

A Pilot Study Investigating the Impact of Topical Nasal Steroid Spray in Allergic Rhinitis Patients with Dry Eye

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Keywords

Dry eye · Nasal steroid · Allergic rhinitis · Treatment · Immunoglobulin E · Therapy · Schirmer test

Abstract

Objective: The aim of this study is to demonstrate the effect of nasal steroid treatment on intraocular pressure and dry eye in allergic rhinitis patients with dry eye. **Materials and Methods:** Twenty-nine patients with a diagnosis of allergic rhinitis and dry eye were included. Symptoms and findings of patients before and after nasal steroid therapy were compared. **Result:** Ocular Surface Disease Index scores for dry eye symptoms showed significant improvement after nasal steroid treatment ($p = 0.003$). In the Schirmer test, no significant change was observed in the right or left eye ($p = 0.167$ and $p = 0.489$). For the tear film break-up time, no significant change was observed in the right or left eye ($p = 0.076$ and $p = 0.170$). No significant change was observed in the right eye or the left eye in an intraocular pressure test ($p = 0.893$ and $p = 0.495$). **Conclusion:** In our study, symptoms of dry eye with allergic rhinitis were significantly improved with nasal steroid therapy, without affecting the intraocular pressure.

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Introduction

Dry eye is a tear disorder caused by insufficient tear secretion or excessive evaporation of tears [1]. Patients present with nonspecific complaints such as burning, stinging, and foreign-body sensations in the eye and pain. These symptoms can lead to serious consequences such as blurred vision, photophobia, corneal epithelial defects, and even corneal ulcerations [2]. Tests such as the Schirmer I test and tear film break-up time (TBUT) measurement, which are simple and helpful in the diagnosis of dry eye, are frequently used in ophthalmology clinics for the patients with dry eyes [3].

Corticosteroids have an important role in the inflammatory process in dry eye pathogenesis [4]. Corticosteroids are also the most effective drugs in the treatment of allergic diseases [4–7]. However, complications such as increased intraocular pressure and cataract formation have been reported in long-term treatments [6].

Allergic rhinitis (AR) is a type 1 hypersensitivity reaction caused by the development of immunoglobulin E in

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Ocular Surface Disease Index® (OSDI®)²

Ask your patients the following 12 questions, and circle the number in the box that best represents each answer. Then, fill in boxes A, B, C, D, and E according to the instructions beside each.

Have you experienced any of the following during the last week?	All of the time	Most of the time	Half of the time	Some of the time	None of the time
1. Eyes that are sensitive to light?	4	3	2	1	0
2. Eyes that feel gritty?	4	3	2	1	0
3. Painful or sore eyes?	4	3	2	1	0
4. Blurred vision?	4	3	2	1	0
5. Poor vision?	4	3	2	1	0

Subtotal score for answers 1 to 5 (A)

Have problems with your eyes limited you in performing any of the following during the last week?	All of the time	Most of the time	Half of the time	Some of the time	None of the time	N/A
6. Reading?	4	3	2	1	0	N/A
7. Driving at night?	4	3	2	1	0	N/A
8. Working with a computer or bank machine (ATM)?	4	3	2	1	0	N/A
9. Poor vision?	4	3	2	1	0	N/A

Subtotal score for answers 6 to 9 (B)

Have your eyes felt uncomfortable in any of the following situations during the last week?	All of the time	Most of the time	Half of the time	Some of the time	None of the time	N/A
10. Windy conditions?	4	3	2	1	0	N/A
11. Places or areas with low humidity (very dry)?	4	3	2	1	0	N/A
12. Areas that are air conditioned?	4	3	2	1	0	N/A

Subtotal score for answers 10 to 12 (C)

Add subtotals A, B, and C to obtain D (D = sum of scores for all questions answered) (D)

Total number of questions answered (do not include questions answered N/A) (E)

Please turn over the questionnaire to calculate the patient's final OSDI® score.

Evaluating the OSDI® Score¹

The OSDI® is assessed on a scale of 0 to 100, with higher scores representing greater disability. The index demonstrates sensitivity and specificity in distinguishing between normal subjects and patients with dry eye disease. The OSDI® is a valid and reliable instrument for measuring dry eye disease (normal, mild to moderate, and severe) and effect on vision-related function.

