Double Blind Single Crossover Clinical Evaluation of Disodium Cromoglicate in Bronchial Asthma

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The trial consisted of 2 consecutive periods, each of 6 weeks duration. In the first period the patients received by inhalation 4 times daily either disodium cromoglycate (DSCG, ‘Intal’ ‘Lomudal’ of Fisons, England) or a similar powder as a placebo. In the second period treatments were crossed over so that the patients who had previously taken placebo were put on the active drug and vice versa. Patients were interviewed and examined weekly or bi-weekly. In order to avoid a carry over effect from the previous period only the last four weeks of each period were used for statistical computer analysis.

The patients were given score-cards where they recorded and graded twice daily their symptoms. The number of doses of each drug used was recorded twice daily. Patients on maintenance steroid treatment were advised not to change the dose. In evaluating the drug consumption, medications were assigned numerical values.

Symptoms were scored as to cough, amount of sputum, night sleep and physical capacity during the day.

All patients had reversible airway obstruction proven by pulmonary function test and most of them were atopic, with positive skin-tests to common allergens.

After the first period there was a definite subjective favourable response to DSCG as well as to the placebo in 30 of the 36 patients who completed the study. However, when questioned at the end of the second period 12 out of 17 patients who changed from placebo to DSCG either improved or experienced further improvement when compared to the placebo. Moreover, of the 19 patients who changed from DSCG to the placebo 14 felt worse.

At the end of the trial 26 patients expressed their preference for DSCG, 5 preferred the placebo and 5 had no preference. There was no significant difference whether the patient took DSCG or placebo first.

When the scoring of the total drug consumption was plotted for each patient, there was a significant reduction of usage during the DSCG period as compared to the placebo. This was more obvious if the number of doses of inhaled isoprenalin was considered separately.
There was no correlation between the clinical severity of asthma and the response to DSCG. However, it seemed that the more atopic the individual the better is his subjective response to DSCG.