

Research Article

Association between Clinical Signs and Subjective Symptoms of Dry Eye Disease in Patients with and without Primary Sjögren's Syndrome

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Running Title: Signs and Symptoms in Sjögren's and Non-Sjögren's Dry Eye

Abstract

Purpose: To compare objective clinical signs and subjective symptoms of dry eye disease in patients with and without primary Sjögren's syndrome (SS).

Methods: This study included patients diagnosed with dry eye disease (DED) due to primary Sjögren's syndrome and patients with DED without SS (non-SS DED), all meeting the inclusion criteria at Helal Hospital (Tehran, Iran). Objective clinical assessments—including tear film breakup time (TBUT), Oxford corneal staining, tear osmolarity, and Schirmer's test I—were conducted in both groups. Subjective symptoms were assessed with the Ocular Surface Disease Index (OSDI) questionnaire. Correlation coefficients were calculated using linear regression analysis.

Results: This study was conducted from January 2023 to February 2024. Forty patients were included: 20 with SS DED and 20 with non-SS DED. The non-SS DED group had a significantly higher OSDI score (41.66 ± 7.50) than the SS DED group (37.29 ± 6.04 ; $p = 0.05$). Tear secretion measured by Schirmer I was significantly higher in the non-SS DED group ($p = 0.00$), while corneal staining scores were higher in the SS DED group ($p = 0.00$). The association between OSDI scores and objective clinical test results was weak in both groups. Among SS DED patients, OSDI scores showed a significant moderate correlation with disease duration ($r = -0.529$, $p = 0.017$). Additionally, within this group, higher tear osmolarity showed a very weak correlation with lower OSDI scores ($r = -0.383$, $p = 0.096$).

Conclusion: There is a weak and inconsistent association between subjective symptoms (OSDI scores) and objective clinical signs of DED in both patients with and without primary SS. Patients with SS may underreport their discomfort despite having more severe clinical signs of DED.

Keywords: Clinical signs; Subjective symptoms; Dry eye, Sjögren's syndrome

Introduction

Primary Sjögren's syndrome (pSS) is a chronic systemic autoimmune disease marked by lymphocytic infiltration of exocrine glands, mainly the lacrimal and salivary glands, leading to dry eye (xerophthalmia) and dry mouth (xerostomia)(1,2). Although pSS predominantly affects middle-aged women, it can occur in individuals of all ages and genders (2). The global prevalence of pSS is estimated to be around 61 cases per 100,000 individuals, with the highest rates reported in European populations (3). In certain regions, such as China, the prevalence may be as high as 5.6% in women, with a marked female predominance (female-to-male ratio of 9:1), likely related to hormonal influences(4).

Sjögren's syndrome is classified as either primary, when it occurs in isolation, or secondary, when associated with other systemic autoimmune diseases such as systemic lupus erythematosus, rheumatoid arthritis, or scleroderma (5,6). While pSS is primarily recognized for its effects on the exocrine glands, it may also involve multiple organ systems, including the joints, lungs, kidneys, liver, and nervous system (7). More than 90% of pSS patients experience ocular or oral dryness as a predominant symptom (8).

Dry eye disease (DED) is a multifactorial ocular surface condition defined by tear film homeostasis disruption, leading to discomfort, visual disturbances, and tear film instability(9). DED can occur as part of pSS or independently, and thus is broadly classified into Sjögren's syndrome-related dry eye (SS DED) and non-Sjögren's syndrome-related dry eye (non-SS DED) (10). The prevalence of DED in the general population ranges from 5% to 50%, and may reach up to 75% in populations over the age of 40 (11). Despite its prevalence, pSS remains underdiagnosed among patients presenting with DED; approximately two-thirds of SS-related DED cases are not initially recognized as having Sjögren's syndrome (12).

Assessment of DED involves both objective clinical tests and subjective symptom questionnaires. Objective tests include tear film breakup time (TBUT), Schirmer I test, ocular surface staining

(with fluorescein, rose bengal, or lissamine green), and conjunctival impression cytology (13). Subjective symptoms are commonly evaluated using validated questionnaires such as the Ocular Surface Disease Index (OSDI), which quantifies the frequency and impact of dry eye symptoms on daily life and visual function (14). The OSDI is a 12-item, self-administered questionnaire that categorizes disease severity from normal to severe based on the total score.

