Validation of oral health impact profile-14 and its association with hypossialia in a Sjögren's Syndrome Portuguese population

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ABSTRACT

Aims: The objective of this study was to perform the Portuguese transcultural adaptation of the original Brazilian version of the Oral Health Impact Profile-14 (OHIP-14) while evaluating the association between hyposalivation and quality of life in a Sjögren's Syndrome population.

Methods: The original Brazilian version of the Oral Health Impact Profile-14 was culturally adapted following the guidelines for cross-cultural adaptation of health-related quality of life measures. The questionnaires were administered by trained and calibrated dental doctors to 86 patients with Sjögren's Syndrome. Oral Health Impact Profile-14 properties were examined, including, reliability, internal consistency and test-retest reliability, using Cronbach's alpha, total and inter-item correlation, and intra-class correlation coefficients, respectively. Whole saliva secretion rates and hyposalivation-related variables were collected and statistically analyzed. Spearman's rho correlations were obtained between salivary flows and OHIP-14 domains and total score. Alpha was set at 0.05. Informed consents and local ethical committee clearance were obtained.

Results: Each question of the questionnaire performed adequately. Cronbach alpha values for the 14 questions were 0.89 for both test administrations and were lower if item removed. Scores for both questionnaire administration and ICC results presented good to excellent reliability with ICC ranging from 84% to 92%. Mean salivary flow rate was 0.05 (SD: 0.03) ml/min and mean stimulated salivary flow was 0.57 (SD: 0.44) ml/min, which are within expected values in a population with hyposalivation.

The results describe a negative and significant correlation between total OHIP-14-PT score, physical pain, physical disability domain and stimulated and differential salivary flows. There was a negative and significant correlation between unstimulated salivary flow with physical pain.

Conclusion: Within the limitations of this study, the OHIP-14-PT seems to be a valid and reliable instrument for measuring oral health related quality of life in patients with Sjögren's Syndrome. Both differential and stimulated salivary flows seem to correlate negatively with age and the quality of life is significantly diminished by lower stimulated salivary flow rates.

Keywords: Epidemiology saliva; Oral health; Psychometrics; Quality of life.

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INTRODUCTION

Autoimmune diseases are known to affect not only the physical well-being of a patient but their psychological and social dimensions as well[1]. Of these, Sjögren's Syndrome (SS) is one of the most prevalent[2] with a primary pathologic feature of lymphocytic infiltrate of the salivary and lacrimal glands[3].

Because of gland involvement, the cardinal signs of SS are lack of tears and saliva being the latter mandatory in maintaining oral cavity homeostasis[4]. In fact, saliva has a whole range of functions: it modulates the digestive process; mediates taste sensations; repairs soft tissue and ensures oral microflora balance as well as enamel remineralization. Most importantly, a whole range of immune and defensive processes take place via salivary proteins[4].

For this homeostasis to be maintained, an adequate

amount of saliva must be secreted[5].

When salivary function is diminished (hyposalivation) several oral complaints, such as xerostomia, generalized oral discomfort, burning mouth and tongue syndrome, traumatic oral lesions, tooth wear, oral soft tissue lesions and microorganism colonization, caries, candidiasis, halitosis, intolerance to acidic and spicy foods, poor retention of dentures, disturbances in taste and mastication, polydipsia, dysgeusia, dysphasia and dysphonia, may occur, as well as periodontal disease, although less frequently[4–6].

Thus, lack of saliva may not only have a negative impact on oral health but also on systemic health as a whole[5] and as such, the development of questionnaires which measure this effect in quality of life (QoL) is desired.

This QoL considers the human body interconnected and as a whole is characterized by both subjective and objective factors that are evaluated by questionnaires. These questionnaires have been widely used in the evaluation of oral health needs and, combined with clinical indicators, are capable of identifying not only patients' symptoms due to oral diseases but also patients' ability to perform their daily activities and so measuring overall QoL[4,5,7–10].

