference in the results between the total material of 30 patients and the results for those who had allergy and/or nasal eosinophilia.

Table 3. Daily mean score for nasal symptoms during the former and latter treatment period from the 30 patients score cards.

	FCB / placebo	placebo / FCB
blockage	1.21 / 1.07	1.38 / 0.87
discharge	0.84 / 0.97	1.26 / 0.81
sneezing	0.90 / 0.96	0.95 / 0.86

The use of clemastine tablets was slight in both groups, with no difference between the FCB and the placebo group. Rhinomanometry also failed to demonstrate differences between the groups.
Side effects occurred in 10 out of 36 patients. The distribution is given in Table 4. They were never more than moderate and were evenly distributed on the FCB and placebo group.

Table 4. Side effects in 10 out of 36 patients during one of the treatment periods.

	FCB	placebo
irritation of the mucous membrane	2	2
dry nose		1
tendency to crusting in the nose	2	
headaches		2
facial swelling and erythema	1	

DISCUSSION

An effect of corticosteroids in the topical treatment of perennial rhinitis can be expected particularly in patients with demonstrable allergy and/or nasal eosinophilia (Mygind, 1979). Among the 30 patients who completed the present trial 26 (88.7%) had either allergy demonstrated by prick tests or nasal eosinophilia. In 17 cases (59%) allergy was demonstrable and in 22 (73%) eosinophilia. These findings agree with previous ones. Balle et al., (1980) found allergy in 58% and Viner and Jackman (1976) in 64% out of 1271 patients with perennial rhinitis.
At the completion of the trial 20 out of 30 patients reported that they had felt an effect of the treatment only when they were on FCB, whereas 5 preferred placebo ($p < 0.01$). This result indicates a success rate comparable with that found for other corticosteroids (Mygind, 1982). However, the effect is uncertain when the results from the patient score cards are analysed. Thus, there seems to be a positive therapeutic effect of FCB, especially in the P/FCB group, but this effect is not statistically significant ($0.1 < 0 < 0.2$), irrespective of whether the total material is assessed or only the results in patients with eosinophilia and/or allergy.
That the clinical effect of 4 mg FCB is uncertain is supported by the findings of McKenna et al. (1982) who compared the effect of various doses of FCB upon nasal symptoms in 22 patients with perennial rhinitis. They found an effect of 4 mg as well as 8 mg daily, but better on 8 mg.
The present results indicate that FCB in a daily dose of 4 mg has some effect upon the nasal symptoms in perennial rhinitis, in particular blockage and discharge. Presumably, FCB is less potent than existing corticosteroids for topical application. Therefore, an increase of the dosage from 4 to 8 mg might be considered. Like other trials, the present one showed only a few and harmless side effects.

ZUSAMMENFASSUNG

Der Effekt von Fluocortin Butylester (FCB) in der topikalen Behandlung von perennialem Rhinitis wurde in einer doppel-blinden Untersuchung mittels einer cross-over Technik untersucht. Die tägl. Dosierung war 4 mg.

Aus den 30 Patienten, die die Untersuchung durchgeführt haben, gab es 26 die entweder Allergie od. nasale Eosinophilie ausgewiesen hatten.

20 aus den 30 Patienten haben FCB gegenüber Placebo bevorzugt. Ausserdem gab es ein positiver, aber nicht statistisch signifikant therapeutischer Effekt lt. den Patient Score Cards ($0.1 < p < 0.2$). Mit anderen Worten waren die Resultate positiv, aber keineswegs definitiv. Es wird konkludiert, dass die Dosierung möglicherweise erhöht werden muss, damit ein zuverlässigerer Effekt erreicht werden kann.

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