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Usefulness of implementing the OHIP-14 questionnaire to assess the impact of xerostomia and hyposalivation on quality of life in patients with primary Sjögren's syndrome

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Abstract

Background: The aim of this study is to analyze if the results of the Oral Health Impact Profile-14 questionnaire (OHIP-14) in patients with primary Sjögren's syndrome (pSS) are correlated with salivary flow and level of xerostomia.

Methods: This observational cross-sectional study was conducted in 61 patients (60 women, one man, mean age 57.64 [13.52]) diagnosed of pSS according to the American-European Criteria (2002). After recording demographic, medical and dental data (decayed-missing-filled teeth index [DMFT]), unstimulated (UWS) and stimulated (SWS) salivary flows were collected. Subsequently, UWS flow was categorized into two groups (<0.1 ml/min and ≥0.1 ml/min) and SWS into three groups (<0.1 ml/min, 0.1–0.7 ml/min and >0.7 ml/min). Patients also filled out a visual analog scale (VAS) for xerostomia and OHIP-14 for self-reported quality of life (QoL).

Results: Data showed positive and significant correlation between OHIP-14 and xerostomia, based on VAS results ($r = 0.52$; $p = 0.001$). Furthermore, there was a negative correlation between UWS and OHIP-14 scores ($r = -0.34$; $p = 0.006$) and VAS for xerostomia ($r = -0.22$; $p = 0.09$). No significant correlation was found between SWS and OHIP-14 or VAS neither between DMFT and OHIP-14. When assessing the level of QoL by the UWS and SWS flow categories a significant association was found for UWS ($p = 0.001$) but not for SWS ($p = 0.11$). The OHIP-14 values were higher in the groups with lower salivary flow. The multiple linear regression to predict OHIP-14 only selected VAS for xerostomia as a statistically significant predictor.

Conclusions: Increased level of xerostomia and reduced UWS flow decrease oral health-related QoL in patients with pSS.

KEYWORDS
hyposalivation, OHIP-14, oral health quality of life, Sjögren's syndrome, xerostomia

1 | INTRODUCTION

Sjögren's syndrome (SS) is a systemic autoimmune rheumatic disease, characterized by a lymphocytic infiltration of the exocrine glands, resulting in permanent signs and symptoms of oral and ocular dryness. It may appear as an isolated disorder (primary SS) or as secondary SS when it comes along with another autoimmune disease, such as systemic lupus erythematosus, rheumatoid arthritis, or scleroderma. It may course localized or associated with systemic involvement.[1,2]

As other autoimmune diseases, primary SS (pSS) affects more predominantly to women[2] and it usually appears between the 4th and 5th decade of life,[3] although it may occur at any age. In the oral cavity, its main sign and symptom is hyposalivation and oral dryness. Within the oral cavity, saliva has multiple functions, since it lubricates both hard and soft oral tissues, has antibacterial and antifungal properties, buffer activity, and it facilitates digestion and tooth remineralization. Hence, in these patients characterized by reduced salivary flow, the risk of suffering opportunistic infections, tooth decay and tooth loss, oral lesions, and oral soreness increases.[4,5] Due to salivary dysfunction, patients with pSS often have difficulties chewing, swallowing food and speaking. All these oral manifestations have a negative impact on SS patient's social functioning and health-related quality of life.[6]

Oral Health-related Quality of Life (OHRQoL) has been defined as "the absence of negative impacts of oral conditions on social life and a positive sense of dentofacial self-confidence".[7] Although OHRQoL may be measured using different tools, the most widely used is the short version of the Oral Health Impact Profile-49 (OHIP-49) questionnaire, the so called OHIP-14 questionnaire developed by Slade and Spencer in 1994.[8] A recent systematic review analyzing the OHRQoL in rheumatic diseases, concluded that the OHIP-14 questionnaire was the most widely used tool (in seven out of eight studies in SS patients).[9] Since xerostomia is one of the main complaints of pSS patients, it has been hypothesized that the decrease in QoL reported by these patients is dependent on this parameter, although, there is not clear evidence whether the levels of xerostomia and salivary flow rates influence OHRQoL.[10–12] Therefore, the aim of this study was to evaluate the impact of xerostomia and hyposalivation in OHRQoL in patients with pSS using the OHIP-14 questionnaire.

