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 lachrymal 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 xerophtalmia (3). Despite their extensive appplication, 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 no-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 testing 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 match 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. No differences were found in the results of the traditional ocular tests between the two groups. Mean scores of the VAS for ocular dryness were 60.3±30.5 in pSS and 60.1±30.9 mm in no-SS dry-eye-disease respectively (p=0.81). According to the OSDI scores, we distinguished four severity dry eye groups: "normal" (score=0-12), "mild" (score=13-22), "moderate" (score=23-32) and a severe (score=33-100). The breakdown of pSS patients and controls into the four groups based on the OSDI score is reported in Figure 1. Overall, no differences were found in the OSDI score distribution between pSS and controls. The OSDI was significantly correlated with both GLS (r=0.52) and TBUT (r=-0.53). No significant correlation was detected between OSDI and Schirmer's test (r=-0.19). As far as subjective dryness was concerned, OSDI correlated with the scores of the VAS for ocular dryness (r=0.67). On the contrary, no correlation was found among the latter and the results of each of the ocular tests performed. A statistically significant correlation was also observed between OSDI and artificial tear usage (p=0.003) and between OSDI and VAS scores for fatigue (r=0.52). No correlations were found between OSDI and patients' age, menopausal status, concomitant thyroiditis, ESSDAI score or positivity for antinuclear antibodies, anti-Ro/SSA, anti-La/SSB and rheumatoid factor.

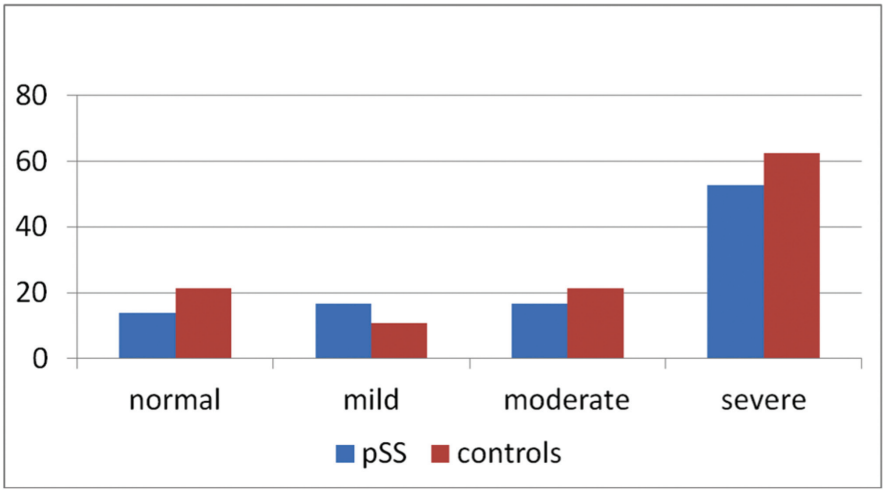

Fig. 1. According to the OSDI questionnaire, a "normal" score (0–12) was detected in 5/64 (13.9%) pSS patients and in 6/28 (21.4%) controls, a "mild" severity score (13–22) in 6/64 (16.7%) pSS patients *vs*. 3/28 (10.7%) controls, a "moderate" score (23–32) in 6/64 (16.7%) pSS patients *vs*. 6/28 (21.4%) controls, and a "severe" dry eye (33–100) in 19/64 (52.8%) pSS patients *vs*. 13/28 (46.4%) controls, respectively.

In conclusion, the OSDI provided a useful assessment of the impact of dry eye on patient "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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