While both objective and subjective assessments are widely used in clinical practice and research, numerous studies have demonstrated a weak or inconsistent correlation between clinical signs and patient-reported symptoms of DED (15,16). This discordance complicates both diagnosis and management, as changes in symptoms may not necessarily reflect changes in ocular surface pathology. Various factors may contribute to this disconnect, including altered corneal nerve sensitivity, chronicity of disease, psychological adaptation, and limitations of current diagnostic tools.

Given these challenges, a better understanding of the relationship between objective clinical signs and subjective symptoms in DED, particularly in the context of primary Sjögren's syndrome, is essential for optimizing diagnosis and treatment. Therefore, the aim of this study was to evaluate the association between objective clinical signs and subjective symptoms of DED in patients with and without primary Sjögren's syndrome.

Methods

This prospective, cross-sectional observational study received approval from the Human Ethics Committee of Shahid Beheshti University of Medical Sciences (IR.SBMU.REC.1401.011) and adhered to the Declaration of Helsinki. Written informed consent was obtained from all participants before enrollment.

A total of forty patients with dry eye disease (DED) referred to Helal Hospital, Tehran, Iran, between 2023 and 2024 were included by consecutive sampling. The study population comprised twenty patients with DED associated with primary Sjögren's syndrome (SS DED), diagnosed based on the 2002 American-European Consensus Group classification criteria (14) and/or the 2016 American College of Rheumatology/European League Against Rheumatism (EULAR) criteria (15), and twenty patients with DED without evidence of pSS (non-SS DED). Diagnosis of DED was made according to the Tear Film and Ocular Surface Society Dry Eye Workshop (TFOS DEWS II) definition and classification report (16).

Inclusion criteria were the presence of DED symptoms (at least one of the following: foreign body sensation, fluctuating visual acuity, ocular discomfort, dryness, redness, or photophobia), tear film breakup time (TBUT) less than 10 seconds, and Schirmer I test ≤ 10 mm/5 min, as defined by the DEWS criteria (17). Exclusion criteria were: age <18 years; active ocular infection or allergy; eyelid deformity or abnormal lid motility; refractive surgery within the past year; current pregnancy or lactation; abnormal nasolacrimal drainage; punctal plug placement within 30 days before testing; or systemic diseases affecting tear production.

All participants underwent a comprehensive ophthalmic examination. Objective clinical assessments included measurement of tear osmolarity, tear film breakup time (TBUT), corneal staining using the Oxford scale, and Schirmer's test I. Subjective symptoms were evaluated using the Ocular Surface Disease Index (OSDI) questionnaire. For each patient, the more severely affected eye was selected for data analysis.

The OSDI questionnaire was administered under standardized conditions (air temperature 20–22°C, humidity 20–25%) following instruction on its completion. OSDI scores were calculated

according to established methodology, with higher scores indicating greater symptom severity (18).

TBUT was measured according to the International Dry Eye Workshop guidelines (19). Fluorescein sodium was applied via a moistened strip, and the interval between the last blink and the first dry spot was averaged across three measurements per eye. Schirmer I testing was performed without anesthesia: a standard Whatman filter paper strip was placed in the lower eyelid fornix for 5 minutes, and the wetted length was recorded in millimeters. Tear osmolality was measured with the TearLab Osmolarity System. Samples were obtained from the inferior lateral tear meniscus before any drops or dyes were instilled. Corneal staining was graded on the Oxford scale after fluorescein instillation, assessed under cobalt blue-filtered light using slit-lamp biomicroscopy.

Data were analyzed with SPSS 23.0 (SPSS, Inc., Chicago, IL, USA). The Shapiro–Wilk test assessed normality of quantitative variables. Pearson correlation coefficients were computed to evaluate associations between variables. Statistical significance was set at $p < 0.05$. Results are reported as mean $\pm$ SD and percentages.

Results

Among the participants, 20 patients (16 female, 4 male; mean age 48.6 ± 6.25 years) had primary SS DED, and 20 (15 female, 5 male; mean age 47.15 ± 7.21 years) had non-Sjögren’s dry eye (non-SS DED). Age did not differ significantly between groups ($p = 0.078$). The SS DED group had a higher proportion of female patients (80%) than the non-SS DED group (75%), consistent with the known female predominance in Sjögren’s syndrome. Mean disease duration was comparable (21.65 ± 4.45 years in SS DED vs. 22.05 ± 4.76 years in non-SS DED).