The Oral Health Impact Profile (OHIP 49) is a widely free to use dimension specific questionnaire with 49 questions, that assesses the extent at which oral health influences quality of life by self-reporting dysfunctions, discomforts and disabilities attributed to oral conditions[11,12]. However this is a lengthy and time consuming questionnaire and for that purpose a shorter 14 item questionnaire was developed (OHIP-14)[12,13]. These 14 questions are divided in 7 domains each measuring a different dimension[10], briefly: functional limitation (Q1 and Q2), physical pain (Q3 and Q4), psychological discomfort (Q5 and Q6), physical disability (Q7 and Q8), psychological disability (Q9 and Q10), social disability (Q11 and Q12) and Handicap (Q13 and Q14). The score for the domains are calculated by adding the score of the respective questions and as such have a total possible score of 8. The highest possible score equates to 56 indicating a very poor quality of life.

This instrument has been translated and validated in languages from different regions of the world including Portuguese from Brazil[12,14–20] as well as used in association with other questionnaires like the Geriatric Oral Health Assessment Index (GOHAI)[21]. A comprehensive search for a culturally adapted to Portugal version of this questionnaire on scientific research engines

has not yielded results and for this purpose we have used the Brazilian version already translated[15] and have culturally adapted it to obtain a Oral health impact profile 14 – Portuguese language (OHIP-14-PT). The cross-cultural adaptation of health questionnaires aims at achieving equivalence between the original source and the target versions and is more than the simple linguistic translation of the questions[22–24]. In fact, it relies on an extended adaptation framework designed to maximize the attainment of semantic, idiomatic, experiential, and conceptual matching between both parts of the process. Guidelines have been established for cross-cultural adaptation of health questionnaires underpinning the need for such procedures[22–24].

These are necessary to generate an increased confidence that the impact of a disease or its treatment is described in a similar manner in multinational trials or outcome evaluations[25].

The objective of this study was to culturally adapt the original Portuguese Brazilian version of the OHIP-14 and test its validity and reliability for use among Portuguese adult while determining the relation, if any, between hypossialia and QoL in a population with SS.

MATERIALS AND METHODS

CULTURAL ADAPTATION

The OHIP-14 was adapted following the guidelines for cross-cultural adaptation of health-related measures comparing semantic, idiomatic, experiential, and conceptual equivalence[22–24]. Finally, the resulting OHIP-14-PT was read and commented upon by three different dentists from the field of oral medicine. The final version of OHIP-14-PT is also depicted in Table I.

PATIENTS AND THE INTERVENTION

86 SS participants took part in this trial. The inclusion criteria were: (a) non stimulated salivary flow < 0.1 ml min^{-1}; (b) stimulated salivary flow > 0.2 ml min^{-1}; (c) at least 18 years of age. The exclusion criteria considered were: (a) wearer of full dental prosthesis; (b) Pregnant, lactating; (c) Non-Portuguese Speaker.

All eligible participants gave their written consent at the first stage of screening and before study admission. All patients had a full medical history, and saliva samples were collected at the Instituto Português de Reumatologia (IPR) by a research team of the Faculdade de Medicina Dentária da Universidade de Lisboa (FMDUL).

TABLE I. ORIGINAL, BRAZILIAN AND PORTUGUESE VERSION OF ORAL HEALTH IMPACT PROFILE 14[15].

