Efficacy of daily intranasal fluticasone propionate on ocular symptoms associated with seasonal allergic rhinitis

BACKGROUND

- Allergic rhinitis is an inflammatory condition characterized by symptoms of nasal discharge, itching, sneezing, congestion and ocular symptoms.
- Intranasal corticosteroids are the drug of choice for patients with allergic rhinitis. Their effects against nasal symptoms are well studied and proven, but their effect on ocular symptoms is unclear.

OBJECTIVE

- To demonstrate that a 14-day course of 200 mcg/d of nasal fluticasone propionate is superior to placebo in relieving ocular symptoms associated with allergic rhinitis (AR).

METHODS

- **Design:** Multiple site, randomized, double-blind, parallel-group, placebo-controlled trial; Duration: 14 days
- **Inclusion criteria:** 12 years or older with a history of AR for 2 years or longer, had positive skin test results to an allergen relevant to the pollen season and geographic region (mountain cedar), were in overall good general health, and were able to provide voluntary, written consent. Patients were required to have allergic conjunctivitis symptoms of at least moderate severity with an instantaneous total ocular symptom score (iTOSS) of 4 or higher and an instantaneous nasal congestion symptom score of 2 or higher on the morning of randomization and a mean iTOSS of 4 or higher and an instantaneous nasal congestion symptom score of 2 or higher for 3 of the 5 days during the placebo lead-in.
- **Exclusion criteria:** pregnant or breastfeeding, known or suspected intolerance or hypersensitivity to the study materials, nasal disorders that investigators believed would have interfered with the study, history or current evidence of a clinically significant uncontrolled disease, such as respiratory disease, cardiac arrhythmias, congestive heart failure, malignant tumor, diabetes mellitus, hypertension, or current infection, impairments in learning, long-term or intermittent use of corticosteroids and intended travel outside of the geographic region for more than 48 hours.
- **Primary outcome measure:** Mean change from baseline over the treatment period in daily reflective total ocular symptom score (rTOSS).
- **Secondary outcome measures:**
    - Mean change from baseline in A, as well as PM, rTOSS
    - Mean change from baseline in individual AM, as well as PM, reflective ocular symptom scores for eye ithching/burning, tearing/watering, and redness.
    - Mean change from baseline in AM pre-dose instantaneous total ocular symptom scores (iTOSS)
    - Mean change from baseline in reflective nasal congestion symptom score (rNCSS)
    - End-of-treatment assessment of response to therapy for ocular symptoms
    - Mean change in objective assessment of conjunctival redness

Mean changes from baseline in mini rhinoconjunctivits quality of life questionnaire (MiniRQLQ) scores

Mean changes from baseline in individual MiniRQLQ scores: Domain-activities, domain-practical problems, domain-nose symptoms, domain-eye symptoms, and domain-other symptoms.

- 626 patients received either
    - Fluticasone propionate 50 mcg/actuation nasal spray: 2 sprays in each nostril every morning (314 patients)
      OR
    - Placebo nasal spray: 2 sprays in each nostril every morning (312 patients)
- Power was not stated
- Data handling method was intention-to-treat

RESULTS

- 12 patients withdrew: 2 to adverse effects, 1 lost to follow-up, 3 protocol violations, 4 withdrew consent and 2 for other reasons
- **Primary outcome measure:** The least squares mean change from baseline in rTOSS was significantly greater for fluticasone than for placebo (−0.97 vs −0.61; *P* = .002)
- **Secondary outcome measures:** All of the other secondary end points were found to be statistically significant, except the least squares mean change from baseline during the entire treatment period in conjunctival redness.
- **Author's conclusion:** This study supports the efficacy of fluticasone in treating ocular symptoms associated with AR.

STRENGTHS

- Placebo-controlled experimental design was used
- Random assignment for each group was used

LIMITATIONS

- Bias since funded by manufacturer of Flonase®, GlaxoSmithKline
- Bias due to authors affiliations with GlaxoSmithKline
- Maximum dose of Flonase® was used
- Authors bias was present within multiple sections within the study: methods, discussion and conclusion
- Viewed previous set criterion (-0.6) as ambitious
- Concluded that Flonase® was effective against ocular symptoms associated with allergic rhinitis instead of just mountain cedar allergy
- Power was not stated
- Standardization of each site was not addressed
- Unblinding was a possibility due to the smell/taste of nasal spray
- Limited to mountain cedar allergy
- Inadequate study length for testing safety
- Compliance wasn't addressed

CONCLUSION

- The results of this study showed that fluticasone monotherapy produced reductions in ocular symptoms in patients with a mountain cedar allergy.
    - Results were statistically significant, but not clinical significant
    - Currently, oral antihistamines are used for controlled ocular symptoms of allergic rhinitis
- Further research:
    - Bigger studies to compare the efficacy of fluticasone with other intranasal corticosteroids in treating the common ocular symptoms of allergic rhinitis

Reference: Ratner P, Van Bavel J, Mohar D, Jacobs RL, Hampel F, Howland W, Karwal R. Efficacy of daily intranasal fluticasone propionate on ocular symptoms associated with seasonal allergic rhinitis. Ann Allergy Asthma Immunol. 2015 Feb;114(2):141-7. doi: 10.1016/j.anai.2014.11.012.

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