Assessing Your Patient's Dry Eye Disease¹,²

Use your answers D and E from side 1 to compare the sum of scores for all questions answered (D) and the number of questions answered (E) with the chart below. Find where your patient's score would fall. Match the corresponding shade of red to the key below to determine whether your patient's score indicates normal, mild, moderate, or severe dry eye disease.

*Values to determine dry eye severity calculated using the OSDI® formula.
 $OSDI^{\circ} = (\text{sum of scores}) \times 25$
 $(\# \text{ of questions answered})$

Normal Mild Moderate Severe

Patient's Name: _____ Date: _____

How long has the patient experienced dry eye disease? _____

Eye Care Professional's Comments: _____

1. Data on file, Allergan, Inc.
2. Schiffman RM, Christianson MD, Jacobsen G, Hirsch JD, Reis BL. Reliability and validity of the Ocular Surface Disease Index. Arch Ophthalmol. 2000;118:615-621

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Fig. 1. Ocular surface disease index (OSDI) scores.

the rhino-ocular mucosa due to allergens, and it is diagnosed based on the history, a physical examination, and appropriate skin testing [8]. A significant relationship between dry eye and AR in adults has been reported [9]. Dry eye is characterized by high tear film instability. TBUT measurements have revealed that tear film instability is higher in children with allergic disease such as AR, allergic conjunctivitis, and asthma [10].

The most effective treatment for nasal symptoms of AR is known to be nasal steroids [11]. Many patients with AR have ocular symptoms [12]. The use of nasal steroids has been clearly demonstrated in studies to alleviate allergic ocular symptoms [13–15].

The aim of this study is to evaluate the efficacy of nasal steroid treatment for intraocular pressure and dry eye in AR patients with dry eye.

Materials and Methods

This is a prospective study. Approval (dated February 1, 2017; decision No. 3/22) was received from the Ethical Board for Clinical Research at Bezmialem Vakif University, Faculty of Medicine. Written informed consent was obtained from all of the patients.

This study included 29 patients (18 females [62%] and 11 males [38%]) who were brought to the Ear Nose and Throat Department and the Eye Department from February to July 2017. The 29 pa-

tients diagnosed with allergic and dry eye symptoms underwent a skin prick test and had at least one allergic reaction, followed by the Schirmer I test and a dry eye test with TBUT. We included patients with clinical symptoms such as itchy and stuffy nose, sneezing, aqueous nasal discharge, a positive skin prick test, and dry eye symptoms.

We planned nasal steroid (beclomethasone dipropionate) treatment for patients with AR and dry eye. Patients were divided into 2 groups, i.e., pre- and posttreatment. Beclomethasone dipropionate was applied in a 2 × 2 puff (50 µg) dose for 6 weeks. Patients' Schirmer I and TBUT test results for dry eye and intraocular pressures were compared before and after nasal steroid therapy.

Any patients who were taking corticosteroids, nonsteroid anti-inflammatory drugs, bronchodilators, mast cell stabilizers, photochemotherapy, or immunosuppressants during the 6 months prior to this study were not included. Patients with a history of dry eye predating the onset of AR, a history of chronic contact lens use, recent changes in prescription, or a history of eye surgery were excluded from this study. We performed a nasal endoscopy to exclude the presence of rhinosinusitis with or without nasal polyps. Nasal cytology was used to exclude the presence of mixed AR/non-AR. Skin-prick tests were performed on all the subjects after the necessary diagnostic and therapeutic procedures were completed. The technique of the skin-prick test was explained to the participants.

In the Schirmer I test (with topical anesthesia), 35-mm-long and 5-mm-wide absorbent strips were used. Schirmer I test results were expressed as the wet length of the strip measured after 5 min. Results of 6 mm or less were accepted as dry eye [16]. For the TBUT test, 2 min after the application of fluorescein dye, the TBUT is measured at the slit lamp by using the cobalt blue filter over the light source. The patient is asked to blink once and then keep his or her eyes open. TBUT is defined as the time in seconds between the patient's last blink and the first appearance of a random dry spot on the corneal surface. The test is repeated 3 times, and the mean value is recorded [17]. A TBUT test score of 10 s was accepted as abnormal [18]. We accepted the Schirmer I test or TBUT test positivity as indicative of dry eye with the presence of dry eye symptoms.

