

ORIGINAL ARTICLE

Translation, validation, and construct reliability of a Portuguese version of the Xerostomia Inventory

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OBJECTIVES: To generate and validate at pretest level a cross-culturally adapted Portuguese version of Xerostomia Inventory (XI), a 11-item questionnaire designed to measure specific xerostomia rating of patients complaints.

METHODS: The original English version of the XI was translated into Portuguese following the guidelines for cross-cultural adaptation of health-related quality of life measures. Thirty patients with primary Sjögren syndrome were recruited for this study. The questionnaires were administered by trained and calibrated dental doctors to each patient. XI 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 (ICC), respectively. Construct validity supported by objective measurements of xerostomia intra-oral signs and salivary secretion was investigated. Alpha was set at 0.05. Informed consents and local ethical committee clearance were obtained.

RESULTS: Internal consistency and test-retest reliability were excellent (Cronbach's $\alpha = 0.9$; ICC range = 0.79–0.94). Scatterplot interpolation and Pearson correlation coefficient suggested the presence of a strong, negative, and significant correlation between salivation and the XI scores indicating construct validity.

CONCLUSION: The Portuguese version of the XI can be considered a reliable and valid instrument to measure patients' xerostomia symptoms.

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Introduction

In the aftermath of globalization which characterizes the XXI century, the number of multinational and multicultural research projects has increased considerably, introducing the need for adaptation of health status-related measures to different international settings (Anderson *et al*, 1993). The cross-cultural adaptation of health questionnaires aims at reaching equivalence between the original source and the target versions and is more than the simple linguistic translation of the questions. 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 (Beaton *et al*, 2000). Guidelines have been established for cross-cultural adaptation of health questionnaires underpinning the need for such procedures. 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 (Anderson *et al*, 1993; Beaton *et al*, 2000; Sousa and Rojjanasrirat, 2011).

The dry mouth symptom which is usually designated as xerostomia is a common complaint, especially whereas the elderly are concerned, with numerous implications ranging from diminished quality of life to persistent oral pain, among other complications. Causes of xerostomia are many and diverse with medication, head and neck radiation being the most frequent besides other of systemic nature (Porter *et al*, 2004; Turner and Ship, 2007).

Measuring salivary flow is advisable whenever studying patients with dry mouth condition, but being able to evaluate the severity of the xerostomia preferably as a continuous variable would be important (Porter *et al*, 2004; von Bültzingslöwen *et al*, 2007; Turner and Ship, 2007; Napeñas *et al*, 2009).

However, xerostomia is subjective with different symptoms, and thus, its assessment can only be performed by questionnaires using discriminative questions (van der Putten *et al*, 2011).

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Until the end of the XX century, the single-item approach for measuring xerostomia has dominated salivary research, and the lack of a valid, dimensional instrument for measuring xerostomia has hampered approaches to studying the condition (Thomson *et al*, 1999; van der Putten *et al*, 2011).

The Xerostomia Inventory (XI) is an 11-item questionnaire that was developed in 1999 and covers both experiential and behavioral aspects of xerostomia (Thomson *et al*, 1999). Scores to the 11 items are summated, providing a single score representing the subjective severity of xerostomia. The questionnaire has shown acceptable content, concurrent and longitudinal construct validity, responsiveness, temporal stability and has been increasingly used in clinic and research (Thomson *et al*, 1999, 2000; Thomson and Williams, 2000).

Methods

This was a descriptive cross-sectional survey type of study with the aim of developing a Portuguese version of the Xerostomia Inventory (XI-PL) and assess at the pretest level its reliability, repeatability, and validity.

