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THE EFFECT OF DISODIUM CROMOGLYCATÉ * IN PERENNIAL ALLERGIC RHINITIS

A Controlled Clinical Study

By

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The causative factors involved in perennial rhinitis can rarely be treated on an allergological basis although hyposensitization and antihistamine treatment can often be of value.

In addition to these treatment methods disodium cromoglycate has also been used in symptomatic treatment. Despite the good results achieved by treating allergic bronchial asthma with disodium cromoglycate its effect on perennial allergic rhinitis has been variable. Some authors have achieved good results (1, 2, 4, 6) while others (7, 8) are uncertain about its effect.

The object of this study was to compare the clinical effectiveness of disodium cromoglycate with placebo on patients with perennial allergic rhinitis.

METHODS

The investigation was carried out as a double-blind cross-over study on patients from the ENT outpatient clinic at Haukeland Hospital. All patients went through a routine ENT examination, including bacteriological examinations, eosinophilic cell count in nasal secretion, and sinus X-rays. Haemoglobin, sedimentation rate, white blood cell count and IgE samples from peripheral blood were recorded. The patients underwent intracutaneous testing with a standard series of 38 allergens, and challenge tests with suspected allergens were made on the nasal and conjunctival mucosa. Only patients who had a history of perennial allergic rhinitis for more than 1 year were included in this study.

* Lomudal Nasal®. Fison Limited.

The patients were randomly allocated to treatment with disodium cromoglycate or placebo. The capsules of coded medication contained either 10 mg disodium cromoglycate and 10 mg lactose, or 20 mg lactose only. The contents of one capsule were insufflated into both nostrils four times a day for 4 weeks and then changed to the opposite medication for the following 4 weeks.

TABLE 1
Patient Characteristics.

Variable		Value of frequency for	
		SCG-Placebo	Placebo-SCG
Age	mean	28.9	21.9
	range	15-57	15-42
Sex	male	6	3
	female	4	4
Duration of disease in years	mean	4.9	6.8
	range	1-16	1-17
Symptom severity	mild	3	2
	moderate	5	5
	moderate/severe	2	0
Hyposensitized	yes	0	3
	no	10	4
Skin test positive	house dust	4	4
	grasses	3	2
	animals	3	2
	negative	2	1

TABLE 2
Wilcoxon Matched Pairs Rank Test of Diary Card Scores.

Symptom	Group size	Mean monthly total for		Wilcoxon <i>t</i> -value	Significance
		Active	Placebo		
Blockage	14	27.4	28.4	31.0	$P > 0.10$
Running	14	23.6	26.2	34.5	$P > 0.10$
Sneezing	14	17.9	18.1	42.0	$P > 0.10$

Each patient was examined prior to treatment, 4 weeks after treatment when the drugs were changed, and finally after 8 weeks when treatment was terminated. The patients kept daily diaries noting the severity of symptoms

(nasal stenosis, rhinorrhea, sneezing and itching), using 0-3 grading where 0 = no symptoms, 3 = considerable symptoms. In addition, the clinician recorded his own evaluation of the patients' symptoms according to the same grading system. The patients were also asked at the end of the trial which treatment period they preferred.

TABLE 3
Wilcoxon Matched Pairs Rank Test of Clinical Scores.

Symptom	Group size	Mean scores for		Wilcoxon <i>t</i> -value	Significance
		Active	Placebo		
Blockage	17	1.1	1.3	15.0 (8)	$P > 0.10$
Running	17	0.8	1.4	8.5 (9)	$P > 0.10$
Sneezing	16	0.8	0.9	15.0 (8)	$P > 0.10$
Itching	13	0.5	0.8	8.5 (7)	$P > 0.10$

TABLE 4
Summary of Side Effects.

Side effects	No. of complaints during	
	DSCG	Placebo
Nasal irritation	1	3
Headache	4	2
Nausea	1	0
Others	4	3

Others include: mild initial sleepiness from DSCG, dryness in nose, itching of facial skin, enhancement of nervous disease with placebo.

RESULTS

Details of the material are shown in Table 1. Twenty-one patients entered the study, but four of these had to be considered drop-outs, one due to the use of steroids and three due to lack of cooperation. Six of the remaining 17 patients who completed the planned treatment preferred disodium cromoglycate, two of the patients preferred placebo, and nine patients had no preference. No significant effect from the use

of disodium cromoglycate was found upon assessment of clinical examinations and the patients' diaries (Tables 2 and 3). The side effects of the treatment were moderate and consisted mainly of headache (Table 4). There was no significant difference between the side effects of disodium cromoglycate and placebo. Several of the patients thought the method of application cumbersome.

DISCUSSION

The relatively small number of patients, and the fact that the majority of them had moderate symptoms when treatment was initiated, reduces the possibility of a more accurate assessment of the therapeutic effects. It has been reported that an aqueous solution is more suitable for nasal application than powder, but varying results have been published regarding this form of treatment (1, 2, 7). Holopainen et al. (5) have given higher doses, and the disappointing clinical effect of disodium cromoglycate in our experiment could be the result of too low dosage.

It is claimed that the best results are achieved after 2-3 weeks of treatment, but despite the fact that our patients used disodium cromoglycate for 4 weeks we were unable to verify this.

There is evidence to suppose that disodium cromoglycate has a better effect on patients with a positive intradermal test (3). The results of our experiment did not verify this, even though 14 of the patients had positive intradermal tests. Other publications (4) also fail to support this claim.

The conclusion must be, therefore, that in our study 10 mg disodium cromoglycate applied in powder form four times daily is no better than placebo in the treatment of perennial allergic rhinitis.

SUMMARY

The clinical effect of disodium cromoglycate was compared with placebo in patients with perennial allergic rhinitis.

The results of a double-blind cross-over trial in 17 patients suggest that insufflation with 10 mg disodium cromoglycate four times a day has no better effect than placebo.

No significant differences between the side effect of disodium cromoglycate and placebo were noted.

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