2 | MATERIALS AND METHODS

2.1 | Study design and participants

The present study is a cross-sectional observational study using the STROBE guidelines for reporting. This study is part of the EPOX-SSp project between the network of rheumatology hospital services in the Community of Madrid (Spain) and the Department of Dental Clinical Specialties at the Faculty of Odontology in the Complutense University of Madrid (Spain).[13] Patients over 18 years old diagnosed of pSS according to the American-European Criteria of 2002[14] between October 2015 and June 2017 were invited to participate. These patients signed an informed consent approved by the Ethics Committee at the Hospital La Paz, Madrid (no: HULP PI-1891) and followed investigational procedures according to the principles of Helsinki and its following revisions. Recruited patients were subsequently evaluated in the Faculty of Odontology for their oral related assessment. If patients had a history of another connective tissue disease they were excluded. The rheumatologist selected the patients and listed the pSS and demographic features. Selected patients were told to get in contact with the Oral Medicine Postgraduate Program at the Department of Dental Clinical Specialties, Faculty of Dentistry at Complutense University of Madrid in Spain, where the study was conducted.

2.2 | Salivary flow rates

Unstimulated (UWS) and stimulated whole salivary (SWS) flows were obtained between 8.00 and 10.00 am by a specialist in oral medicine (LR). Patients were previously advised not to drink, eat, smoke, or brush their teeth at least 1 h and a half prior to the appointment. Patients were advised to be relaxed and to try to spit out all the saliva in a graduated sterile plastic tube. First, UWS flow was collected for 15 min by drooling method. Subsequently, to collect SWS flow, patients were asked to chew an unflavored paraffin gum (1 g) (Ivoclar Vivadent, Schaan, Lichtenstein) for 10 min and during that time SWS flow was collected. These flow rates were recorded in mL/min. Hyposalivation was considered when UWS flow was <0.1 ml/min and SWS flow <0.7 ml/min. Furthermore, the degree of hyposalivation measured by UWS flow was categorized into two groups (<0.1 ml/min and ≥0.1 ml/min) and SWS into three different groups (<0.1 ml/min, 0.1–0.7 ml/min, and >0.7 ml/min) following the European League Against Rheumatism (EULAR) recommendations for the management of Sjögren's syndrome.[15]

2.3 | DMFT index

Every patient had a complete dental examination by a specialist in oral medicine (JS) in which the DMFT (decayed-missing-filled teeth) index and its components were calculated. Third molars were excluded, thus being the maximum possible score 28 points.[16]

2.4 | Patient reported outcomes measures (PROMs)

For assessing OHRQoL, the Spanish version of the OHIP-14 questionnaire was used.[17] This tool consists of 14 items organized into seven categories (functional limitations, physical pain, psychological discomfort, physical disability, social disability, and handicap). Responses are measured on a scale ranging from 0 to 4, being 0 = never and 4 = always. The sum of such ratings from the 14 questions generates a total score which could range from 0 to 56, where the higher the score indicates the lower OHRQoL.

Based on Vitali's pSS diagnosis criteria,[14] a patient was considered to have xerostomia if he/she answered "yes" to at least one of the following questions: (1) Have you had a daily feeling of dry mouth for more than 3 months? (2) Do you frequently drink liquids to aid in swallowing dry food?

To assess the self-reported level of xerostomia in these patients, a visual analog scale (VAS) was used.[18] This scale was made up of eight items: dryness of oral mucosa (lips, mouth, tongue, and throat), difficulty in swallowing and speaking caused by dryness, presence of saliva in the mouth and level of thirst. Patients were asked to mark their responses to each item from 1 to 10 (10 maximum) by drawing a vertical line on the horizontal scale.

2.5 | Sample size calculation

The primary objective was to evaluate the correlation between the results of the UWS flow and those of the OHIP-14 questionnaire. Sample size was calculated using the previous correlation obtained between UWS and OHIP-14 ($r = -0.46$) reported by Stewart et al.[11] Using the appropriate formula[19] and assuming a power of 95% and two-tailed $\alpha = 0.05$, 56 participants were considered.