Assessing Dry Eye Disease

We used our answers D and E (Fig. 1) to compare the sum of scores for all questions answered (D) and the number of questions answered (E) with the chart below. We found where our patient's score would fall. We matched the corresponding shade of red to the key below to determine whether our patient's score indicated normal, mild, moderate, or severe dry eye disease [15] (Fig. 1).

Evaluating the Ocular Surface Disease Index Score

The Ocular Surface Disease Index (OSDI) is assessed on a scale of 0 to 100, with higher scores representing greater disability. The index demonstrates sensitivity and specificity in distinguishing between normal subjects and patients with dry eye disease. The OSDI is a valid and reliable instrument for measuring dry eye disease (normal, mild to moderate, and severe) and its effect on vision-related function [19] (Fig. 1).

Skin Prick Test

Standard allergen extracts of the brand Alyostal ST-IR (Stallergenes S.A., France) were used for skin prick tests. Allergen extracts were drawn into Quick test applicators with 8 heads, and they were

Table 1. Pre- and posttest values of topical nasal steroid therapy in patients with allergic rhinitis and dry eye

Variable	Group 1	Group 2	p
Sex, n			
Male		18	
Female		11	
Age, years			
Median		30.8±4.6	
Range		17–43	
OSDI score	35.5±20.9	29.8±20.7	0.003**
Schirmer test result, mm/5 min			
Right	15.2±9.9	17.3±11.3	0.167
Left	17.4±11.0	18.6±11.0	0.489
TBUT, s			
Right	9.0±6.8	11.4±7.1	0.076
Left	10.7±5.8	12±6.7	0.170
Intraocular pressure, mm Hg			
Right	17.0±2.1	16.9±1.6	0.893
Left	16.8±2.0	16.6±1.7	0.495

OSDI, Ocular Surface Disease Index; TBUT, tear film break-up time. Paired-samples test (* $p < 0.05$ and ** $p < 0.001$).

applied to the skin on the ventral side of the forearm after the testing site was cleansed with alcohol. Topical histamine hydrochloride was used as a positive skin test control, and isotonic NaCl was used as a negative control. The results were read at the 15th min after application. Test validity criteria were set as >3 mm for positive controls and <3 mm for negative controls. A skin reaction with an induration of 3 mm or more was accepted as positive [3]. Fourteen common allergens plus a negative and a positive control were applied to the skin of the forearm with two 8-headed applicators.

Statistical Analysis

The Number Cruncher Statistical System (NCSS, 2007) and Power Analysis and Sample Size (PASS, 2008) statistical software (USA) was employed for evaluation of the data gathered in this study. Besides descriptive statistics (means ± SD) for evaluation of the data, a paired-sample test was used to compare quantitative data and to compare normally distributed parameters between groups. $p < 0.001$ and $p < 0.05$ were considered statistically significant.

Results

This study included 29 AR and dry eye patients (18 females and 11 males; mean age 30.8 ± 4.6 years, range 17–43) who were examined in our clinic. We included AR patients with seasonal symptoms in this study. The patients were assigned to 2 groups: before (group 1) and after (group 2) topical nasal steroid (beclomethasone dipropionate) treatment.

Table 2. Allergen variance

Allergen	Value
<i>Dermatophagoides pteronyssinus</i>	12 (41.3)
<i>Dermatophagoides farina</i>	9 (31.0)
Tree mix	8 (27.5)
Grass mix	6 (20.6)
Cockroach	3 (10.3)
Pine	2 (6.8)
Cat feather	2 (6.8)
Nuts	1 (3.4)
Penicillium mix	–
<i>Cladosporium</i>	1 (3.4)
Cacao	2 (6.8)
Egg	3 (10.3)
Wheat	2 (6.8)
Alterina	1 (3.4)

Values are presented as numbers (%). The total number of patients was 29.

When OSDI scores were assessed before and after topical nasal steroid treatment, dry eye symptoms were statistically significantly reduced ($p = 0.003$; Table 1). When the Schirmer test was administered before and after topical nasal steroids, no statistically significant change was observed in the right or left eye ($p = 0.167$ and $p = 0.489$; Table 1). When the TBUT test was conducted before and after topical nasal steroid therapy, no statistically significant change was observed in the right or left eye ($p = 0.076$ and $p = 0.170$; Table 1). When the intraocular pressure test was done before and after topical nasal steroid, there was no statistically significant change in the right or left eye ($p = 0.893$ and $p = 0.495$; Table 1).

