

# Ocular Surface Disease Burden and Symptom Severity in Patients with Allergic Conjunctivitis: A Prospective Observational Study

Punam Radhesham Kela<sup>1</sup>, Sushila Kaura<sup>2</sup>, Ujwala Desai<sup>3</sup>

1. Research Scholar, Jayoti Vidyapeeth Women's University, Jaipur, Rajasthan, India Orchid ID 0009-0001-3944-8385 [punamkelaphd@gmail.com](mailto:punamkelaphd@gmail.com)
2. Associate Professor, Department of Pharmaceutical Sciences, Jayoti Vidyapeeth Women's University, Jaipur Orchid ID 0000-0003-1679-2762 [sushilakaura@gmail.com](mailto:sushilakaura@gmail.com)
3. Assistant Professor, PES Modern college of Pharmacy Nigdi Pune 44 Orchid iD 0000-0001-6510-0385 [ujudesai@gmail.com](mailto:ujudesai@gmail.com)

**Corresponding author:** Punam Radhesham Kela, Research Scholar, Jayoti Vidyapeeth Women's University, Jaipur, Rajasthan, India Orchid ID 0009-0001-3944-8385 [punamkelaphd@gmail.com](mailto:punamkelaphd@gmail.com)

## Abstract

**Background:** Allergic conjunctivitis (AC) is an inflammatory ocular-surface disorder that may coexist with dry-eye disease (DED), increasing symptom burden and affecting daily functioning. The present study evaluated the burden and distribution of ocular-surface symptoms among patients with AC using the Ocular Surface Disease Index (OSDI).

**Methods:** This prospective observational cohort included 1047 patients diagnosed with ocular allergy and recruited from ophthalmology clinics. Demographic characteristics, medical and allergic history, ocular and systemic symptoms, refractive status, OSDI responses and health-related quality-of-life measures were collected. OSDI severity was categorized as normal, mild, moderate or severe. Categorical associations were assessed using chi-square testing. Continuous OSDI and quality-of-life outcomes between participants with and without refractive error were compared using the Mann–Whitney U test. Follow-up assessments were planned at 1, 3 and 6 months.

**Results:** The cohort comprised 544 males (52.0%) and 503 females (48.0%), with a mean age of  $30.52 \pm 17.49$  years. Dry-eye symptoms were reported by 955/1047 participants (91.2%). The mean OSDI total score was  $14.74 \pm 5.00$ . OSDI severity was normal in 7.4%, mild in 18.9%, moderate in 26.1% and severe in 47.6%. Thus, 92.6% were classified within the mild-to-severe categories. OSDI severity was significantly associated with sex ( $p = 0.032$ ) and reported dry-eye symptoms ( $p = 0.001$ ), whereas age group was not significantly associated ( $p = 0.390$ ). Refractive-error status was not significantly associated with OSDI score ( $p = 0.836$ ) or overall quality-of-life percentage ( $p = 0.476$ ).

**Conclusion:** Ocular-surface symptom burden was substantial in this large AC cohort, with nearly half of participants classified as having severe OSDI-defined disease. The findings support routine assessment of ocular-surface symptoms in patients with AC. Because objective tear-film testing and treatment-specific longitudinal comparisons were not available for the present analysis, OSDI findings should not be interpreted as a formal diagnosis of DED or as evidence of comparative efficacy of cyclosporine versus tacrolimus.

**Keywords:** Allergic Conjunctivitis; Dry Eye Disease; Ocular Surface Disease Index; OSDI; Ocular Surface; Quality Of Life; Refractive Error.

**How to cite this article:** Punam Radhesham Kela<sup>1</sup> Sushila Kaura<sup>2</sup> Ujwala Desai<sup>3</sup>. Ocular Surface Disease Burden and Symptom Severity in Patients with Allergic Conjunctivitis: A Prospective Observational Study. Int J Drug Deliv Technol. 2026;16(85s):1547-1551. DOI: 10.25258/ijddt.16.85s.162.