2.6 | Statistical analysis

Categorical data were shown as number and percentage while continuous variables as means (SD). Categorical variables were compared using chi-square test or Fisher's exact test. Kolmogorov–Smirnov goodness-of-fit was used to determine the normal distribution of the quantitative variables. Mann–Whitney *U* was used to analyze the association between categorical and numerical variables. Kruskall–Wallis's test with Bonferroni correction were used for multiple comparisons. Spearman's rank correlation (*r*) coefficient was calculated to analyze the correlations between two quantitative variables. Multiple linear regression tests were performed to predict OHIP-14. Variables stayed in the models if they were significant predictors of OHIP-14 when a criterion of a 10% change in estimate was used. Differences were considered significant when *p* was ≤0.05. Data was analyzed using SPSS version 27.0 (SPSS inc.).

3 | RESULTS

3.1 | Study sample

Sixty-seven subjects attended the oral medicine clinics at the Complutense University of Madrid where they were evaluated. Among them, 61 patients (60 women, one man) fulfilled the inclusion criteria proposed by the AECG (2002) and were included. The mean time of disease diagnosis was 103.90 (81.35) months. Mean age was 57.64 (13.52). The clinical features and serological manifestations from this selected sample of pSS patients are depicted in Table 1.

TABLE 1 pSS clinical characteristics

Variables	Mean (SD) or *n* (%)
Age	57.64 (13.52)
Sex	
Male	1 (1.6%)
Female	60 (98.4%)
Smokers	8 (13.1%)
Cigarettes/day	0.75 (3.05)
Time since diagnosis of pSS/months	103.9 (81.35)
pSS characteristics (Vitali et al.[14])	
Oral symptoms	59 (96.7%)
Ocular symptoms	61 (100%)
Salivary gland involvement	32 (52.5%)
Ocular signs	53 (86.9%)
Histopathology (minor salivary glands)	32 (52.5%)
Autoantibodies (anti-Ro/anti-La)	55 (90.2%)
UWS hyposalivation	37 (60.7%)
SWS hyposalivation	34 (55.7%)

TABLE 2 OHIP-14 score results

OHIP-14 domains	Mean (SD)
Functional limitation	**3.80 (2.21)**
Trouble pronouncing words	2.00 (1.28)
Worsened taste	1.72 (1.54)
Physical pain	**4.72 (2.20)**
Aching in mouth	1.95 (1.49)
Discomfort eating food	2.61 (1.32)
Psychological discomfort	**4.23 (3.00)**
Feeling self-conscious	2.31 (1.32)
Feeling tense	2.05 (1.60)
Physical discomfort	**2.97 (2.48)**
Poor diet	1.46 (1.40)
Interrupted meals	1.39 (1.44)
Physical disability	**3.03 (2.66)**
Difficulty relaxing	1.43 (1.40)
Embarrassment	1.21 (1.42)
Social disability	**2.38 (2.33)**
Irritability with other people	1.08 (1.32)
Difficulties doing usual jobs	1.57 (1.45)
Handicap	**2.57 (2.52)**
Life less satisfying	1.57 (1.45)
Inability to function	0.92 (1.24)
Total score	**23.13 (14.16)**

3.2 | Salivary flow rates, DMFT index, and PROMs

The percentage of pSS patients suffering from hyposalivation according to UWS and SWS salivary flow rates was 60.7% and 55.7%,

respectively, being their mean UWS and SWS flow rates 0.12 (0.16) and 0.68 (0.68) ml/min, respectively.

The mean number of DMFT index was 16.91 (8.28) in these patients: being 1.46 (2.71) decayed, 6.63 (8.38) missing and 8.84 (6.34) filled teeth.

The mean OHIP-14 score was 23.13 (14.16). The mean scores for each domain and question are depicted in Table 2. The mean xerostomia VAS score was 46.69 (14.43). The mean scores for each item are depicted in Table 3.

3.3 | Associations and correlations

When comparing VAS for xerostomia between the two categorized groups of UWS (<0.1 and ≥0.1 ml/min), we observed that patients with a salivary flow lower than 0.1 ml/min obtained significant greater scores of VAS for xerostomia ($p = 0.034$) and OHIP-14 ($p = 0.001$). If we observe the results of the categorized SWS groups (<0.1, 0.1–0.7, and >0.7 ml/min) we can notice how the differences in VAS for xerostomia among the groups were statistically significant ($p = 0.013$). But the VAS scores in the group with <0.1 ml/min was lower than in the rest of the groups. When applying the Bonferroni correction, we observed significant differences only between the group with levels <0.1 and the group with 0.1–0.7 ml/min ($p = 0.012$) and between the group with 0.1–0.7 and the group >0.7 ml/min ($p = 0.033$). In the case of OHIP-14, no significant differences were observed among the three groups, but it was observed that OHIP-14 values were higher the lower the salivary flow rate (Table 4).

