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Validity and reliability of a Portuguese version of the Summated Xerostomia Inventory-5

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Objectives: The aim of this study was to validate and determine the reliability of the Portuguese version of the Summated Xerostomia Inventory.

Background: Many conditions such as head and neck radiation, autoimmune diseases or polypharmacy are characterised by hyposalivation which can affect oral and systemic quality of life. As such, this condition must be assessed, and the English version of the Xerostomia Inventory has been increasingly used to determine the severity of dry mouth perception.

Materials and methods: This was a descriptive cross-sectional study, which employed volunteers suffering from hyposalivation after local ethical committee clearance. Each patient signed an informed consent and responded to the Portuguese version of the questionnaire in the form of an interview. This was repeated again after 2 weeks. A standard single question provided a validity check. Data were analysed using Cronbach's α to test its reliability and total and interitem correlation, and intraclass correlation to determine its internal consistency and test-retest reliability. Significance was set at .05.

Results: A sample of 103 volunteers was recruited. Cronbach's α was .84 and .87 for the first and second test administrations, respectively. The intraclass correlation coefficient value for the test-retest reliability was .93, and scores for the individual items ranged from .79 to .90. The correlation between the total score of the questionnaire and standard single dry mouth question was .66, indicating a very good correlation.

Conclusion: Demonstrating excellent psychometric properties, the Summated Xerostomia Inventory (Portuguese Version) is a valid tool for quantifying Xerostomia in a dry mouth-afflicted population.

KEYWORDS
quality of life, questionnaire, reliability and validity, saliva, xerostomia

1 | INTRODUCTION

Oral cavity homeostasis depends greatly on proper salivary function.[1,2] Individuals with salivary gland impairment and consequent diminished salivary secretion rates experience a plethora of signs and symptoms such as greater susceptibility to intraoral infections, dental caries, periodontitis, mucositis, dysphagia, dysgeusia, dysosmia and difficulties in using dental prostheses, among others.[2-5] Thus, hyposalivation can lead to social, nutritional or behavioural changes and affect not only oral quality of life but general quality of life as well.[3,5-10]

Certain medications, head and neck radiation, and autoimmune diseases—such as Sjögren's syndrome (among others)—are the major causes of salivary gland hypofunction, characterised by a diminished salivary output.[4,5,8,9,11,12] Xerostomia is considered the subjective feeling of dry mouth[4] and may develop as the salivary output decreases, or it may arise de novo. The exact nature of the relationship between hyposalivation and Xerostomia has yet to be determined.[2,3,10,12,13] Both dimensions of salivary secretion rates, unstimulated or stimulated, are regularly used as an objective indicator to evaluate dry mouth.[12] Nevertheless, the level of Xerostomia also needs to be assessed because it is, from a patient-centred perspective, an important outcome which can affect quality of life.[11] Moreover, the prevalence of Xerostomia may be increasing as life expectancy extends.[4,11,12]

Being a subjective sensation, several questionnaires have been created for the measurement of the degree of Xerostomia, and these range from a single item up to an 11-item questionnaire.[14-18] The single-item question has arisen first, but is limited.[3,11] Multidimensional instruments have proved to be of greater utility as they have the capacity to place respondents on a continuum of Xerostomia symptoms, thus producing more accurate evaluations of oral dryness.[19] The Xerostomia Inventory (XI) is an 11-item summated rating scale, which results in a single score representing the severity of dry mouth perception.[18-20] This questionnaire was developed in the 1990s and includes both the experiential and behavioural aspects of this condition. It has been shown to have acceptable psychometric features.[11,14-17,19-22] Despite the continuing importance and utility of the single-item approach, the XI has gained in popularity in salivary research in recent years.[3,4,7,20,23,24]

First published in 2011, the shortened Xerostomia Inventory (SXI) is a short-form 5-item version of the original questionnaire.[22] This was done because some questions in the XI tapped into dimensions other than Xerostomia alone, and also because a shorter version would be handier in the clinical environment. Also, some of the original questions were not adequate for patients with reduced mobility and frail constitution, and as such were removed.

