

TOPICAL SODIUM CROMOGLYCATE CREAM IN ATOPIC ECZEMA

T Thirumoorthy
Y C Giam
V S Rajan

SYNOPSIS

A double blind clinical trial using 5% sodium cromoglycate cream was carried out on 20 patients with atopic dermatitis. The patients applied the active cream of half the body and the cream base on the other half. At the end of 4 weeks of treatment, the final clinical assessment was made.

The results showed no difference between the sodium cromoglycate treated side and the cream base treated side. At 4 months follow-up, 2 patients were weaned off prednisolone and 2 others were controlled with topical hydrocortisone when previously needing full strength betamethasone valerate. There appears to be a suggestion of steroid sparing effect after sodium cromoglycate therapy.

INTRODUCTION

Atopic eczema is a common chronic skin condition often associated with bronchial asthma and recurrent rhinitis. Sodium cromoglycate (SCG) has been used with good results in atopic patients to prevent symptoms of bronchial asthma and allergic rhino-conjunctivitis. A steroid sparing effect was also noted in these patients (1). We performed a double blind study comparing 5% sodium cromoglycate cream (developed by Fisons) and the cream base. This is the first time a clinical study was done using a SCG cream formulation. Previous studies used a 10% sodium cromoglycate ointment.

METHOD

Twenty patients were offered and accepted to participate in this study. All patients had a definite diagnosis of atopic eczema. They had long standing stable eczema of moderate severity but none of them were in acute exacerbation. On admission into the study, after informed consent, the patients were weaned off oral and topical steroids two weeks before starting on the trial.

Each patient was allocated outwardly identical tubes of cream, one marked for left side and one for the right; to be applied to the affected parts respectively twice daily for 4 weeks. The contents of the tubes were not known to either the patient nor the doctor. For each patient, one side of the body was treated with active agent 5% sodium cromoglycate cream, the other side with the cream base. The patients were treated on an outpatient basis.

The patients were assessed by one of the authors before treatment, two weeks and 4 weeks after the onset of the trial creams. The clinical assessment included evaluation of redness, dryness, lichenification, fissuring, scaling, excoriation, itching, vesiculation and oedema graded from 0 to 3. The overall severity of the eczema and severity of itch was also assessed by the patient.

Middle Road Hospital
Singapore 0718

T Thirumoorthy, MBBS, Dip Ven (Lond), MRCP (UK)
Senior Registrar

Y C Giam, MBBS, M. Med (Paed)
Senior Registrar

V S Rajan, MBBS, Dip Derm (Lond), FRCP (Edin, Glas)
Director & Senior Consultant Dermatologist
Clinical Association Professor of Dermato-Venereology

The patients were allowed to take chlorpheniramine maleate tablets for pruritis and apply topical hydrocortisone to the face. No blood or urinary levels of SCG were taken during the trial.

PATIENTS

Of the 20 patients there were 8 males and 12 females. The age range was 1 to 42 years (mean age 18 years). The patients had eczema for 9 months to 31 years (mean age 10 years). Eight patients suffered from bronchial asthma and 5 others from recurrent rhinitis.

Seven of the twenty patients had systemic prednisolone therapy during the course of illness. Four were on intermittent courses and three on long term continuous therapy.

RESULTS

There was no significant difference in the severity of the eczema, the physical signs or pruritis between the SCG treated side and the cream base treated side in any of the 20 patients throughout the study.

At the end of two weeks, 10 patients showed an overall mild improvement in the eczema. The other 10 showed a mild deterioration in the eczema. Of these 10, two patients withdrew from the trial because of the deterioration and intolerable symptoms. By the end of 4 weeks, only 1 patient showed bilateral improvement compared to that before the study. In two patients the eczema was unchanged. The other 15 patients showed bilateral deterioration.

Two patients on long-term oral prednisolone therapy for several months managed without prednisolone for period of two and four months after the use of the SCG cream. Two other patients, who prior to the study had been on 0.1% betamethasone valerate were managed on hydrocortisone cream for periods of four and eight months after the use of SCG cream.

CONCLUSION AND DISCUSSION

In conclusion, unlike Haider (2), in our present study, the patients with moderate atopic eczema, did not show improvement with the use of 5% SCG cream. Similar studies done by Zachariae et al (3), Croner et al (4) and Thirumoorthy and Greaves (5) did not show 10% SCG ointment useful in the control of atopic eczema. Zachariae et al (3) found only a single significant difference favouring the SCG

preparation in that fewer excoriations were seen on the lower limbs at the end of one week.

Croner et al (4) found that the use of topical steroids was significantly lower in the group treated with SCG during the study. In this present study, some of the patients could be taken off oral prednisolone therapy and others maintained on hydrocortisone alone in place of flourinated steroids. Although one could suggest that there is a general over usage of steroids in atopic patients, the possibility of SCG having a steroid sparing effect in atopic eczema needs further investigations.

We have found that with the cream base pustulosis, secondary infection and stinging sensation was not experienced by our patients, in contrast to patients on the ointment base studies (5). The cream base also has a better patient acceptability especially in hot humid environments.

Only long-term controlled studies can confirm the steroid sparing effect of sodium cromoglycate. Future studies should incorporate a steroid preparation in the SCG cream so that deterioration from steroid withdrawal does not occur and it is also likely then that patients will agree to participate in long-term studies. A search for a higher concentration of SCG in a suitable base needs to be continued.

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