## Introduction

Allergic conjunctivitis (AC) is a common ocular hypersensitivity disorder characterized by itching, conjunctival hyperemia, tearing and ocular discomfort. Ocular allergy encompasses a spectrum ranging from seasonal and perennial allergic conjunctivitis to more severe keratoconjunctivides. The inflammatory response involves allergen recognition, immunoglobulin E (IgE), mast-cell activation and release of downstream inflammatory mediators. Persistent inflammation can disturb ocular-surface homeostasis and contribute to chronic symptoms [1,2]. Dry eye disease (DED) is a multifactorial disorder characterized by loss of tear-film homeostasis accompanied by ocular symptoms and variable contributions from tear-film instability, hyperosmolarity, ocular-surface inflammation and neurosensory abnormalities [3]. Because ocular allergy and DED share inflammatory and tear-film-related mechanisms, the two conditions may coexist. Ocular

allergy has therefore been proposed as a clinically relevant risk factor for ocular-surface dysfunction [4]. The overlap is clinically important because itching, burning, tearing, redness and visual disturbance can be attributed to allergic disease alone. Concurrent ocular-surface symptoms may consequently remain under-recognized. A systematic review and meta-analysis reported a pooled 47.2% prevalence of dry-eye comorbidity among patients with AC when the definitions used by individual studies were applied [5]. A hospital-based Indian study of 132 patients with AC also reported substantial DED, with OSDI identifying mild, moderate and severe disease in 20.45%, 18.18% and 31.81%, respectively [6]. Patient-reported instruments such as the OSDI are useful for characterizing symptom burden, but questionnaire-based severity should be distinguished from clinically confirmed DED. The TFOS DEWS II framework

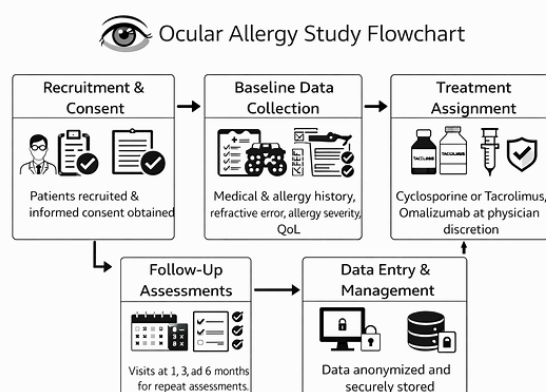
# Ocular Surface Disease Burden and Symptom Severity in Patients with Allergic Conjunctivitis: A Prospective Observational Study

emphasizes that DED is multifactorial and involves loss of tear-film homeostasis, while symptoms and visual disturbance form important components of its clinical presentation [3]. Consequently, a large burden of OSDI-defined symptoms in an AC population is clinically meaningful but does not by itself establish the presence of objective tear-film abnormalities [4]. The present study focused specifically on ocular-surface disease within a broader prospective observational cohort of patients with ocular allergy. The objective was to characterize dry-eye/ocular-surface symptom burden using OSDI, describe the distribution of OSDI severity, evaluate associations with demographic and clinical characteristics, and examine whether refractive-error status was associated with OSDI and quality-of-life outcomes. This focused approach permits a clinically interpretable analysis without attributing unreported treatment effects to the observed outcomes. To evaluate the burden and distribution of ocular-surface disease symptoms among patients with allergic conjunctivitis using the Ocular Surface Disease Index, and to examine their relationships with selected demographic and clinical characteristics, including refractive-error status.

## Materials and Methods

### Study design and population

This prospective observational cohort study included patients diagnosed with eye allergies who were recruited from ophthalmology clinics. Participants were eligible from 6 years of age. The study included 1047 participants. The study workflow comprised recruitment and consent, baseline clinical and allergy-history assessment, treatment assignment according to clinical evaluation, follow-up assessment and anonymized data management (Figure 1) [5-6].



**Figure 1. Flowchart of recruitment, treatment assignment, follow-up and analysis of patients**

### Data collection

Data collected during the study included demographic characteristics, medical and allergic history, allergen exposure, ocular and systemic symptoms, treatment history, refractive status and patient-reported outcomes. The Ocular Surface Disease Index (OSDI) was used to characterize dry-eye/ocular-surface symptoms. A health-related quality-of-life questionnaire was also

administered. Follow-up assessments were planned at 1, 3 and 6 months [7-8].

### Outcome measures

The primary outcome was the distribution of OSDI severity across four categories: normal, mild, moderate and severe. Secondary outcomes included mean OSDI total score, OSDI percentage score, individual ocular symptom patterns, reported dry-eye symptoms, demographic associations, and comparisons of OSDI and quality-of-life measures according to refractive-error status [9-10].

### Statistical analysis

Descriptive statistics were summarized using frequencies, percentages, means, medians and standard deviations. Chi-square testing was used to evaluate associations between categorical variables. The Mann-Whitney U test was used to compare continuous OSDI and quality-of-life variables between participants with and without refractive error. Binary logistic regression was also used in the broader refractive-error analysis. Statistical significance was defined as  $p < 0.05$  [11-13].