The XI questionnaire

The XI consists of the following 11 items: 'I sip liquids to aid in swallowing food', 'My mouth feels dry when eating a meal', 'My lips feel dry', 'I have difficulties swallowing certain foods', 'My mouth feels dry', 'I get up at night to drink', 'I have difficulty in eating dry foods', 'My eyes feel dry', 'I suck sweets or cough lollies to relieve dry mouth', 'The inside of my nose feels dry', and 'The skin of my face feels dry'. Study participants were asked to indicate which 1 of 5 response options best described their symptoms over the preceding 2 weeks. The response options were 'Never' (scoring 1), 'Hardly ever' (2), 'Occasionally' (3), 'Fairly often' (4), or 'Very often' (5). The 11 scale scores are summed up to originate a final score which can range from 11 to 55 (Table 1). Higher scores imply greater severity in xerostomia.

Translation into Portuguese

The XI was translated into Portuguese by four different translators through the use of the so-called forward-backward approach, thereby mostly following the guidelines for cross-cultural adaptation of health-related measures (Beaton *et al*, 2000; Sousa and Rojjanasrirat, 2011). The forward translation into Portuguese was performed by two independent, bilingual translators whose native language was Portuguese. One of them was an expert in psychometric questionnaires; the other had no specific experience in that field. The two forward translations were compared and synthesized into one common version by an expert panel, consisting of a dentist and a psychologist, specialized in the field of dentistry. When competing options for a translation were debated, other bilingual experts were consulted. The resulting common forward translation was translated back into English by two independent, profes-

Table 1 Original version and Portuguese version of Xerostomia Inventory (Thomson *et al*, 1999)

I sip liquids to aid in swallowing food Bebo um pouco de líquido para me ajudar a engolir os alimentos
My mouth feels dry when eating a meal Sinto a boca seca durante as refeições
I get up at night to drink Levanto-me de noite para beber
My mouth feels dry Sinto a boca seca
I have difficulty in eating dry foods Tenho dificuldade em comer alimentos secos
I suck sweets or cough lollies to relieve dry mouth Chupo rebuçados ou pastilhas para a tosse para aliviar a secura da boca
I have difficulties swallowing certain foods Tenho dificuldade em engolir certos alimentos
The skin of my face feels dry Sinto a pele da cara seca
My eyes feel dry Sinto os olhos secos
My lips feel dry Sinto os lábios secos
The inside of my nose feels dry Sinto o interior do nariz seco
Scoring: 'Never' (1), 'Hardly ever' (2), 'Occasionally' (3), 'Fairly often' (4), or 'Very often' (5) 'Nunca' (1), 'Quase nunca' (2), 'Ocasionalmente' (3), 'Com relativa frequência' (4), ou 'Com frequência' (5)

sional translators whose native language was English. The two back-translations were discussed again by the expert panel, comparing semantic, experiential, and conceptual equivalence between the two versions. The expert panel then reviewed the back-translations against the original XI. Finally, the resulting XI-PL was read and commented upon by three different dentists from the field of oral medicine. The final version of XI-PL is also depicted in Table 1.

Patients and the intervention

This study employed a convenient and consecutive sample of 30 patients with primary Sjögren syndrome who were previously recruited for a randomized clinical trial on gustatory stimulants of salivary secretion at the Portuguese Institute of Rheumatology (PIR). The inclusion criteria for entry into the trial were: (i) primary Sjögren syndrome diagnosis according to the American-European Consensus Group; (ii) unstimulated whole saliva flow < 0.1 ml min⁻¹; (iii) stimulated whole saliva flow > 0.2 ml min⁻¹; (iv) more than 18 years of age.

Written informed consent was obtained from all eligible participants as the first stage of screening and before study admission. All patients had a full medical history, and saliva samples were collected at the Portuguese Institute of Rheumatology or at the Oral Biochemistry and Biology Research Group (GIBBO) laboratory.

Each patient was given a XI-PL version of the questionnaire and asked to answer immediately after reading the question.

This procedure was repeated once after 2 weeks, to obtain a second questionnaire enabling the study of the test-retest reliability and time stability of the XI-PL.

Saliva was collected expressly for this study to determine and evaluate construct validity, by established methods (Mata *et al*, 2009).

