The PSS-Qol: development and first psychometric testing of a new patient-reported outcome measure for PSS patients

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Background/Purpose

Patients with primary Sjögren Syndrome (PSS) are affected by glandular and extraglandular manifestations leading to physical and mental impairment. To what extent these factors affect the health related quality of life (HRQL) of these patients is largely unexplored. Disease activity scores for PSS have been developed but there is no disease-specific HRQL questionnaire available so far. The aim of this study was to develop a questionnaire for the assessment of HRQL in PSS.

Methods

Based on the concepts of a previous qualitative study, a questionnaire for the assessment of HRQL in PSS (PSS-Qol) was developed. Psychometric testing of PSS-Qol was performed after revising the first draft with feedback of patients (n=6) and clinicians (n=4). Convergent construct validity was assessed by correlating the score with the EULAR Sjögren’s Syndrome Patient Reported Index (ESSPRI), EULAR Sjögren’s Syndrome Disease Activity Index (ESSDAI) and Euro-Qol 5D (EQ-5D.). Reliability was examined by asking patients to complete the questionnaire twice 1-2 weeks apart. An English Version of the PSS-Qol was developed by using standard methodology with forward and back translation.

Results

Out of the 75 PSS patients, 91% were female, mean (±SD) age was 58.5±12.5 years. PSS-Qol consists of 25 questions and can be divided into two main categories: physical (discomfort and dryness) and psychosocial. The internal consistency of the PSS-Qol revealed a Cronbach’s α of 0.892. Strong and moderate correlations were found between the PSS-Qol and ESSPRI (corr coeff=0.755) and EQ-5D pain/discomfort (corr coeff=0.531). Reproducibility of the PSS-Qol was high, yielding an ICC of 0.958 (95% CI 0.926 to 0.981). Subsequently, the final German version of PSS-Qol was translated forward and back by native speakers (see figure 1).

Conclusion

A questionnaire to assess the HRQL in PSS patients has been developed and tested for its psychometric properties. The PSS-Qol should allow for a better and more comprehensive assessment on patients’ HRQL in PSS. Multicentre studies for further validation are needed.