



CLINICAL EFFICACY AND SAFETY PROFILE OF SODIUM CROMOGLYCAT 4% (LECROLIN) IN THE TREATMENT OF ALLERGIC CONJUNCTIVITIS

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Abstract: Allergic conjunctivitis is one of the most common ocular allergic disorders and represents a significant medical and quality-of-life burden. Increasing rates of sensitization to environmental allergens necessitate effective and well-tolerated topical therapies with pathogenetically targeted mechanisms of action. Sodium cromoglycate, a mast-cell stabilizing agent, has been used in the management of allergic ocular diseases for several decades.

Keywords: allergic conjunctivitis; seasonal allergic conjunctivitis; chronic allergic conjunctivitis; sodium cromoglycate; cromolyn sodium; Lecrolin; mast-cell stabilizer; topical ophthalmic therapy; ocular allergy.

Introduction. Allergic conjunctivitis is a common ocular manifestation of allergic disease characterized by ocular itching, conjunctival hyperemia, lacrimation, chemosis, and eyelid edema. Although allergic conjunctivitis is generally not associated with permanent visual impairment, persistent or recurrent symptoms may substantially affect patients' daily activities, sleep, work performance, and overall quality of life.

The pathophysiology of allergic conjunctivitis involves allergen-induced activation of conjunctival mast cells and subsequent release of histamine and other inflammatory mediators. Consequently, pharmacological strategies aimed at inhibiting mast-cell activation and mediator release represent an important component of topical therapy.

Sodium cromoglycate (cromolyn sodium) is a topical mast-cell stabilizer that inhibits the release of histamine and other inflammatory mediators involved in type I hypersensitivity reactions. Previous clinical studies have demonstrated the efficacy of topical sodium cromoglycate in patients with allergic conjunctivitis, including seasonal allergic conjunctivitis. A systematic review and meta-analysis of topical treatments found evidence supporting the clinical benefit of mast-cell stabilizers, including sodium cromoglycate, compared with placebo.

Clinical trials have also demonstrated that ophthalmic sodium cromoglycate is effective and well tolerated in seasonal allergic conjunctivitis. In a multicenter double-blind comparative study, 4% sodium cromoglycate administered twice daily was found to be comparable in efficacy and tolerability to 2% sodium cromoglycate administered four times daily.

Lecrolin 4% is an ophthalmic formulation containing sodium cromoglycate at a concentration of 40 mg/mL.

The present study was undertaken to assess the clinical efficacy and safety of Lecrolin 4% in patients with seasonal and chronic allergic conjunctivitis and to evaluate the dynamics of clinical symptom resolution during treatment.

Materials and Methods

The study included 60 patients (120 eyes) with clinically diagnosed seasonal or chronic allergic conjunctivitis. Patients were allocated into two groups:

-Intervention group: 30 patients who received Lecrolin 4% ophthalmic solution in addition to basic therapy.

-Control group: 30 patients who received conventional topical antiallergic therapy.

The intervention group received 1–2 drops of Lecrolin 4% four times daily for 4 weeks.

The severity of the principal clinical manifestations of allergic conjunctivitis was assessed using a 4-point clinical grading scale. The following parameters were evaluated:

- ocular itching;
- foreign-body sensation;
- conjunctival hyperemia;
- lacrimation;
- eyelid edema;
- follicular changes.

Clinical assessments were performed dynamically during the treatment period, with particular attention to the early treatment response and the degree of resolution of clinical signs by days 8 and 12–16.

Treatment tolerability was evaluated throughout the observation period. Particular attention was paid to local ocular reactions and potential systemic adverse effects. Because topical ophthalmic sodium cromoglycate is associated with limited systemic exposure, systemic adverse reactions are considered uncommon. Previous clinical studies have generally reported good tolerability, with transient local stinging or burning among the more commonly described adverse effects.

Clinical outcomes were compared between the intervention and control groups. Categorical outcomes were expressed as percentages.

For publication in an international peer-reviewed journal, the statistical analysis should additionally specify the statistical tests used, p-values, confidence intervals, and effect sizes. These parameters should be calculated from the original patient-level dataset before submission.

Results. A relatively rapid improvement in subjective symptoms was observed following initiation of Lecrolin 4% therapy. Within the first 3 days, more than 75% of patients in the intervention group reported a reduction in ocular itching and foreign-body sensation.

This early improvement is consistent with the established clinical efficacy of topical mast-cell stabilizers in allergic conjunctivitis, although mast-cell stabilizers may have a slower onset of action than some topical antihistamine or dual-action agents.