## Results

### Participant profile

A total of 1047 participants were included. Males represented 52.0% ( $n = 544$ ) and females 48.0% ( $n = 503$ ). Young adults aged 19–35 years constituted the largest age group (35.6%), followed by middle-aged adults aged 36–60 years (30.6%). The mean age was  $30.52 \pm 17.49$  years. The complete demographic distribution is presented in Table 1.

**Table 1. Demographic distribution of the study population**

| Characteristic               | n   | %    |
|------------------------------|-----|------|
| Female                       | 503 | 48.0 |
| Male                         | 544 | 52.0 |
| Children (<12 y)             | 196 | 18.7 |
| Adolescents (12–18 y)        | 97  | 9.3  |
| Young adults (19–35 y)       | 373 | 35.6 |
| Middle-aged adults (36–60 y) | 320 | 30.6 |
| Geriatrics (>60 y)           | 61  | 5.8  |

### 4.2 Ocular symptoms and ocular-surface burden

Dry-eye symptoms were reported by 955 of 1047 participants (91.2%). At the individual symptom level, itching was reported by 628 participants (60.0%), watery eyes by 556 (53.1%), redness by 543 (51.9%), swelling by 378 (36.1%) and dark circles by 318 (30.4%). Discharge, blinking and wrinkle-related symptoms were less frequent. The distribution of ocular symptoms is shown in Table 2.

**Table 2. Distribution of current ocular symptoms among participants**

| Ocular | Absent, n (%) | Present, n (%) |
|--------|---------------|----------------|
|--------|---------------|----------------|

# Ocular Surface Disease Burden and Symptom Severity in Patients with Allergic Conjunctivitis: A Prospective Observational Study

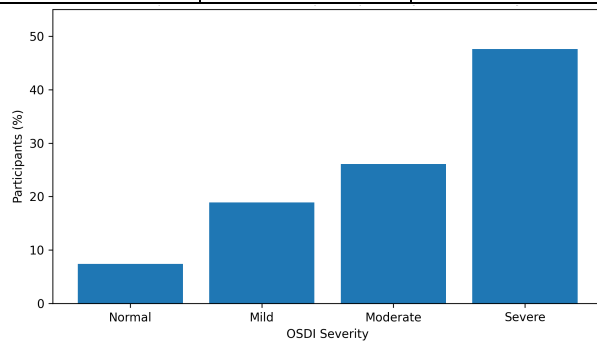
| symptom      |             |            |
|--------------|-------------|------------|
| Itching      | 419 (40.0)  | 628 (60.0) |
| Watery eyes  | 491 (46.9)  | 556 (53.1) |
| Redness      | 504 (48.1)  | 543 (51.9) |
| Swelling     | 669 (63.9)  | 378 (36.1) |
| Dark circles | 729 (69.6)  | 318 (30.4) |
| Discharge    | 1008 (96.3) | 39 (3.7)   |
| Blinking     | 1025 (97.9) | 22 (2.1)   |
| Wrinkle      | 972 (92.8)  | 75 (7.2)   |

## OSDI severity

The mean OSDI total score was  $14.74 \pm 5.00$ , with a median of 15 (interquartile range, 11–19). OSDI severity was classified as normal in 78 participants (7.4%), mild in 198 (18.9%), moderate in 273 (26.1%) and severe in 498 (47.6%). Thus, 969 participants (92.6%) were classified within the mild-to-severe categories. Severe OSDI-defined disease represented the largest single category (Table 3; Figure 2).

**Table 3. OSDI severity distribution in patients with allergic conjunctivitis (N = 1047).**

| OSDI category    | n    | %     |
|------------------|------|-------|
| Normal           | 78   | 7.4   |
| Mild dry eye     | 198  | 18.9  |
| Moderate dry eye | 273  | 26.1  |
| Severe dry eye   | 498  | 47.6  |
| Total            | 1047 | 100.0 |



**Figure 2. Distribution of participants by OSDI Severity**

**Associations with demographic and clinical variables**  
OSDI severity was significantly associated with sex ( $p = 0.032$ ). Severe OSDI-defined disease was recorded in 44.2% of females and 50.8% of males. No significant association was observed between age group and OSDI severity ( $p = 0.390$ ). Alcohol consumption, smoking and recreational drug use were not significantly associated with OSDI severity. Among current symptoms, the presence of dry-eye symptoms was significantly

associated with OSDI severity ( $p = 0.001$ ). Respiratory symptoms ( $p = 0.086$ ) and skin symptoms ( $p = 0.769$ ) were not significantly associated with OSDI severity. Selected associations are summarized in Table 4.