In our study, the most common allergens identified by the skin prick test were *Dermatophagoides pteronyssinus* (41.3%), *D. farinae* (31.0%), tree mix (27.5%), and grass mix (20.6%) (Table 2). We included patients who had at least one allergic reaction in the skin prick test. In addition to them, we have observed that some patients had sensitivity to more than one allergen.

Discussion

Corticosteroids are among the most effective drugs in the treatment of allergic diseases [7]. Corticosteroids have been shown to play a significant role in the treatment of dry eye disease and AR [9]. The development of corticosteroids with a low systemic absorption, which has a top-

ical effect, has benefited from the therapeutic effects of these drugs, making it possible to keep side effects to a minimum [20]. In our study, we wanted to evaluate the effect of topical nasal steroid treatment on dry eye in patients with AR and dry eye.

Dry eye is characterized by decreased tear production and increased evaporation rates of the tear film barrier, with eventual surface cell desiccation and damage. An estimated 5–34% of the adult population suffers from some form of dry eye [18, 21]. Studies showing that proinflammatory cytokines play a role in dry eye pathogenesis have begun to take anti-inflammatory treatment protocols to the foreground in the treatment of this disease [22, 23]. Corticosteroids are used in the inflammatory process especially in dry eye pathogenesis due to their strong anti-inflammatory effects [4, 5]. It has been reported that ophthalmic anti-inflammatory agents such as methylprednisolone [24] and dexamethasone [7] yield effective results in dry eye cases [5]. Ophthalmic methylprednisolone has been shown in animal experiments to reduce inflammation, provide corneal epithelial surface smoothness, and maintain epithelial barrier function [25]. However, since long-term treatments can cause complications such as an intraocular pressure increase and cataract formation, cases should be carefully monitored [6].

Corticosteroid-induced glaucoma can develop in all age groups and in both genders. It is known that the use of topical corticosteroids in particular can lead to glaucoma [26]. It is known that the use of ophthalmic corticosteroids leads to accumulation of glycosaminoglycan in the eye tissues and that these biomolecules can cause edema due to their water-holding properties, resulting in primary open-angle glaucoma and consequently an intraocular pressure increase [20].

Nasal corticosteroids are increasingly used in the treatment of AR [11]. Compared with ophthalmic-applied corticosteroids, inhaler and nasal corticosteroids are known to have a very low side effect potential [26]. Inhaler and nasal corticosteroids are absorbed through the nasal and oropharyngeal mucosa. Then, they reach the target tissue without entering the systemic circulation and being destroyed by the kidney and the liver [27]. Not only systemic corticosteroids but also ophthalmic steroids are known to cause cataracts and glaucoma, but these side effects may develop depending on the duration and dose of treatment [28]. In the study of Oztürk et al. [29], endoscopic sinus surgery was performed and 26 patients who had used budesonide or beclomethasone for 3–19 months after the operation were observed; no significant intraocular pressure elevation was detected in

these cases. For this reason, we would like to use topical nasal steroid therapy with less potential side effects instead of ophthalmic corticosteroids in patients with dry eye and AR. In our study, we observed a significant improvement in OSDI scores, which revealed dry eye symptoms without affecting intraocular pressures after nasal steroid treatment ($p = 0.003$; Table 1). We did not observe any side effects with nasal beclomethasone dipropionate after the 6 weeks of treatment. After the beclomethasone dipropionate treatment, we saw significant improvement in AR symptoms with dry eye pathology. We recommend nasal steroid treatment in patients with AR and dry eye symptoms.

We published the first study in the literature emphasizing the importance of the association of dry eye with AR [9]. This study is a continuation of our previous study and showed that only 6 weeks of nasal steroid treatment in dry eye and AR-associated patients were significant for OSDI scores that showed dry eye symptoms ($p = 0.003$) without affecting the intraocular pressure ($p > 0.05$), although the results were not significant in the Schirmer I and TBUT tests ($p > 0.05$). We think that the reason is that the nasal steroid dose is not as potent as oral and eye drop steroids. Therefore it does not increase the intraocular pressure. We accepted Schirmer I test or TBUT test positivity as indicative of dry eye with the presence of dry eye symptoms. In some patients we observed the Schirmer I test results within the normal limits, despite the presence of dry eye symptoms and TBUT test positivity. For this

reason, we think that tear secretion is reactionally increased in the active period of seasonal AR. We are planning to assess the osmolarity of reactive tears secreted during the active phase of AR in future studies.