Similarly, the OHIP-14 total score was significantly associated with xerostomia ($p = 0.001$) and with hyposalivation measured by UWS flow ($p = 0.002$) and by SWS flow ($p = 0.02$) (Table 5). There was also a significant association between those patients' experiencing xerostomia and the total VAS scores ($p = 0.006$), as well as with hyposalivation measured by UWS flow ($p = 0.01$), but not with SWS flow ($p = 0.15$).

There was a statistically significant negative correlation between UWS and OHIP-14 total score ($r = -0.34$; $p = 0.006$). However, the negative correlation between SWS and OHIP-14 score was not significant ($r = -0.24$; $p = 0.06$) (Table 6). Furthermore, there was a positive significant correlation between the OHIP-14 total score and the total VAS score for xerostomia ($r = 0.52$; $p = 0.001$). However, the correlations between UWS flow rate ($r = -0.22$; $p = 0.09$) and between SWS ($r = -0.11$; $p = 0.9$) and the total VAS score for xerostomia were not significant.

The correlations between overall DMFT index and OHIP-14 score were also non-significant ($r = 0.04$; $p = 0.75$). Similarly, when analyzing each item of the DMFT index versus the OHIP-14 total score, the correlations were not significant: decayed teeth and total OHIP-14 score ($r = 0.11$; $p = 0.93$); missing teeth and total OHIP-14 score ($r = 0.71$; $p = 0.59$) nor filling teeth with total OHIP-14 score ($r = 0.38$; $p = 0.77$).

3.4 | Multiple linear regression

Two models were realized. The first model included OHIP-14 as dependent variable and as independent variables included gender, age, time from pSS diagnosis, number of cigarettes, xerostomia (yes/no), VAS for xerostomia, DMFT, UWS and SWS flow rates, UWS and SWS hyposalivation, and SWS flow categorized. This model showed that all these variables statistically significantly predicted OHIP-14 results, $F(12,47) = 4.29$, $p < 0.001$, $R^2 = 0.523$. The independent variables included explained the 52.3% of the variability of our dependent variable (OHIP-14). Only the result of VAS for xerostomia contributed statistically significantly to the prediction ($p < 0.001$). The next variable to contribute to the prediction was UWS hyposalivation but it was not significant ($p = 0.068$) (Table 7).

TABLE 3 VAS for xerostomia results

VAS score	Mean (SD)
Dry lips	5.15 (2.99)
Dry mouth	5.41 (2.84)
Dry tongue	4.00 (2.87)
Dry throat	6.70 (2.82)
Difficulty in swallowing	5.97 (2.98)
Difficulty in speaking	6.74 (2.60)
Amount of saliva	6.26 (3.79)
Level of thirst	6.36 (2.74)
Total score	46.69 (14.43)

TABLE 4 Associations between VAS scale and OHIP-14 among the groups of UWS and SWS levels

UWS levels	**<0.1 ml/min ($n = 37$)**		**≥0.1 ml/min ($n = 24$)**	***p***
VAS for xerostomia	49.97 (16.41)		41.96 (9.40)	$p = 0.034$*
OHIP-14	28.36 (12.58)		15.60 (13.06)	$p = 0.001$*
SWS levels	**<0.1 ml/min ($n = 13$)**	**0.1–0.7 ml/min ($n = 21$)**	**>0.7 ml/min ($n = 27$)**	***p***
VAS for xerostomia	41.00 (16.85)	54.29 (12.81)	43.52 (12.24)	$p = 0.013$*
OHIP-14	27.85 (12.48)	25.38 (13.18)	19.11 (15.01)	$p = 0.11$

Note: Mann–Whitney *U* test was used to analyze the results regarding UWS; Kruskall–Wallis test with Bonferroni correction was used to analyze the results regarding SWS; *Significant.