By day 8, complete regression of conjunctival hyperemia and eyelid edema, together with a reduction in follicular changes, was observed in 68% of patients in the intervention group.

In comparison, the corresponding proportion in the control group was 46%.

These findings indicate a more pronounced clinical improvement in the Lecrolin-treated group during the early follow-up period.

By days 12–16, complete resolution of the recorded clinical manifestations of allergic conjunctivitis was observed in 92% of patients receiving Lecrolin 4%.

The progressive improvement observed during treatment suggests that regular administration of sodium cromoglycate may provide sustained control of allergic ocular inflammation.

Previous controlled clinical studies have similarly demonstrated beneficial effects of sodium cromoglycate compared with placebo in allergic conjunctivitis.

An additional clinically relevant finding was a reported 40–50% reduction in the requirement for topical glucocorticosteroid therapy among patients receiving Lecrolin 4%.

The potential steroid-sparing role of sodium cromoglycate is clinically important because prolonged or repeated topical corticosteroid exposure may increase the risk of ocular complications, including steroid-induced ocular hypertension/glaucoma and cataract. However, because the present study did not provide detailed quantitative corticosteroid-use data or a predefined corticosteroid-sparing endpoint, this finding should be considered exploratory and requires confirmation in prospective controlled studies.

No clinically relevant systemic adverse effects were observed during the treatment period. The favorable systemic safety profile is consistent with the pharmacological characteristics of topical sodium cromoglycate and with previously published clinical experience. Earlier studies have reported good overall tolerability, with transient local irritation, stinging, or burning representing the principal reported ocular adverse effects.

Discussion. The findings of this study indicate that Lecrolin 4% may provide clinically meaningful improvement in patients with seasonal and chronic allergic conjunctivitis.

The mechanism of action of sodium cromoglycate is primarily related to stabilization of mast-cell membranes and inhibition of the release of inflammatory mediators. This mechanism directly targets an important component of the pathophysiology of allergic ocular inflammation.

The observed improvement in ocular itching, foreign-body sensation, conjunctival hyperemia, and eyelid edema is consistent with previous clinical evidence supporting the use of topical sodium cromoglycate in allergic conjunctivitis. A systematic review of topical therapies found that patients treated with sodium cromoglycate were more likely to perceive clinical benefit than those receiving placebo, although the authors noted limitations in the available evidence and insufficient evidence to establish superiority of one topical drug class over another.

The present findings are also consistent with randomized controlled studies in which sodium cromoglycate demonstrated efficacy over placebo and favorable tolerability.

The 4% formulation is of particular interest because a multicenter double-blind study demonstrated that 4% sodium cromoglycate administered twice daily was as effective and well tolerated as 2% sodium cromoglycate administered four times daily in seasonal allergic conjunctivitis.

An important observation in the present study was the apparent reduction in the need for topical corticosteroids. From a clinical perspective, minimizing corticosteroid exposure is desirable, particularly in patients requiring recurrent or prolonged treatment. Nevertheless, this observation should be interpreted cautiously because the current dataset does not provide sufficient information to establish a statistically confirmed steroid-sparing effect.

The study has several limitations. First, the sample size was relatively small. Second, the study population combined seasonal and chronic allergic conjunctivitis, which may represent clinically heterogeneous phenotypes. Third, the available data do not specify the randomization procedure, masking, baseline comparability of the groups, or detailed statistical methodology.

Finally, validated patient-reported outcome measures and quality-of-life instruments were not reported.

Future prospective randomized controlled studies should include larger patient populations, standardized diagnostic criteria, validated symptom scores, objective inflammatory biomarkers where appropriate, patient-reported quality-of-life outcomes, and predefined statistical endpoints.

Conclusions. Lecrolin 4% ophthalmic solution containing sodium cromoglycate demonstrated a favorable clinical response and tolerability profile in patients with seasonal and chronic allergic conjunctivitis.

More than 75% of treated patients reported improvement in subjective symptoms during the first 3 days of therapy, while by day 8 a greater proportion of patients in the intervention group demonstrated regression of conjunctival hyperemia, eyelid edema, and follicular changes compared with the control group. By days 12–16, complete resolution of the recorded clinical manifestations was observed in 92% of patients receiving Lecrolin 4%.

The observed reduction in the requirement for topical corticosteroids suggests a potential steroid-sparing benefit; however, this finding requires confirmation through adequately powered randomized controlled trials with predefined corticosteroid-use endpoints.

Overall, sodium cromoglycate 4% may represent a useful and well-tolerated component of topical therapy for allergic conjunctivitis, particularly when long-term control and minimization of corticosteroid exposure are clinical priorities.

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