A limitation of our study is the lack of a control group to prove that the subjective posttreatment improvement evaluated via questionnaires is not a placebo effect. In this study the sample size was small, so further studies with a larger number of patients are needed to confirm our findings.

Conclusion

We showed that only 6 weeks of nasal steroid therapy in dry eye and AR-associated patients had a significant effect on dry eye symptoms. Also, we showed that the use of nasal steroids at the recommended doses does not increase intraocular pressure. Further studies are needed to fully elucidate the mechanism of treatment of AR and dry eye.

Disclosure Statement

None.

Funding Sources

None.

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Ocular Surface Disease Index[®] (OSDI[®])

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3. Painful or sore eyes?	4	3	2	1	0
4. Blurred vision?	4	3	2	1	0
5. Poor vision?	4	3	2	1	0

Subtotal score for answers 1 to 5 (A)

Have problems with your eyes limited you in performing any of the following during the last week?	All of the time	Most of the time	Half of the time	Some of the time	None of the time	NA
6. Reading?	4	3	2	1	0	NA
7. Driving at night?	4	3	2	1	0	NA
8. Working with a computer or bank machine (ATM)?	4	3	2	1	0	NA
9. Poor vision?	4	3	2	1	0	NA

Subtotal score for answers 6 to 9 (B)

Have your eyes felt uncomfortable in any of the following situations during the last week?	All of the time	Most of the time	Half of the time	Some of the time	None of the time	NA
10. Windy conditions?	4	3	2	1	0	NA
11. Places or areas with low humidity (very dry)?	4	3	2	1	0	NA
12. Areas that are air conditioned?	4	3	2	1	0	NA

Subtotal score for answers 10 to 12 (C)

ADD SUBTOTAL A, B, AND C TO OSGDI D
(D = sum of scores for all questions answered)

(D)

Total number of questions answered
(do not include questions marked NA)

(E)

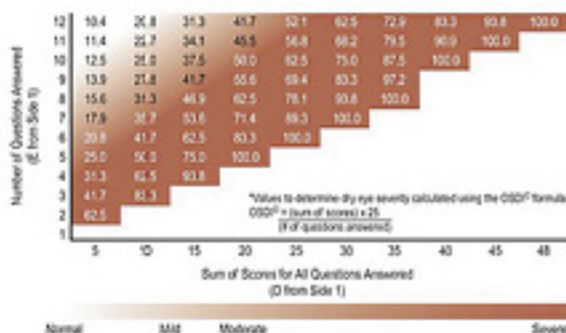
Please turn over the questionnaire to calculate the patient's final OSDI[®] score.

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Assessing Your Patient's Dry Eye Disease^{1,2}

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Patient's Name: _____ Date: _____

How long has the patient experienced dry eye disease? _____

Eye Care Professional's Comments: _____

1. Beta et al, Allergan, Inc.
2. Schiffman RM, Christianson MD, Jacobson G, Hirsch JD, Reis BL. Reliability and validity of the Ocular Surface Disease Index. Arch Ophthalmol. 2000;118:415-421

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<i>Cladosporium</i>	1 (3.4)
Cacao	2 (6.8)
Egg	3 (10.3)
Wheat	2 (6.8)
Alterina	1 (3.4)

Values are presented as numbers (%). The total number of patients was 29.

Variable	Group 1	Group 2	<i>p</i>
Sex, <i>n</i>			
Male	18		
Female	11		
Age, years			
Median	30.8±4.6		
Range	17–43		
OSDI score	35.5±20.9	29.8±20.7	0.003**
Schirmer test result, mm/5 min			
Right	15.2±9.9	17.3±11.3	0.167
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TBUT, s			
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Intraocular pressure, mm Hg			
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OSDI, Ocular Surface Disease Index; TBUT, tear film break-up time. Paired-samples test (* <i>p</i> < 0.05 and ** <i>p</i> < 0.001).			