The scores for the 5 questions are summed, which results in a single score which represents, subjectively, the severity of Xerostomia. The new questionnaire has been increasingly used clinically and in research with excellent results.[14-17] A version of the XI-11 (XI-PL) in Portuguese was prevalidated in 2012,[17] but no Portuguese version of the SXI has been developed. Moreover, no systematic examination of the test-retest reliability of the SXI (or XI) has yet been conducted. Accordingly, the aim of this study was to extract, pretest, validate and determine the reliability of a Portuguese version of the SXI (SXI-PL).

2 | MATERIALS AND METHODS

This was a cross-sectional study with the aim of developing a version of the SXI (SXI-PL) in Portuguese and assess its psychometric characteristics. The original SXI is a questionnaire composed of 5 questions from which the respondent can choose from 3 available answers: "never" (scoring 1), "occasionally" (scoring 2) or "frequently" (scoring 3). The scores from the 5 questions are summed, with the result representing the degree of Xerostomia the subject feels. In this study, a sample of participants that were concurrently recruited in the context of two different clinical trials conducted by our team was invited to participate.

The 5 questions to be included in the SXI-PL were picked from the original XI-PL,[22] which had been previously translated and validated in 2012.[17] They were the same items as those included in the SXI.

The resulting SXI-PL was analysed by 3 specialists in oral medicine. All agreed on maintaining the original phrasing. The revised version of the SXI-PL is shown in Table 1.

This study employed a sample of 103 volunteers suffering from hyposalivation. The inclusion criteria for the study were as follows: (i) unstimulated whole saliva secretion rate <0.2 mL/min; (ii) stimulated whole saliva secretion rate >0.2 mL/min; and (iii) above 18 years of age. Exclusion criteria were as follows: (i) wearer of complete dental prosthesis; (ii) those who were pregnant or lactating; and (iii) non-speakers of Portuguese.

All eligible participants gave their written informed consent before study admission.

A full medical history was taken, and saliva collection was performed at the Portuguese Institute of Rheumatology and at several home-care facilities.

Upon arrival at the collection site, the volunteers were instructed to brush their teeth with a given medium, soft-bristled manual toothbrush with a dentifrice included (Medibase®, Kent, UK) and wait for 1 hour. With the head tilted forward, unstimulated salivary secretion rate was measured by asking the participants to swallow all saliva present in oral cavity and then to let it accumulate naturally without swallowing. For the stimulated salivary secretion rate, a paraffin wax pellet (CRT Buffer; Ivoclar-Vivadent, Liechtenstein) was given to the patient for chewing. The patients were told to keep their eyes open at

TABLE 1 Original and Portuguese versions of the shortened Xerostomia Inventory (SXI) and single-item question

SXI	
My mouth feels dry when eating a meal	Sinto a boca seca durante as refeiçõoes
My mouth feels dry	Sinto a boca seca
I have difficulty in eating dry foods	Tenho dificuldade em comer alimentos secos
I have difficulties swallowing certain foods	Tenho dificuldade em engolir certos alimentos
My lips feel dry	Sinto os lábios secos
Scoring: Never (1), Occasionally (2), Frequently (3)	Nunca (1), Ocasionalmente (2), Com frequência (3)
Standard question	
How often does your mouth feel dry?	Com que frequência sente a boca seca?
Scoring: Never, Occasionally, Frequently, Always	Nunca, Ocasionalmente, Com frequência, Sempre

all times. This collection went on for 5 minutes at the end of which the participants were instructed to collect all their accumulated saliva in a preweighed 50-mL falcon. After this procedure, the saliva containing the falcon tube was weighed (Mettler, Kern PCB 2000-1®, Mettler-Toledo, OH, USA) and stimulated salivary secretion rate determined in mL/min ± standard deviation (SD).[25]

Each patient answered to the SXI-PL version of the questionnaire in the form of a standardised interview. Participants were told that the question asked had no definitive right answer and so were instructed to give the answer that immediately came to mind.

Participants were instructed to request 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, to evaluate the test-retest reliability of the SXI-PL.

Participants were also asked to respond "never," "occasionally," "frequently" or "always" to the single item: "How often does your mouth feel dry." This was done to provide a concurrent validity check.

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.