TABLE 5 Associations between OHIP-14 and xerostomia (yes/no), UWS hyposalivation, SWS hyposalivation

	Xerostomia[a]		UWS hyposalivation[a]		SWS hyposalivation[a]	
OHIP-14 domains	**Yes ($N = 56$)**	**No ($N = 5$)**	**Yes ($N = 37$)**	**No ($N = 24$)**	**Yes ($N = 33$)**	**No ($N = 28$)**
Functional limitation	4.02 (2.15)	1.40 (1.34)	4.35 (2.21)	2.96 (1.97)	4.48 (1.97)	3 (2.24)
	$p = 0.01$*		$p = 0.01$*		$p = 0.09$*	
Trouble pronouncing words	2.11 (1.26)	0.80 (0.84)	2.27 (1.26)	1.58 (1.21)	2.21 (1.17)	1.75 (1.38)
	$p = 0.02$*		$p = 0.03$*		$p = 0.16$	
Worsened taste	1.84 (1.55)	0.40 (0.55)	1.92 (1.66)	1.42 (1.36)	2.09 (1.59)	1.29 (1.38)
	$p = 0.05$*		$p = 0.26$		$p = 0.04$*	
Physical pain	4.96 (2.05)	2.00 (2.12)	5.24 (2.05)	3.92 (2.22)	5.18 (2.40)	4.18 (2.40)
	$p = 0.01$*		$p = 0.02$*		$p = 0.07$*	
Aching in mouth	2.07 (1.47)	1.95 (1.49)	2.14 (1.49)	1.67 (1.47)	2.03 (1.47)	1.86 (1.53)
	$p = 0.03$*		$p = 0.23$		$p = 0.66$	
Discomfort eating food	2.71 (1.29)	1.40 (1.14)	2.97 (1.17)	2.04 (1.37)	3 (1.17)	2.14 (1.35)
	$p = 0.03$*		$p = 0.007$*		$p = 0.01$*	
Psychological discomfort	4.54 (2.93)	0.80 (0.84)	5.22 (2.85)	2.71 (2.61)	5 (2.89)	3.32 (2.91)
	$p = 0.01$*		$p = 0.002$*		$p = 0.04$*	
Feeling self-conscious	2.50 (1.51)	0.20 (0.45)	2.70 (1.47)	1.71 (1.60)	2.61 (1.49)	1.96 (1.64)
	$p = 0.004$*		$p = 0.02$*		$p = 0.13$	
Feeling tense	2.21 (1.57)	0.20 (0.45)	2.62 (1.48)	1.17 (1.40)	2.52 (1.44)	1.50 (1.64)
	$p = 0.009$*		$p = 0.001$*		$p = 0.02$*	
Physical discomfort	3.20 (2.45)	0.40 (0.55)	3.89 (2.38)	1.54 (1.91)	3.82 (2.39)	1.96 (2.19)
	$p = 0.02$*		$p = 0.001$*		$p = 0.02$*	
Poor diet	1.57 (1.39)	0.20 (0.45)	1.95 (1.41)	0.71 (0.99)	1.85 (1.39)	1 (1.28)
	$p = 0.02$*		$p = 0.001$*		$p = 0.01$*	
Interrupted meals	1.52 (1.44)	0	1.78 (1.44)	0.79 (1.25)	1.79 (1.39)	0.93 (1.39)
	$p = 0.02$*		$p = 0.006$*		$p = 0.01$*	
Psychological disability	3.29 (2.63)	0.20 (0.45)	3.70 (2.68)	2.00 (2.34)	2.70 (2.04)	2 (2.62)
	$p = 0.01$*		$p = 0.001$*		$p = 0.12$	
Difficulty relaxing	1.73 (1.53)	0	1.92 (1.55)	1.08 (1.41)	1.82 (1.47)	1.32 (1.61)
	$p = 0.012$*		$p = 0.3$		$p = 0.16$	
Embarrassment	1.55 (1.39)	0	1.81 (1.41)	0.83 (1.17)	1.70 (1.38)	1.11 (1.37)
	$p = 0.01$*		$p = 0.008$*		$p = 0.09$	
Social disability	2.57 (2.33)	0.20 (0.45)	2.81 (2.12)	1.71 (2.53)	2.70 (2.03)	2 (2.62)
	$p = 0.02$*		$p = 0.03$*		$p = 0.10$	
Irritability with other people	1.32 (1.44)	0	1.46 (0.23)	0.83 (1.37)	1.04 (1.57)	1.36 (1.29)
	$p = 0.03$*		$p = 0.06$		$p = 0.17$	
Difficulties doing usual jobs	1.18 (1.33)	0	1.27 (1.33)	0.79 (1.28)	1.24 (1.26)	0.89 (1.42)
	$p = 0.03$*		$p = 0.08$		$p = 0.11$	
Handicap	2.79 (2.52)	2.57 (2.52)	3.19 (2.49)	1.63 (2.32)	2.11 (2.67)	2.97 (2.36)
	$p = 0.02$*		$p = 0.02$*		$p = 0.12$	
Life less satisfying	1.71 (1.44)	0	1.97 (1.36)	0.96 (1.39)	1.85 (1.35)	1.25 (1.53)
	$p = 0.01$*		$p = 0.009$*		$p = 0.10$	
Inability to function	1.00 (1.26)	0	1.14 (1.34)	0.58 (1.02)	1.03 (1.12)	0.79 (1.28)
	$p = 0.07$*		$p = 0.07$*		$p = 0.28$	
Total score	33.20 (1859)	6.40 (32)	27.7 (13.03)	16.08 (13.11)	27 (12.35)	18.57 (15)
	$p = 0.001$*		$p = 0.002$*		$p = 0.02$*	