Original	Brazilian	Adaptation
Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures	Você teve problemas para falar alguma palavra por causa de problemas com seus dentes, sua boca ou prótese dentária?	Teve problemas em pronunciar alguma palavra?
Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?	Você sentiu que o sabor dos alimentos ficou pior por causa de problemas com seus dentes, sua boca ou prótese dentária?	Sentiu que o sabor dos alimentos tem piorado?
Have you had painful aching in your mouth?	Você sentiu dores em sua boca ou nos seus dentes?	Sentiu dores na sua boca ou nos seus dentes?
Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?	Você se sentiu incomodado ao comer algum alimento por causa de problemas com seus dentes, sua boca ou prótese dentária?	Sentiu-se desconfortável ao comer algum alimento?
Have you been self-conscious because of your teeth, mouth or dentures?	Você ficou preocupado por causa de problemas com seus dentes, sua boca ou prótese dentária?	Sentiu-se preocupado(a)?
Have you felt tense because of problems with your teeth, mouth or dentures?	Você sentiu-se estressado por causa de problemas com seus dentes, boca ou prótese dentária?	Sentiu-se nervoso(a)?
Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?	Sua alimentação ficou prejudicada por causa de problemas com seus dentes, sua boca ou prótese dentária?	A sua alimentação ficou prejudicada?
Have you had to interrupt meals because of problems with your teeth, mouth or dentures?	Você teve que parar suas refeições por causa de problemas com seus dentes, sua boca ou prótese dentária?	Teve que interromper as suas refeições?
Have you found it difficult to relax because of problems with your teeth, mouth or dentures?	Você encontrou dificuldades para relaxar por causa de problemas com seus dentes, boca ou prótese dentária?	Encontrou dificuldade para relaxar?
Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?	Você sentiu-se envergonhado por causa de problemas com seus dentes, boca ou prótese dentária?	Sentiu-se envergonhado(a)?
Have you been a bit irritable with other people because of problems with your teeth or mouth?	Você ficou irritado com outra pessoa por causa de problemas com seus dentes, sua boca ou prótese dentária?	Ficou irritado(a) com as outras pessoas?
Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?	Você teve dificuldade em realizer as suas actividades diárias por cause de problemas com seus dentesm sua boca ou prótese dentária?	Teve dificuldade em realizar as suas tarefas diárias?
Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?	Você sentiu que a vida, em geral, ficou pior por causa de problemas com seus dentes, sua boca ou prótese dentária?	Sentiu que a sua vida, em geral, ficou pior?
Have you been totally unable to function because of problems with your teeth, mouth or dentures?	Você ficou totalmente incapaz de fazer as suas atividades diárias por causa de problemas com seus dentes, sua boca ou prótese dentária?	Ficou totalmente incapacitado para realizar as suas atividades?
Scoring		
Never (0)	Nunca (0)	Nunca (0)
Rarely (1)	Quase Nunca (1)	Raramente (1)
Sometimes (2)	Ocasionalmente (2)	Às vezes (2)
Repeatedly (3)	Bastantes vezes (3)	Repetidamente (3)
Always (4)	Frequentemente (4)	Sempre (4)

The ethical committees of the participating institutions approved the study protocol, which was conducted in full compliance with the World Medical Association Declaration of Helsinki and its most recent amendments and always followed good clinical practice guidelines.

Each patient answered to the OHIP-14-PT version of the questionnaire in the form of a standardized interview. Participants were told that each question had no definitive right answer and were instructed to give the answer that immediately came to mind.

Participants were told to request to the interviewer for additional clarification or to repeat the question if they could not understand before providing a response. This procedure was repeated with a 2-week interval, in order to evaluate the test-retest reliability of the OHIP-14-PT.

Saliva was collected expressly for this study by established methods[26–29] to determine and evaluate its association with QoL.

STATISTICAL ANALYSES
DATA ANALYSIS
To analyze the data, the SPSS program (version 22.0; Chicago, IL, USA) was used. Patients who failed to answer more than two questions were removed from the study[30].

The dependent variable was the OHIP-14-PT overall score and its domains, expressed as the summated score ± standard deviation (SD). Significance was set at $\alpha = 0.05$.

Floor and ceiling effects were assessed on the first administration of the questionnaire for the determination of content validity and were considered to be present if more than 15% of the patients achieved the highest or the lowest possible scores[25].

INTERNAL CONSISTENCY
Internal consistency of the OHIP-14-PT was assessed by calculating Cronbach's alpha. Values of Cronbach alpha of at least 0.80 were considered good[31].

Despite only 14 questions, inter-item correlations were calculated to determine the possibility of inflation of the Cronbach alpha because of questionnaire length[32].

All questions were correlated with the overall score (item-total correlation) and also evaluated whether Cronbach's alpha was improved by removal of any item. For the scales to be considered sufficiently reliable for use in groups of patients, inter-item correlation should be above 0.4 although values above 0.2 could be considered acceptable[33,34].

TEST-RETEST RELIABILITY
After a 2-week interval, each patient was administrated once again the OHIP-14-PT questionnaire. Test-retest reliability of the OHIP-14-PT total score and subscore for every question was assessed by calculating intra-class correlation coefficients (1) – model: two-way random; type: absolute agreement – and 95% confidence intervals (CI). ICCs were interpreted according to Fleiss, namely ICC < 0.40 = poor; ICC > 0.40 but ICC < 0.75 = fair to good reliability; and ICC > 0.75 = excellent reliability[35].

CORRELATIONS
To determine the relationship between hypossialia with Quality of life, Spearman's rho correlations were obtained between total OHIP-14-PT scores and domains with unstimulated, stimulated and differential salivary flows. It was hypothesized a priori that a negative correlation existed between saliva production and OHIP-14-PT scores.