**Table 4. Selected associations with OSDI severity.**

| Variable             | comparison                                         | p value |
|----------------------|----------------------------------------------------|---------|
| Sex                  | Severe OSDI: female 44.2% vs male 50.8%            | 0.032   |
| Age group            | Normal/mild/moderate/severe across five age groups | 0.390   |
| Alcohol              | OSDI severity categories by exposure               | 0.803   |
| Smoking              |                                                    | 0.664   |
| Recreational drugs   |                                                    | 0.927   |
| Dry-eye symptoms     | OSDI severity by symptom status                    | 0.001   |
| Respiratory symptoms |                                                    | 0.086   |
| Skin symptoms        |                                                    | 0.769   |

## Relationship with refractive error and quality of life

Refractive error was present in 244 participants (23.3%). No statistically significant difference was observed between participants with and without refractive error in OSDI total score ( $14.89 \pm 4.80$  vs  $14.69 \pm 5.07$ ;  $p = 0.836$ ) or OSDI percentage score ( $31.01 \pm 10.01$  vs  $30.61 \pm 10.55$ ;  $p = 0.836$ ). Overall quality-of-life percentage also did not differ significantly between the two groups ( $25.86 \pm 6.60$  vs  $25.53 \pm 6.89$ ;  $p = 0.476$ ). The overall quality-of-life score was  $53.7 \pm 5.52$ , with an overall quality-of-life average of  $25.61 \pm 6.82\%$ . Among individual domains, environment had the highest mean score ( $16.98 \pm 2.73$ ), whereas social relationships had the lowest mean score ( $4.96 \pm 2.94$ ). These findings indicate a broad patient-reported burden, although the observational design does not permit causal attribution of quality-of-life impairment to dry-eye disease alone.

## Treatment exposure

Medication exposure was recorded in the study, with 57.4% of participants represented in the tacrolimus 0.03% category, 21.1% in the cyclosporine 0.1% category and 21.5% in a category receiving both treatments. These data describe treatment exposure rather than comparative treatment efficacy. Treatment-specific baseline OSDI values, longitudinal OSDI changes, effect sizes and between-treatment statistical comparisons were not available in the reported results. Therefore, treatment efficacy was not analyzed as an endpoint in the present study.

## Discussion

The principal finding of the present analysis was the high ocular-surface symptom burden among patients with allergic conjunctivitis. More than nine in ten participants reported dry-eye symptoms, while 47.6% were classified as having severe OSDI-defined disease. The mean OSDI score was  $14.74 \pm 5.00$ . Although OSDI is a patient-reported instrument and should not be considered a substitute for objective tear-film or ocular-surface testing, the observed symptom burden highlights the clinical relevance of assessing ocular-surface symptoms in patients with AC.

The findings are consistent with the established biological overlap between ocular allergy and dry eye. Ocular allergy can promote ocular-surface inflammation, alter tear-film stability and increase epithelial stress, while dry-eye mechanisms may amplify inflammatory signaling and symptom perception. The TFOS DEWS II framework emphasizes that dry eye is a multifactorial disorder involving loss of tear-film homeostasis, with symptoms and visual disturbance forming important components of its clinical presentation.

The proportion of severe OSDI-defined disease in the present cohort was higher than that reported in a 2023 hospital-based Indian study of 132 patients with AC, in which 31.81% had severe DED according to OSDI [6]. Direct numerical comparison should, however, be interpreted cautiously because the study populations, sampling settings, AC characteristics and diagnostic procedures differed. The Indian study used OSDI together with Schirmer testing and tear-film break-up time, whereas the present analysis primarily documents questionnaire-based OSDI assessment. Therefore, the observed difference may reflect differences in population characteristics and methodology rather than a difference in the underlying prevalence of DED.

A systematic review and meta-analysis reported a pooled 47.2% prevalence of dry-eye comorbidity among patients with AC. In the present cohort, 91.2% of participants reported dry-eye symptoms, while 47.6% were classified as having severe OSDI-defined disease. These outcomes should not be considered equivalent. The presence of symptoms represents a broader measure than a formal diagnosis of DED, whereas OSDI severity represents a questionnaire-based assessment of symptom burden. The difference emphasizes the importance of distinguishing reported ocular-surface symptoms from clinically confirmed DED.

Sex was significantly associated with OSDI severity in the present cohort, with severe disease reported in 50.8% of males and 44.2% of females. TFOS DEWS II epidemiological evidence has documented variation in DED prevalence according to demographic and geographic characteristics. However, the present observational data cannot establish the reasons for the observed sex association. Potential factors including disease subtype, treatment exposure, contact-lens use, environmental exposure and objective tear-film

parameters were not sufficiently characterized in the available analysis.

