Ocular Surface Disease Index (OSDI): a potential useful instrument for the assessment of vision-targeted health-related quality of life (VT-HRQ) in primary Sjögren’s syndrome (pSS) clinical trials?

Sirs,

Primary Sjögren’s syndrome (pSS) is a chronic, systemic inflammatory disorder characterised by a progressive hypofunction of the salivary and lacrimal glands, frequently associated with a variety of scattered extraglandular manifestations, including malignant lymphoproliferative disorders (1, 2). According to the vast majority of the classification criteria set for pSS, Schirmer’s test and Green Lissamine staining (GLS) represent the classical diagnostic tools for the assessment of pSS xeropthalmia (3). Despite their extensive application, these traditional diagnostic tests as well as the Tear break-up time (T-BUT) are scarcely correlated with patients’ dry eye symptoms making the evaluation of dry eye in pSS a challenging task both in daily practice and in clinical trials (4).

In addition, comprehensive patient-reported outcomes instrument (PRO) focusing on the impact of dry eye on pSS everyday life are lacking (5, 6). Thus, a growing interest has arisen in developing new diagnostic tools that allow the clinicians to improve pSS assessment in clinical practice and research trials. This emerging trend reflects the general efforts of the last ten years in searching for novel specific and not invasive biomarkers for pSS (7-11). The Ocular Surface Disease Index (OSDI) is a 12-item questionnaire which is commonly adopted for the assessment of vision-targeted health-related quality of life (VT-HRQ) in patients with autoimmune dry-eye-disease (10). The OSDI is articulated in three subscales and explores vision-related function, environmental triggers and their effect on vision. In this prospective observational study we analysed the utility of the OSDI in the assessment of VT-HRQ in consecutive patients with pSS and in patients with dry eye-related with different factors (11).

Moreover, we explored any eventual correlations among OSDI, patients’ subjective ocular dryness, artificial tear usage and Schirmer’s test, T-BUT and GLS findings. All the patients underwent a detailed evaluation, including a complete history, physical exam and laboratory analysis. The same ophthalmologist performed the Schirmer’s test without anesthesia, TBUT and GLS and administered the OSDI. Patients’ perception of subjective symptoms was assessed by 100-mm visual analogue scales (VAS) for dry eye, dry mouth, fatigue and pain. The ESSDAI was calculated in order to evaluate pSS activity (12). Spearman’s rho, chi square and ANOVA test were used for statistical analysis. Thirty-six consecutive female fulfilling the AECG criteria for pSS (13) (mean age ±SD=56±14 yrs; mean disease duration ±SD=4.2±4.6 yrs) were enrolled in the study. Thirty-six age and sex matched female (mean age ±SD=55±11 yrs; mean disease duration ±SD=3.8±6.1 yrs) with no-SS dry-eye-disease were included as controls.

In conclusion, the OSDI provided a useful assessment of the impact of dry eye on patients “dry eye-related” quality of life. Considering its strong association with patients’ perception of symptoms OSDI may constitute a valid instrument to evaluate treatment effectiveness in routine clinical practice and might also be considered as a useful PRO instrument for the assessment of VT-HRQ in pSS clinical trials.

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