RESULTS
There were no difficulties in culturally adapting the questionnaire. Idiomatic equivalences were discussed, and consensus reached between members of the panel. The final version was considered to be perfectly understood by any Portuguese speaking person.

Data on the demographic and salivary characteristics of the data set are presented in Table II.

Data on internal consistency for each question is presented in Table III. Positive correlations between all items in the analysis of the matrix of the inter-items correlation coefficients were found. The value of coefficients ranged from 0.10 to 0.71 with the significance level at p < 0.01. Average inter-item correlations were 0.43. The item total correlations and contribution for scale stability and variance are also presented. The results presented a similar and homogeneous contribution for scale dimensionality for each item in the scale.

Scores for both questionnaire administration and ICC results showed excellent reliability with ICC ranging from 75% to 95%. ICC for the 7 domains of the scale ranged from 88% to 92% with the exception of the functional limitation domain with 84% correlation.

Cronbach alpha values for the 14 questions were 0.89 for both test administrations, respectively, and were lower if item removed. These results suggest that all 14 questions contribute positively to the questionnaire's internal consistency.

Mean total OHIP-14-PT scores and standard devia-

TABLE II. DEMOGRAPHIC AND SALIVARY CHARACTERISTICS OF SAMPLED POPULATION (N=86). THESE VALUES ARE WITHIN EXPECTED VALUES IN A POPULATION WITH HYPOSALIVATION

	Mean	Standard Deviation
Unstimulated Salivary Flow	0.05	0.03
Stimulated salivary flow	0.53	0.44
Age	57.7	13.1
Gender	Female – 85 Male – 1	

TABLE III. INTRA-CLASS CORRELATION COEFFICIENT (ICC) AND INTER-TOTAL COEFFICIENT (ITC) ARE DISPLAYED

Questions	ICC	Min	Max	ITC
Question 1	0.90	0.84	0.93	0.49
Question 2	0.79	0.67	0.86	0.37
Question 3	0.92	0.88	0.95	0.57
Question 4	0.91	0.87	0.94	0.62
Question 5	0.88	0.82	0.92	0.55
Question 6	0.94	0.90	0.96	0.67
Question 7	0.92	0.88	0.95	0.79
Question 8	0.91	0.86	0.94	0.61
Question 9	0.90	0.84	0.93	0.61
Question 10	0.86	0.78	0.91	0.65
Question 11	0.82	0.73	0.88	0.56
Question 12	0.95	0.93	0.97	0.62
Question 13	0.90	0.85	0.94	0.58
Question 14	0.75	0.61	0.83	0.37
Total Score	0.94	0.91	0.97	n/a

TABLE IV. MEAN SCORES AND STANDARD DEVIATION FOR THE DOMAINS OF BOTH ADMINISTRATIONS OF THE PORTUGUESE VERSION OF THE OHIP-14-PT QUESTIONNAIRE

Domains	First Round		Second Round	
	Mean	SD	Mean	SD
Functional Limitation	2.9	2.1	2.9	1.8
Physical Pain	3.7	2.2	3.7	2.1
Psychological Discomfort	4.3	2.6	4.3	2.6
Physical Disability	2.5	2.3	2.6	2.3
Psychological Disability	2.8	2.1	2.9	1.9
Social Disability	2.3	2.0	2.3	2.0
Handicap	2.7	2.2	2.4	2.0

SD: standard deviation

TABLE V. SPEARMAN INTER-ITEM CORRELATION TABLE BETWEEN UNSTIMULATED (USF), STIMULATED (SSF), DIFFERENTIAL SALIVARY FLOWS (DSF), AND OHIP-14-PT TOTAL SCORE AND DOMAINS FOR FIRST ROUND.

	USF	SSF	DFS
Age	-0.02	-0.11	-0.1
Functional Limitation	-0.01	-0.20	-0.19
Physical Pain	-0.25*	-0.45*	-0.44*
Psychological Discomfort	-0.06	-0.18	-0.26
Physical Disability	-0.15	-0.34*	-0.34*
Psychological Disability	-0.17	-0.21	-0.19
Social Disability	-0.09	-0.01	-0.02
Handicap	-0.07	-0.14	-0.15
Total score	-0.16	-0.31*	-0.31*

tion were 21.2 (SD, 11.7) and 21.0 (SD, 11.1) for first test administration and two-week delayed repetition, respectively.