The study protocol was approved by the Faculty of Dentistry of the University of Lisbon ethical committee

and the Portuguese Institute of Rheumatology ethical committee and was completed accordingly to the guidelines of Good Clinical Practice and conducted in full compliance with the World Medical Association Declaration of Helsinki and its most recent amendments.

Statistical analyses

Internal consistency. Internal consistency of the XI-PL was assessed by calculating Cronbach's alpha. As defined previously for clinical studies, values of Cronbach alpha of at least 0.80 were considered desirable and rated as good (Bland and Altman, 1997).

Although the questionnaire is not very lengthy with only 11 questions, inter-item correlations were calculated as to determine the possibility of inflation of the Cronbach alpha because of length of the questionnaire (Streiner, 2003).

We examined also correlations of all items with the overall score (item-total correlation) and also 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 (Clark and Watson, 1995).

Test-retest reliability

After a 2-week interval, each patient was administrated once again the XI-PL questionnaire. The procedure was identical to the first administration. Test-retest reliability of the XI-PL total score and subscore for every question was assessed by calculating intra-class correlation coefficients (ICC) – model: two-way random; type: absolute agreement – and 95% confidence intervals (CI). ICCs were interpreted according to Fleiss (1986), namely $ICC < 0.40$ = poor reliability; $ICC \geq 0.40$ but $ICC \leq 0.75$ = fair to good reliability; and $ICC > 0.75$ = excellent reliability (Fleiss, 1986).

Construct validity

To determine the construct validity of the XI-PL questionnaire, aspects of the convergent validity were considered. Thus, relationships were examined between PL-XI scores and other measures that are assumed to be derived from the same construct. Therefore, total XI-PL scores were plotted in function of resting, stimulated, and differential (stimulated minus resting) salivary flows, and Pearson correlations analysis was obtained. It was hypothesized *a priori* that a negative correlation existed between saliva production and xerostomia reporting. Pearson's coefficient was interpreted as follows: strong correlation for values > 0.50 ; moderate correlation for values between 0.35 and 0.50; weak correlation for values < 0.35 (Nunnally and Bernstein, 1994; Juniper *et al*, 1996).

Data analysis

A preestablished plan recurring to a statistical package (version 17.0; SPSS Inc., Chicago, IL, USA) was employed to analyze all data. Missing values were substituted by item question mean obtained from all the other questionnaires. If a patient failed to answer

more than two questions in the XI-PL was removed from the study. For temporal stability, 95% confidence intervals were calculated, and for Pearson correlations coefficients, significance was set at $\alpha = 0.05$. Floor and ceiling effects were assessed on the first administration of the RAOS for the determination of content validity. Floor and ceiling effects were considered to be present if more than 15% of the patients achieved the highest or the lowest possible scores (McHorney and Tarlov, 1995).

Results

Whereas translation procedures were concerned no difficulties were encountered. Idiomatic equivalences were discussed and consensus reached swiftly between members of the translating panel. The final version was unanimously found to be perfectly understood by any Portuguese speaking person.

No patients had to be discarded from the study for missing more than two questions. Four patients had one question missed in which the value was replaced with the average values of the other answers from the test, as previously described.

Data on the demographic and salivary characteristics of the data set are presented in Table 2. Age and gender characteristics are accordingly with the previously described for Sjögren syndrome patients.

The mean scores of the 11 questions of the test as its total score are shown in Table 3. Mean total XI-PL scores and standard deviation (s.d.) were 42.2 ± 8.9 and 43.6 ± 8.7 for first test administration and 2 week delayed repetition, respectively. Total XI scores ranged from 19 to 55. No patients scored the minimum score and only one patient scored the maximum score of 55. Data on internal consistency and test-retest reliability are also presented in Table 4. Cronbach alpha values for the 11 questions were 0.90 for both test administrations. Average inter-item correlations were of 0.45. The item-total correlations and contribution for scale stability and variance are also presented. The results showed 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 79% to 94%. Lower limits of 95% confidence interval for ICC ranged from 56% to 87% rating between good and excellent reliability.