Note: *Significant.

[a]Mann–Whitney *U* test.

TABLE 6 Correlation between OHIP-14 and UWS and SWS salivary flow

OHIP-14 domains	UWS salivary flow[a]	SWS salivary flow[a]
Functional limitation	$r = -0.33$; $p = 0.009$*	$r = -0.31$; $p = 0.01$*
Trouble pronouncing words	$r = -0.26$; $p = 0.042$*	$r = -0.15$; $p = 0.25$
Worsened taste	$r = -0.20$; $p = 0.12$	$r = -0.24$; $p = 0.06$
Physical pain	$r = -0.29$; $p = 0.02$*	$r = -0.10$; $p = 0.41$
Aching in mouth	$r = -0.11$; $p = 0.38$	$-r = 0.05$; $p = 0.70$
Discomfort eating food	$r = -0.37$; $p = 0.003$*	$r = -0.25$; $p = 0.05$*
Psychological discomfort	$r = -0.34$; $p = 0.007$*	$r = -0.24$; $p = 0.06$
Feeling self-conscious	$r = -0.24$; $p = 0.06$*	$r = -0.18$; $p = 0.16$
Feeling tense	$r = -0.34$; $p = 0.007$*	$r = -0.29$; $p = 0.02$*
Physical discomfort	$r = -0.39$; $p = 0.002$*	$r = -0.33$; $p = 0.01$*
Poor diet	$r = -0.36$; $p = 0.005$*	$r = -0.28$; $p = 0.02$*
Interrupted meals	$r = -0.34$; $p = 0.008$*	$r = -0.21$; $p = 0.10$
Psychological disability	$r = -0.26$; $p = 0.004$*	$r = -0.15$; $p = 0.24$
Difficulty relaxing	$r = -0.21$; $p = 0.09$	$r = -0.13$; $p = 0.32$
Embarrassment	$r = -0.29$; $p = 0.02$*	$r = -0.19$; $p = 0.13$
Social disability	$r = -0.19$; $p = 0.12$	$r = -0.08$; $p = 0.53$
Irritability with other people	$r = -0.21$; $p = 0.1$	$r = -0.07$; $p = 0.6$
Difficulties doing usual jobs	$r = -0.15$; $p = 0.25$	$r = -0.10$; $p = 0.43$
Handicap	$r = -0.25$; $p = 0.04$*	$r = -0.18$; $p = 0.17$
Life less satisfying	$r = -0.30$; $p = 0.02$*	$r = -0.22$; $p = 0.08$
Inability to function	$r = -0.16$; $p = 0.2$	$r = -0.08$; $p = -0.49$
Total score	$r = -0.34$; $p = 0.006$*	$r = -0.24$; $p = 0.06$

Note: *Significant.
[a]Spearman's correlation test.