The mean scores of the 7 domains are shown in Table IV. Mean scores and standard deviation were higher in physical pain 3.76 (SD, 2.2) and 3.76 (SD, 2.1) and psychological discomfort 4.3 (SD, 2.6) and 4.3 (SD, 2.6) for both administrations.

Only two patients scored the minimum summated value and thus no ceiling or floor effect was detected. No patients scored the maximum summated value.

Spearman correlation coefficients and respective significance levels are described in Table V.

The salivary flows presented negative correlations with all domains. Of these, physical pain correlated significantly with all salivary flows and physical disability and total score only with stimulated and differential salivary flow.

Scatter plots of total OHIP-14-PT scores in function of unstimulated, stimulated, and differential salivary flow rates are depicted in Figure 1.

DISCUSSION

This study intended to perform the validation of the Portuguese version of OHIP-14 and evaluate the association between hyposalivation and quality of life in an Sjögren's Syndrome population.

The main finding of this study suggests that the Portuguese version of the OHIP-14 (OHIP-14-PT) is a reliable and valid form of measure of Oral Health Related Quality of Life (OHRQoL) similarly as its English and Brazilian versions.

Cronbach alpha value for the 14 questions was 0.89 and it determines whether the positions included in a given scale are similar, and if they investigate the same phenomenon. In health-related studies, a Cronbach alpha coefficient over 0.80 is recommended for general internal consistency assessment, thus the score of 0.89 obtained in this study suggests an excellent internal consistency for the OHIP-14-PT and that the 14 questions are measuring the same construct[31,32,36], which is
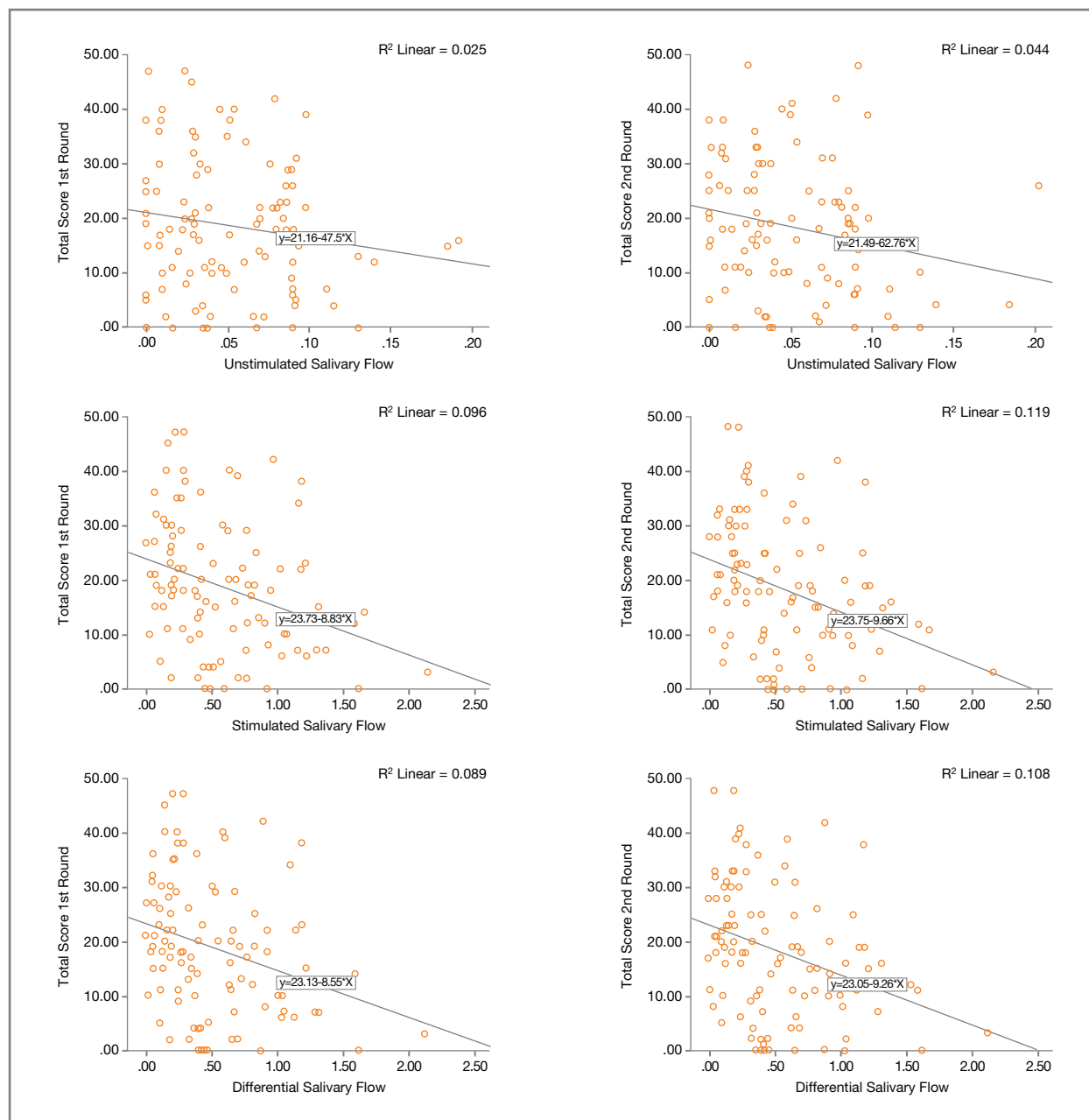