Scatter plots of total XI-PL scores in function of resting, stimulated, and differential salivary flows are depicted in Figure 1a–c. Pearson correlation coefficients and respective significance levels are described in

Table 2 Demographic and salivary characteristics of sampled population

Variable	Value	Unit
Population sample (N)	30	–
Gender (N)	Female (30)	–
Age (mean \pm s.d.)	56.1 \pm 9.68	Years
Resting salivary flow (mean \pm s.d.)	0.063 \pm 0.055	ml min ⁻¹
Stimulated salivary flow (mean \pm s.d.)	0.389 \pm 0.255	ml min ⁻¹

Table 3 Mean scores and standard deviations of both administrations of the Portuguese version of the Xerostomia Inventory (XI) questionnaire. Intra-class correlation coefficient (ICC) and respective 95% confidence intervals are also shown for repeatability assessment. Inter-total coefficient (ITC) for first round questioning is also displayed. Cronbach alpha coefficient and mean inter-item correlations were 0.90 and 0.45, respectively

Questions from the Portuguese version of XI	First round		Second round		ICC	CI 95%		ITC
	Mean	s.d.	Mean	s.d.		Minimum	Maximum	
Sinto a boca seca (My mouth feels dry)	4.50	0.73	4.47	0.78	0.84	0.67	0.93	0.73
Sinto os lábios secos (My lips feel dry)	4.40	0.77	4.50	0.68	0.79	0.56	0.90	0.55
Levanto-me de noite para beber (I get up at night to drink)	2.97	1.50	3.17	1.56	0.91	0.81	0.96	0.31
Sinto a boca seca durante as refeições (My mouth feels dry when eating a meal)	3.53	1.11	3.63	1.19	0.86	0.71	0.93	0.81
Bebo um pouco de líquido para me ajudar a engolir os alimentos (I sip liquids to aid in swallowing food)	3.37	1.25	3.73	1.36	0.91	0.80	0.96	0.77
Chupo rebuçados ou pastilhas para a tosse para aliviar a secura da boca (I suck sweets or cough lollies to relieve dry mouth)	3.23	1.55	3.37	1.61	0.94	0.87	0.97	0.42
Sinto a pele da cara seca (The skin of my face feels dry)	4.27	1.31	4.30	1.12	0.93	0.86	0.97	0.73
Sinto os olhos secos (My eyes feel dry)	4.57	0.97	4.73	0.52	0.83	0.65	0.92	0.57
Tenho dificuldade em engolir certos alimentos (I have difficulties swallowing certain foods)	3.33	1.47	3.73	1.23	0.85	0.69	0.93	0.76
Sinto o interior do nariz seco (The inside of my nose feels dry)	3.83	1.18	4.07	1.01	0.80	0.58	0.91	0.55
Tenho dificuldade em comer alimentos secos (I have difficulty in eating dry food)	3.63	1.33	3.87	1.31	0.87	0.72	0.94	0.80
Total	42.23	8.93	43.57	8.67	0.94	0.86	0.97	1.00

Table 4 Pearson inter-item correlation table between resting, stimulated, and differential salivary flows, and XI total score. Correlation was negative, elevated, and significant, $P < 0.001$

XI total score	Resting saliva flow	Stimulated saliva flow	Stimulated minus resting salivary flow
Pearson correlation	-0.781*	-0.757*	-0.718*
Significant (two-tailed)	0.000	0.000	0.000
N	30	30	30

*Correlation is significant at the 0.01 level (two-tailed).

Table 4. The results showed a negative and significant correlation between total XI-PL scores and resting, stimulated, and differential salivary flows.

Discussion

This study was designed as a descriptive cross-sectional survey aiming at the translation of the XI into Portuguese and describes preliminary psychometric testing. A Portuguese version of the XI was obtained from the original version by established guidelines and administered twice at a 2-week interval to 30 Sjögren syndrome patients. The main finding of this study is the suggestion that after pretesting, the Portuguese version of the XI (XI-PL) seems to be a reliable and valid form of measure xerostomia similarly as its parent English version.