TABLE 7 Multiple linear regression analysis (Model 1)

		95% Confidence interval		
Variables	Coefficient B	Lower limit	Upper limit	*p*
Sex	10.38 (17.45)	−24.72	45.48	0.55
Age	−0.13 (0.15)	−0.43	0.16	0.36
Time since diagnosis of pSS/months	−0.02 (0.02)	−0.06	0.03	0.45
Cigarettes/day	−0.36 (0.50)	−1.37	0.65	0.48
Xerostomia (yes/no)	8.89 (6.74)	−4.67	22.43	0.19
VAS for xerostomia	0.49 (0.11)	0.27	0.73	<0.001
DMFT	0.007 (0.21)	−0.42	0.44	0.97
UWS flow rate	19.05 (17.95)	−17.06	55.16	0.29
SWS flow rate	6.53 (4.56)	−2.65	15.70	0.16
UWS hyposalivation	9.83 (5.26)	−0.76	20.42	0.068
SWS hyposalivation	0.74 (7.44)	−14.24	15.70	0.92
SWS flow categorized	−6.63 (4.24)	−15.16	1.90	0.12

A second model was performed including only the quantitative variables (age, time from pSS diagnosis, number of cigarettes, VAS for xerostomia, DMFT, UWS and SWS flow rates) as some of the variables of the first model could be correlated with each other. The model also selected all the included variables. The model fit was worse than the previous one $F(7,52) = 4.26$, $p < 0.001$, $R^2 = 0.365$. This model only explained the 36.5% of the variability of OHIP-14 results. But this one also only selected VAS for xerostomia as a statistically significant predictor ($p < 0.001$) (Appendix A).

4 | DISCUSSION

The results from the present observational study have shown a positive significant correlation between VAS for xerostomia results and OHIP score, and a negative significant correlation between UWS flow and OHIP-14 score. Furthermore, when comparing the mean results from the OHIP-14 questionnaire with the results from then UWS flow categorized by groups, a significant association was found, meaning that the OHIP-14 total score was higher in those patients with lower UWS flow. The multiple linear regression model, however, only obtained statistical significance for the variable VAS for xerostomia, so this variable seems to be the most influential in the OHIP-14 results. These results, therefore, corroborate that the use of the OHIP-14 questionnaire is a reliable tool for evaluating how the degree of xerostomia affects the OHRQoL of patients affected by pSS. These results are also in line with other studies reporting a decrease of the OHRQoL in pSS patients, comparing their OHIP-14 scores versus a control group.[19–24]

The obtained mean total OHIP-14 score of 23.13 (14.16) agrees with results reported in SS patients by Stewart et al.,[11] with a mean OHIP-14 total score of 23.7 and by Amaral et al.,[12] with a mean total OHIP-14 of 21.2 (11.7). Compared with a healthy Spanish control group, similar in age and gender to our study group, it could be observed that the OHIP-14 score was higher in the present pSS group: 23.13 (14.16) versus 0.80 (2.81)[25] or 5.83 (3.78).[26]

When analyzing each domain of the OHIP-14 questionnaire, the highest oral impact was observed for the domains "physical pain" with a mean score (SD) 4.72 (2.20) and "psychological discomfort" with mean score (SD) of 2.97 (2.48). These results may be related to the difficulties in daily activities such as eating, swallowing, speaking, or wearing dentures, which are common complaints of pSS patients. Also, these results agree with the previously referenced studies which also reported the highest ratings for those two domains.[11,12]

Although hyposalivation is one of the main signs in pSS patients, its correlation with self-reported QoL has been scarcely studied and the few existing studies did not find a significant correlation between the OHIP-14 total score and salivary flow rates. In the study by Amaral et al.,[12] a negative correlation between UWS and OHIP-14 was reported but without reaching statistical significance, except for the domain "physical pain." Similarly, Azuma et al.,[27] reported a weak and non-significant correlation between the OHIP-14 scores and UWS flow and Rusthen et al.,[10] reported a weak correlation between the mean OHIP-14 score and the salivary flow rate. Considering these