The association between current dry-eye symptoms and OSDI severity ( $p = 0.001$ ) is clinically understandable because OSDI itself is a symptom-focused instrument. This association should therefore primarily be interpreted as consistency between the reported symptom status and questionnaire-defined severity rather than evidence of a causal relationship between the two variables.

The absence of a statistically significant relationship between refractive-error status and OSDI score is also relevant. Participants with and without refractive error had similar OSDI values and quality-of-life measures. Refractive error was present in 244 participants (23.3%), while OSDI total score did not differ significantly between participants with and without refractive error ( $14.89 \pm 4.80$  vs  $14.69 \pm 5.07$ ;  $p = 0.836$ ). Overall quality-of-life percentage likewise did not differ significantly between the two groups ( $25.86 \pm 6.60$  vs  $25.53 \pm 6.89$ ;  $p = 0.476$ ). These findings indicate that refractive-error status was not significantly associated with the examined ocular-surface and quality-of-life outcomes in this cohort.

Medication exposure included cyclosporine and tacrolimus, reflecting the use of topical immunomodulatory treatment within the study population. Contemporary ocular-allergy literature recognizes topical anti-inflammatory approaches for persistent or more severe ocular-allergic disease. However, a valid comparative assessment of cyclosporine and tacrolimus would require treatment-group denominators, baseline comparability, predefined endpoints, longitudinal follow-up measurements and appropriate between-group statistical analyses. These treatment-specific comparative data were not available in the present results. Accordingly, medication exposure should be interpreted descriptively rather than as evidence of comparative treatment efficacy. From a clinical perspective, the high frequency of reported dry-eye symptoms and the substantial proportion of participants with moderate or severe OSDI-defined disease indicate that ocular-surface symptoms warrant attention when evaluating patients with AC. Assessment of ocular-surface symptoms may help identify patients who require further evaluation for coexisting dry-eye disease, particularly when symptoms persist despite management of allergic manifestations. However, confirmation of DED should incorporate appropriate clinical and objective ocular-surface assessments rather than relying on OSDI alone.

### Conclusion

In this 1047-patient observational cohort of patients with allergic conjunctivitis, ocular-surface symptoms were highly prevalent, with dry-eye symptoms reported by 91.2% of participants. The mean OSDI score was  $14.74 \pm 5.00$ , and 47.6% of participants were classified as having severe OSDI-defined disease. OSDI severity

was significantly associated with sex and the presence of reported dry-eye symptoms, whereas age group was not significantly associated with OSDI severity. Refractive-error status was not significantly associated with OSDI score or overall quality-of-life measures. These findings highlight the importance of evaluating ocular-surface symptoms in patients with allergic conjunctivitis. Future prospective studies incorporating objective tear-film and corneal assessments, together with standardized longitudinal treatment comparisons, are warranted.

**Conflict of interest:** The authors should declare no conflicts of interest

**Funding:** No

### References

1. Leonardi A, et al. Management of ocular allergy. *Allergy*. 2019;74(9):1611-1630.
2. Craig JP, et al. TFOS DEWS II definition and classification report. *Ocul Surf*. 2017;15(3):276-283.
3. Villani E, et al. Ocular allergy as a risk factor for dry eye in adults and children. *Curr Opin Allergy Clin Immunol*. 2018;18(5):471-476.
4. Akasaka Y, et al. Prevalence of comorbidity between dry eye and allergic conjunctivitis: a systematic review and meta-analysis. *Ocul Surf*. 2022;25:137-146.
5. Schiffman RM, et al. The Ocular Surface Disease Index (OSDI). *Arch Ophthalmol*. 2000;118(4):615-621.
6. Karlsson J, et al. Sex differences in immune responses. *Front Immunol*. 2021;12:631355.
7. Ngo ST, et al. Sex differences in autoimmune disease. *Autoimmun Rev*. 2014;13(10):1047-1052.
8. Becker WJ, et al. Sex differences in migraine. *Cephalalgia*. 2015;35(5):428-436.
9. Schaumberg DA, et al. Hormone replacement therapy and dry eye syndrome. *JAMA*. 2001;286(17):2114-2119.
10. Ngo ST, et al. Sex differences in autoimmune disease. *Autoimmun Rev*. 2014;13(10):1047-1052.
11. Skevington SM, et al. The World Health Organization's WHOQOL-BREF quality of life assessment. *Qual Life Res*. 2004;13(2):299-310.
12. Sullivan DA, et al. The impact of dry eye on daily life: a qualitative study. *Cornea*. 2014;33(9):931-938.
13. Schaumberg DA, et al. Burden of dry eye disease: incidence, prevalence, and optimal management strategies. *Ocul Surf*. 2013;11(2):126-133.