We are perfectly aware of the limitations of this study. The sample size is small and do not reflect all the xerostomic population. However, this was a pretest of the XI-PL. Pretesting is an essential step in multicultural and

linguistic adaptation of any version, with the objective of preevaluating the translated version in a quick manner and then rediscussing it within the expert panel (Beaton *et al*, 2000). This has been accomplished; we have decided to maintain this version as the pretest results were considered very satisfactory. For testing construct validity, we investigated the total XI-PL score correlation with resting, stimulated, and a derived variable obtained from the difference between the former, which expressed the secretion capacity. We chose to do so because xerostomia most frequently arises from the diminishment of salivation and, therefore, could correlate with the patient's own perception of this condition. This is controversial and may be viewed as a study weakness because some authors have reported low correlations between salivation and xerostomia (Thomson *et al*, 1999; Thomson and Williams, 2000). Some studies use a single question consisting in a one-dimensional test for patient self-reported xerostomia and use it for validation check purposes (Thomson *et al*, 1999; Thomson and Williams, 2000). In this study, and considering the population sampled which included only Sjögren syndrome patients, extreme xerostomia and hyposalivation prevalence were highly expectable anticipating a strong correlation between both. In fact, in this study, the XI-PL correlates with salivary flow, and patients with lower resting stimulated and differential salivary flow scored higher test values significantly. Therefore, in our view, dropping the single question in this particular study at pretest level did not compromise the validity assessment. However, in further studies with larger population-based samples, this correlation is expected to drop and the use of the single question is mandatory.