FIGURE 1. Scatter plots of total OHIP-14 scores in function of unstimulated, stimulated, and differential salivary flows. Regression line and 95% confidence interval interpolation are displayed.

consistent to results from similar studies[12,13,19,37–43].

All the inter-item correlations were positive, while the item-total correlations coefficients were above the recommended threshold (0.20) for including an item in a scale[33,34] and was consistent with other studies where inter-item correlations coefficients ranged from 0.01 to 0.83, while item-total correlations coefficients ranged from 0.25 to 0.83[19,39,41].

Overall, all items correlated well with total score and were kept in the questionnaire contributing to its internal consistency also, the test-retest reliability performed well with ICC values considered as excellent.

In this study, the mean scores for total OHIP-14-PT are similar in some studies conducted by others employing OHIP-14 in elderly populations or in oral cancer patients[44–47] although higher than in younger populations[48,49].

This is probably so, because the patients in this study suffered from pathologic salivary gland impairment. Inclusion criteria settled the cut off point at 0.1 ml min[-1]. Despite the fact that results were elevated, no ceiling effect was detected as no patients scored the maximum score for the total test, indicating a good discriminating property for the OHIP-14-PT[25].

Of the domains analyzed, the higher results were from the psychological discomfort and physical pain domains. This could be connected to some activities like eating, speaking, swallowing and wearing dentures. It is known that it is particularly difficult for people with hyposalivation to eat dry foods. Denture wearers may have problems in denture retention, denture sores and with adhesion of the tongue to the palate. These can cause speech and eating difficulties that can cause pain and or psychological distress that in turn, may cause some patients to avoid social engagements or even leading a normal life altogher[6].

Considering the relation between salivary flow and OHRQoL, unstimulated salivary flow showed a negative, but not significant correlation with the domains studied with the exception of physical pain.

This however cannot be said of the stimulated salivary flow and differential salivary flow that correlated negatively and significantly with the physical pain, disability and total score which is consistent with the results of other studies[37,39]. These domains corresponded to the following questions: "Have you had painful aching in your mouth?"; "Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?"; "Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?"; "Have you had to interrupt meals because of problems with your teeth, mouth or dentures?". As we can see these manly refer to eating and it shows that when saliva is needed, the salivary glands simply cannot respond. Considering that it occurs on a fundamental action like eating, it is natural that it affects overall quality of life as well.

However, no strong correlation between salivary flows and quality of life occurred and is similar to some cases where authors have reported low correlations between salivation and xerostomia for example[50,51].

This trial has a number of limitations. Our sample size included only SS participants when it could have included healthy volunteers as well as being greater in size. This fact could affect its general application.

However, SS is major cause of hypossialia and could severely impair the oral and systemic quality of life. The findings suggest a good performance of this scale for monitoring the impact of oral health in the quality of life. Moreover, this was a pretest study and a more comprehensive study should be designed to confirm these findings.

CONCLUSION

In summary and within the limitations of this study, OHIP-14-PT seems to be a valid and reliable instrument for measuring OHRQoL of patients with hyposalivation. Also, differential and stimulated salivary flow correlates negatively with quality of life. This occurs primarily where eating or oral discomfort is concerned which is unsurprisingly due to its importance in our daily life.

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