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Research Article

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

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ABSTRACT

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

Materials and Methods: This study included patients diagnosed with DED due to primary SS 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 using 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<0.01), whereas corneal staining scores were higher in the SS DED group (P<0.01). The association between OSDI scores and objective clinical test results was weak in both groups. Among SS DED patients, OSDI scores showed a moderate and significant 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.

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Introduction

Primary Sjögren's syndrome (PSS) is a chronic systemic autoimmune disease characterized by lymphocytic infiltration of exocrine glands, primarily the lacrimal and salivary glands, resulting in 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 100000 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].

SS is classified as either primary, when it occurs in isolation, or secondary, when it is 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 characterized by disruption of tear film homeostasis, resulting in discomfort, visual disturbances, and tear film instability [9]. DED can occur as part of PSS or independently, and thus is broadly classified into SS-related dry eye (SS DED) and non-SS-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 SS [12].

Assessment of DED involves both objective clinical tests and subjective symptom questionnaires. Objective tests include tear 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, the chronicity of the disease, psychological adaptation, and the 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 SS, is essential for optimizing diagnosis and treatment. Therefore, this study aimed to evaluate the association between objective clinical signs and subjective symptoms of DED in patients with and without primary SS.

Materials and Methods

This is a prospective, cross-sectional observational study. A total of forty patients with DED referred to Helal Hospital, Tehran, Iran, between 2023 and 2024 were included by consecutive sampling. The study population comprised 20 patients with DED associated with primary SSDED, 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 20 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 definition and classification report [16].

The 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), TBUT less than 10 seconds, and Schirmer I test ≤10 mm/5 min, as defined by the DEWS criteria [17]. The exclusion criteria were as follows: 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, TBUT, corneal staining using the Oxford scale, and Schirmer's test I.

Subjective symptoms were evaluated using the OSDI questionnaire. For each patient, the eye most severely affected was selected for data analysis.

The OSDI questionnaire was administered under standardized conditions (air temperature, 20–22 ˚C; humidity, 20–25%) following instructions 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 osmolarity was measured with the tearlab osmolarity system. Samples were obtained from the inferior lateral tear of the 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 software, version 23.0 (SPSS, Inc., Chicago, IL, USA). The Shapiro-Wilk test was used to assess the normality of quantitative variables. The Pearson correlation coefficients were calculated to determine the relationships between variables. Statistical significance was set at $P<0.05$. Results are reported as Mean±SD and percentages.

Results

Among the participants, 20 patients (16 females, 4 males; mean age 48.6±6.25 years) had primary SS DED, and 20 (15 females, 5 males; 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 SS. 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)

Table 1. Comparing clinical and demographic parameters between SS DED and non-SS DED groups (n=20)

Variables	Group	Min	Max	Mean±SD	P
Age (y)	SS DED	38.00	58.00	48.60±6.25	0.44
	Non-SS DED	37.00	58.00	47.15±7.21	
Disease duration (y)	SS DED	14.00	30.00	21.65±4.45	0.76
	Non-SS DED	13.00	29.00	22.05±4.76	
OSDI	SS DED	29.16	45.83	37.29±6.04	0.05
	Non-SS DED	27.00	54.16	41.66±7.50	
TBUT (s)	SS DED	3.00	7.00	4.70±1.21	0.33
	Non-SS DED	3.00	7.00	5.10±1.25	
Schirmer 1 (mm/5 min)	SS DED	2.00	10.00	5.50±2.28	0
	Non-SS DED	5.00	11.00	7.75±1.65	
Corneal staining	SS DED	1.00	3.00	1.75±0.64	0
	Non-SS DED	0.50	2.00	1.13±0.48	
Osmolarity (mOsm/L)	SS DED	298.00	322.00	312.55±5.92	0.47
	Non-SS DED	302.00	320.00	311.45±4.57	

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Abbreviations: DED: Dry eye disease; SS: Sjögren's syndrome; TBUT: Tear film breakup time; OSDI: Ocular surface disease index.

Table 2. Correlation of OSDI scores with clinical parameters in SS DED and Non-SS DED groups

Parameter	SS		Non-SS	
	r	P	r	P
Age (y)	-0.444	0.05*	0.156	0.511
Disease duration (y)	-0.529	0.017*	0.068	0.777
Tear osmolarity (mOsm/L)	-0.383	0.096	0.075	0754
TBUT (s)	-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 breakup time.

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*Correlation is significant at the 0.05 level (2-tailed).

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.

The mean TBUT was 4.7±1.21 s in the SS DED group and 5.1±1.25 s 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 of ≤5 mm, and one patient (10%) had a score of ≤2 mm. In contrast, only one patient (5%) in the non-SS DED group had a Schirmer I test score of ≤5 mm, and none had a score of ≤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 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), indicating that longer disease duration was associated with 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.

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 SS.

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. These 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 condition 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 finding 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, although widely used, may not fully capture the complexity of symptom perception in PSS; alternative tools, such as the national eye institute visual function questionnaire (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 [22-24]. In PSS specifically, immune-mediated nerve damage and an increased density of antigen-presenting cells in the cornea have been documented, which may further alter sensory processing and symptom reporting [20, 25–28].

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.

Conclusion

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.

Limitation

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, standard patient evaluation of eye dryness questionnaire (SPEED), dry eye questionnaire (DEQ), impact of dry eye in everyday life (IDEEL), and symptom assessment in dry eye (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.

Ethical Considerations

Compliance with ethical guidelines

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

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Authors' contributions

Methodology and conceptualization: Ali Abbasi and Shahrokh Ramin; Supervision, investigation and project administration: Shahrokh Ramin, Ali Abbasi, and Mojtaba Mohammadpour; Clinical examination: Shahrokh Ramin and Mojtaba Mohammadpour; Data collection: Mojtaba Mohammadpour; Formal analysis and validation: Ali Abbasi and Masoud Khorrami-Nejad; Funding acquisition: Shahrokh Ramin; Writing, review, and editing: Mojtaba Mohammadpour, Ali Abbasi, and Masoud Khorrami-Nejad; Project administration: All authors.

Conflict of interest

The authors declared no conflict of interest.

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