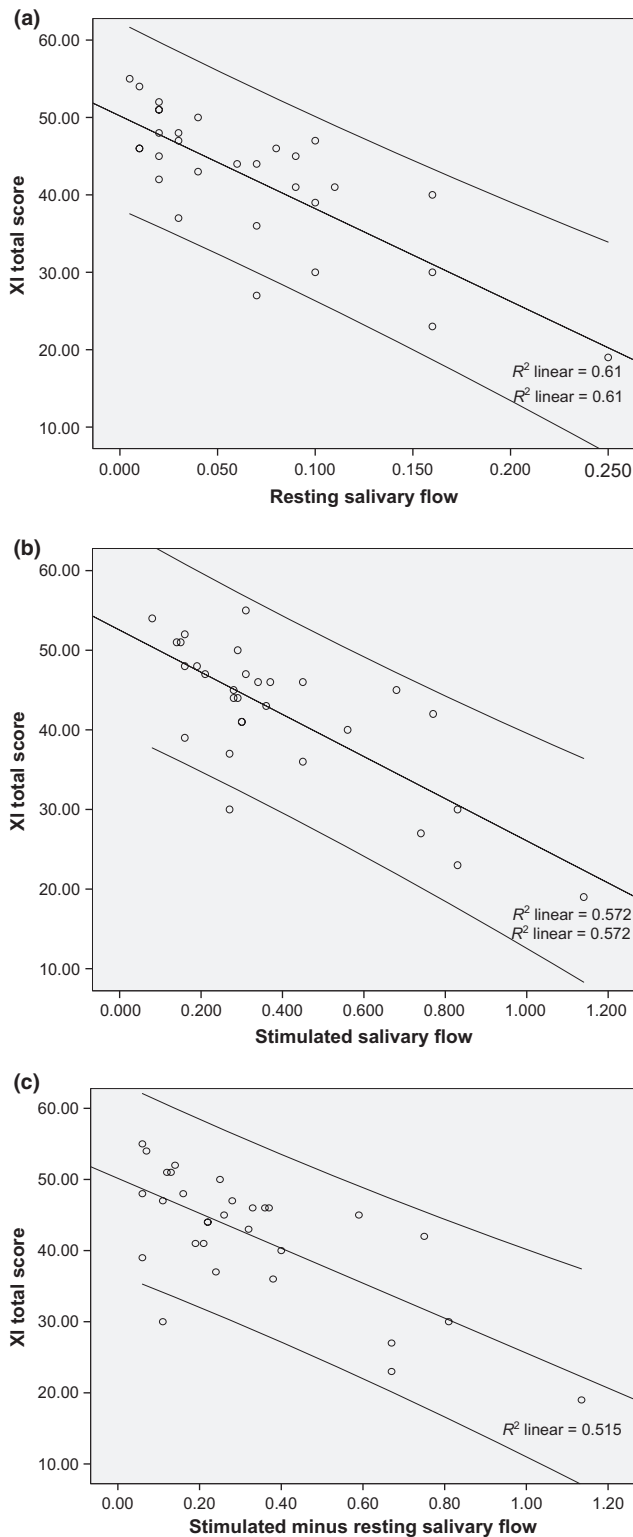


Figure 1 Scatter plots of total XI-PL scores in function of resting (a), stimulated (b), and differential (c) salivary flows. Regression line and 95% confidence interval interpolation are displayed

In this study, the mean scores for total XI-PL are higher than studies conducted by others employing XI in diverse disease states (Thomson *et al*, 1999, 2006;

Thomson and Williams, 2000; Agha-Hosseini *et al*, 2009; Brand *et al*, 2009; Garcia *et al*, 2009; van der Putten *et al*, 2011). These results are probably related to severity of the salivary gland impairment presented by the patients in this study. Inclusion criteria in the main study settled the cut off value for salivary secretion at 0.1 ml min^{-1} for unstimulated saliva and 0.2 ml min^{-1} for stimulated saliva. Despite the fact that results were elevated, no ceiling effect was detected as $<15\%$ of the patients scored the maximum score for the total test, indicating a good discriminating property for the XI-PL (McHorney and Tarlov, 1995).

Cronbach alpha value for the 11 questions was 0.90 for both test administrations. In health-related studies, a Cronbach alpha coefficient over 0.8 is recommended for general internal consistency assessment, thus the score of 0.9 obtained in this study suggests a good internal consistency for the XI-PL and that the 11 questions are measuring the same construct. Moreover, mean inter-item correlation was 0.45. According to Clark and Watson (1995), a mean inter-item correlation of 0.15–0.20 is desirable for scales that measure broad characteristics, while values of 0.40–0.50 are required for scales tapping narrower ones, which is the case in the present study. All items correlated well with total score and were kept in the questionnaire contributing to its internal consistency. Test-retest reliability performed well indicating time stability for the XI-PL.

The existence of a Portuguese version of the test is important and new, because Portuguese is the fifth language in the world spoken by more than 240 million people, which confers the XI-PL a wide clinical and research application. Future studies should try to confirm validation of the XI-PL. A large testing study is now being conducted as validation of the XI-PL should be confirmed in larger and more representative xerostomia population. In this new study, the standard single question is being used as validity check. Moreover and recently, the authors of the XI have published a shorter version which could have improved acceptability and face validity while maintaining its discriminating properties and usefulness (Thomson *et al*, 2011). In summary and within the limitations of this study, XI-PL seems to be a valid and reliable instrument for measuring specific xerostomia rating of patients complaints.

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Conflict of interest

None declared or nothing to disclose.

Author contributions

Professor Antonio Mata was the PI of the project. He mentored the study design, made the data analysis, and wrote the article's final version. Professor Duarte Marques was the study coordinator, supervising all the investigators. He has

implemented the study design and also wrote the final version of the article. Dr. Filipe Freitas was investigator and contributed to the figures and tables of the article. Dr. João Amaral and Dr. Ruben Trindade were investigators of the project. Dr. Filipe Barcelos and Dr. José Vaz Patto were the doctors of the Portuguese Institute for Rheumatological Diseases in charge of the primary Sjögren syndrome diagnosis.

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