unclear findings, we have measured in the present study the pSS patients' salivary flow by UWS and SWS, as well as their self-reported sensation of xerostomia and have correlated these results with the OHRQoL assessed with the OHIP-14 questionnaire. Our results showed a significant negative correlation between UWS flow rate and OHIP-14 results and a non-significant negative correlation between SWS flow and OHIP-14. Moreover, the results of this study show a significant association between UWS hyposalivation and the total OHIP-14 score. The regression model showed how UWS hyposalivation was predictor variable, which was nearly significant ($p = 0.06$). These results, therefore, are in accordance with the most recent criteria for the SS diagnosis[27] and the ones proposed by Vitali et al.,[14] which only consider the UWS flow for the diagnosis of SS. Some authors,[28] however, have argued that the UWS can be influenced by factors, such as the age, use of medications, etc., and have proposed the use of SWS flow as a more reliable method of assessing the glandular function in pSS. The present research has analyzed how different levels of salivary flow rates may influence the OHIP-14 in pSS. When comparing UWS flow rate <0.1 and ≥0.1 ml/min, we observed significant differences in terms of OHIP-14 scores. But no association was observed among the categorized groups of SWS (<0.1, 0.1–0.7, and >0.7 ml/min) and OHIP-14 questionnaire scores. Therefore, the OHIP-14 questionnaire could be helpful in assessing OHRQoL related to changes in UWS flow over time and to assess the response to xerostomia treatments given to these patients.

The results of the present study show that the OHIP-14 questionnaire is a good method to assess how xerostomia and hyposalivation may affect OHRQoL. Baker et al.,[29] also reported that results from the OHIP-14 questionnaire were a good tool for assessing OHRQoL in relation with xerostomia in rheumatic patients. In this study the validity of two questionnaires on OHRQoL, the OHIP-14 and the "Oral Impacts on Daily Performance" was compared, with the OHIP-14 questionnaire showing the best overall results. In this group of pSS patients, the results from the OHIP-14 tool were significantly associated with the self-reported questions and VAS scores for assessing xerostomia, what may imply that the OHIP-14 is a test that can reflect the intensity of dry mouth experienced by the patient. In fact, the variable VAS for xerostomia was the only variable that significantly influenced the linear regression model. Although different questionnaires and scales have been used for assessing xerostomia in SS patients, only one study has demonstrated a correlation between the decrease in UWS flow rate and the VAS scores for xerostomia.[24] These authors reported a negative significant correlation between UWS levels and VAS scores for xerostomia. In the present study, this correlation between UWS flow rate and total VAS score for xerostomia was positive and statistically significant. Therefore, the level of xerostomia suffered by the patient clearly influences the patient's QoL. The greater the degree of xerostomia, the greater the outcome of OHIP-14 and hence the worse the quality of life.

We also evaluated the dental health status of these patients using the DMFT index and tried to correlate these results with the perceived pSS OHRQoL. The lack of statistical association between the highest DMFT index and OHIP-14 scores is difficult to interpret since there are no previous studies assessing this association. Moreover, our DMFT index results were compared with the DMFT data of the Spanish cohort among 65–74 years old in 2020,[30] not observing big differences between our results (16.91 [8.28]) and theirs (14.99), meaning that the present pSS group does not have a worse dental status than the general Spanish population. Thus, our findings manifest that the scores of OHRQoL in the pSS patients of the present study are presumably due to xerostomia, and not to dental health condition, since the multiple linear regression model did not offer significant values ($p = 0.97$) for this variable.

Being a cross-sectional observational study, this clinical investigation has clear limitations since this data only represents a snapshot at a particular time point and does not reflect how the disease process and the impact of other confounding factors may influence the relationship between the oral affectation of pSS and their QoL. Therefore, there is a need of prospective studies evaluating the real impact of salivary flow rate variations in the OHRQoL of these patients suffering from pSS.

5 | CONCLUSION

In conclusion, this study shows that the OHIP-14 questionnaire is a reliable tool for assessing OHRQoL associated with salivary disorders such as xerostomia and hyposalivation in pSS patients.

AUTHOR CONTRIBUTIONS

Mónica Fernández-Castro: conceptualization; methodology; project administration; funding acquisition. Rosa María López-Pintor: conceptualization; investigation; methodology; project administration; statistical analysis; data curation; supervision; writing-review & editing. EPOX-SSp group: data acquisition. Lucía Ramírez: investigation; data acquisition. Julia Serrano: investigation; data acquisition; data interpretation; writing original draft; writing-review & editing. Gonzalo Hernández: supervision; writing-review & editing. Mariano Sanz: supervision; data interpretation; writing-review & editing.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

PEER REVIEW

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DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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