Table 1 summarizes demographic and clinical features. The mean OSDI score was significantly higher in the non-SS DED group (41.66 ± 7.50) than in the SS DED group (37.28 ± 6.04 ; $p < 0.001$). In the SS DED cohort, 5 patients (25%) had moderate symptoms (OSDI 23–32) and 15 (75%) had severe symptoms (OSDI >33). In the non-SS DED cohort, 2 patients (10%) had moderate symptoms and 18 (90%) had severe symptoms.

Table 1. Comparison of Clinical and Demographic Parameters Between SS DED and Non-SS DED Groups.

Variable	Group	N	Minimum	Maximum	Mean $\pm$ SD	P-value
Age (years)	SS DED	20	38.00	58.00	48.60 ± 6.25	0.44
	Non-SS DED	20	37.00	58.00	47.15 ± 7.21	
Disease duration (years)	SS DED	20	14.00	30.00	21.65 ± 4.45	0.76
	Non-SS DED	20	13.00	29.00	22.05 ± 4.76	
OSDI	SS DED	20	29.16	45.83	37.29 ± 6.04	0.05
	Non-SS DED	20	27.00	54.16	41.66 ± 7.50	
TBUT (sec)	SS DED	20	3.00	7.00	4.70 ± 1.21	0.33

	Non-SS DED	20	3.00	7.00	5.10 ± 1.25	
Schirmer1 (mm/5min)	SS DED	20	2.00	10.00	5.50 ± 2.28	0.00
	Non-SS DED	20	5.00	11.00	7.75 ± 1.65	
Corneal Staining	SS DED	20	1.00	3.00	1.75 ± 0.64	0.00
	Non-SS DED	20	0.50	2.00	1.13 ± 0.48	
Osmolarity (mOsm/L)	SS DED	20	298.00	322.00	312.55 ± 5.92	0.47
	Non-SS DED	20	302.00	320.00	311.45 ± 4.57	

DED, dry eye disease; SS, Sjögren's syndrome; TBUT, tear film breakup time; OSDI, ocular surface disease index.

The mean TBUT was 4.7 ± 1.21 seconds in the SS DED group and 5.1 ± 1.25 seconds in the non-SS DED group ($p = 0.33$). The mean Schirmer I test result was significantly lower in the SS DED group (5.50 ± 2.28 mm/5 min) compared to the non-SS DED group (7.75 ± 1.65 mm/5 min; $p = 0.00$). In the SS DED group, eleven patients (55%) had a Schirmer I test score ≤ 5 mm, and one patient (10%) had a score ≤ 2 mm. In contrast, only one patient (5%) in the non-SS DED group had a Schirmer I test score ≤ 5 mm, and none had a score ≤ 2 mm.

Tear osmolarity was similar between groups (312.55 ± 5.92 mOsm/L in SS DED vs. 311.45 ± 4.57 mOsm/L in non-SS DED; $p = 0.47$). The mean corneal staining score (Oxford grading) was significantly higher in the SS DED group (1.75 ± 0.64) than in the non-SS DED group (1.12 ± 0.48 ; $p = 0.00$).

Correlation analyses between OSDI scores and other parameters are presented in Table 2. Subjective symptoms (OSDI) showed weak correlation with objective clinical measures in both groups. In the SS DED group, OSDI scores were significantly and inversely correlated with disease duration ($r = -0.529$, $p = 0.017$), suggesting that longer disease duration was linked to lower reported symptom severity. Higher tear osmolarity also showed a very weak, though non-significant, inverse association with OSDI in the SS DED group ($r = -0.383$, $p = 0.096$). No significant correlations were found between Schirmer I results and OSDI in either group (SS DED: $r = -0.199$, $p = 0.401$; non-SS DED: $r = -0.036$, $p = 0.881$). Likewise, OSDI scores were not significantly associated with corneal staining in either group.

Table 2. Correlation of ocular surface disease index scores with clinical parameters in Sjögren's syndrome dry eye disease and non- Sjögren's syndrome dry eye disease groups

Parameter	Sjögren's syndrome		Non- Sjögren's syndrome	
	r	p	r	p
Age (years)	-0.444	0.05	0.106	0.511
Disease duration (years)	-0.529	0.017	0.068	0.777
Tear osmolarity (mOsm/L)	-0.383	0.096	0.075	0.704
TBUT (seconds)	-0.247	0.293	-0.432	0.057
Schirmer I (mm/5 min)	-0.199	0.401	-0.036	0.881
Corneal staining (Oxford Grade)	-0.128	0.591	0.136	0.567

TBUT; Tear film breakup time

DED, dry eye disease; SS, Sjögren's syndrome; TBUT, tear film breakup time; OSDI, ocular surface disease index. *Correlation is significant at the 0.05 level (2-tailed).

These findings indicate that the relationship between subjective symptoms and objective clinical signs of DED is weak and inconsistent in both patients with and without primary Sjögren's syndrome.

Discussion

The present study demonstrates that the correlation between clinical signs and subjective symptoms of DED is weak and inconsistent in patients with and without pSS. This finding aligns with previous research indicating a poor correlation between objective clinical parameters in DED and patient-reported symptoms, complicating both diagnosis and management of the condition [4,5].

Our results show that only a significant negative correlation was found between disease duration and OSDI scores in the SS DED group, suggesting that patients with longer disease duration may report fewer symptoms, possibly due to sensory adaptation or reduced corneal sensitivity. Such findings are supported by earlier studies, which have reported that advanced DED and pSS are associated with decreased corneal sensation and diminished symptom perception [13–15,18–20]. This may explain why patients with pSS can have more severe clinical signs of DED, such as lower Schirmer I test results and higher corneal staining, yet report less severe symptoms compared to those with non-SS DED.

No significant correlation was observed between Schirmer I test results and OSDI scores in either group, consistent with previous studies that have questioned the clinical utility and reproducibility of the Schirmer test as a standalone diagnostic tool for DED [6–8]. Environmental factors, diurnal variation, and disease subtype may all contribute to this lack of correlation. Similarly, the absence of significant associations between OSDI scores and corneal staining or TBUT further supports the notion that subjective symptoms and objective signs of DED arise from partially independent mechanisms [9,11,12].

Interestingly, we observed a moderate, though not statistically significant, inverse correlation between tear osmolarity and OSDI scores in the SS DED group. This contrasts with some earlier studies that reported a positive correlation between these variables [16]. One plausible explanation is that the OSDI may underestimate symptom severity in pSS patients due to reduced corneal sensitivity, or that chronic inflammation leads to neuroadaptation, diminishing the subjective experience of ocular discomfort despite worsening objective findings [18,19]. Additionally, the OSDI questionnaire, while widely used, may not fully capture the complexity of symptom perception in pSS; alternative tools such as the NEI-VFQ may provide complementary information [21].

The observed dissociation between signs and symptoms in DED is also reflected in the literature, where up to one-third of patients with significant clinical signs may report minimal or no symptoms, and vice versa [5,12]. This phenomenon may result from neurotrophic changes, psychological adaptation, or inherent limitations in current diagnostic methodologies. In pSS specifically, immune-mediated nerve damage and increased density of antigen-presenting cells in the cornea have been documented, which may further alter sensory processing and symptom reporting [20,25–27].

Our findings reinforce the importance of comprehensive DED assessment using both subjective and objective measures, especially in patients with pSS, who may underreport discomfort despite significant ocular surface pathology. Clinicians should be cautious not to rely solely on symptom questionnaires such as the OSDI for diagnosis or monitoring of DED severity in this population. Limitations of this study include the small sample size, inherent to the low prevalence of pSS, and the exclusive use of the OSDI questionnaire for symptom assessment. Future research should incorporate additional patient-reported outcome measures, such as the NEI-VFQ-25, SPEED, DEQ, IDEEL, and SANDE, as well as larger sample sizes and newer objective parameters like tear film thickness, to further elucidate the relationship between signs and symptoms in DED. In conclusion, our study supports previous evidence that the relationship between subjective symptoms and objective clinical signs in DED is weak, particularly in patients with pSS. Diagnosing and managing DED, especially in pSS, requires an integrated approach that combines both patient-reported outcomes and thorough clinical evaluation.

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Ethical considerations

This study was approved by the Ethics Committee of the Shahid Beheshti University of Medical Sciences, Iran (IR.SBMU.REC.1401.011). Written consent forms were obtained from all participants by the ethical standards of the 1964 Declaration of Helsinki and its later ethical standards.

Authors' Contributions: Conceptualization:

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Conflict of interest

The authors declared no conflict of interest.

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