To analyse the data, the SPSS program (version 22.0; Chicago, IL, USA) was used. A patient was removed from the study if he failed to answer more than 2 questions. The dependent variable was the SXI-PL score, expressed as the summated score ± SD. Significance was set at $\alpha = .05$.

Cronbach's α was used to determine internal consistency of the questionnaire. This value was considered desirable and rated as good if it was at least .80.[26]

Despite the length of the 5 question questionnaire, interitem correlations were calculated to determine the possibility of inflation of the Cronbach's α value.[27] This value should be above .4 to be sufficiently reliable.[28]

We also examined correlations of the individual questions with the summated score (item-total correlation), which should be above .3,[16,29] and also if by removing a question, the value of Cronbach's α would be improved.

After the determined two-week interval, the SXI-PL was completed by the participants in the same manner. The intraclass correlation coefficient (ICC) was determined to calculate test-retest reliability of every subscore and total overall score. The model used was two-way random with absolute agreement and 95% confidence intervals. ICC lower than .4 was considered to have low reliability while a range from .4 to .75 has good reliability. The optimal ICC values should be higher than .75.[30]

The means of the total SXI-PL scores were plotted against the standard question response categories to assert concurrent validity. The correlation between the total XI-5-PL scores and the standard question responses was examined using Spearman's ρ.

Floor and ceiling effects were a concern for the assessment of content validity. These should deemed to be influencing the questionnaire if more than 15% of the participants scored in the extremes of the overall summated score.[31]

TABLE 2 Age and salivary characteristics of participants (n = 103)

	Means	SD
Unstimulated secretion rate (mL/min)	0.1	0.0
Stimulated secretion rate (mL/min)	0.6	0.4
Age (y)	61.7	15.5

3 | RESULTS

Salivary secretion rates and age of participants are presented in Table 2. Of the 103 volunteers, 21 were smokers, 86 suffered from Primary Sjögren's syndrome and 17 were polymedicated. The study sample comprised of 91 females (88.3%) and 12 males (11.7%).

Mean total SXI-PL scores were 11.2 (SD, 2.9) and 11.6 (SD, 3.0) for first and second round answers, respectively.

Intraclass correlation coefficient (ICC) and item-total correlation (ITC) values are showed in Table 3. Positive correlations between all items in the interitem correlation matrix were found. The values for the coefficients from the 5 questions ranged from .42 to .70. Average interitem correlations were 0.52. For scale stability, the values of the item-total correlations ranged from .63 to .77. There was an equal contribution for scale dimensionality by each item in the scale. Cronbach's α values for the 5 questions were 0.84 and 0.87 for the first and second test administrations, respectively, and were lower if any items were removed, suggesting that all 5 questions contributed positively to the questionnaire's internal consistency. The questionnaire showed excellent reliability with the intraclass correlation coefficient value for the test-retest reliability of the SXI-PL score being 0.93, and ICC scores for the individual items ranged from .79 to .90. A modest ceiling effect was found, with 18% of participants scoring the maximum value. Finally, there was a strong positive correlation (Spearman's $\rho = .66$) between the standard item response and the SXI total score. Moreover, when plotting mean SXI scores by standard question responses, a statistically significant gradient across the categories of the standard question was observed (Figure 1).

4 | DISCUSSION

This study set out to validate a Portuguese version of the SXI (SXI-PL). The findings suggest that the SXI-PL is a reliable and valid form of measuring Xerostomia, in keeping with its parent English version.

The study has several weaknesses; namely, the sample could have been more diverse and greater in size, as only aged participants on medication or with Sjögren's syndrome (SS) were included. This is likely to have affected the external validity of the study and hence the generalisation of the findings. However, medication and SS are major causes of Xerostomia, and the findings suggest a good performance of the scale. Although smoking can be considered as a confounding factor, we did not find significant differences when comparing with

TABLE 3 Intraclass correlation coefficient (ICC) and item-total correlation (ITC)

	ICC	95% Min	95% Max	ITC
Single question	.80	.71	.87	n/a
My mouth feels dry when eating a meal | Sinto a boca seca durante as refeições	.86	.75	.91	.74
My mouth feels dry | Sinto a boca seca	.79	.70	.86	.61
I have difficulty in eating dry foods | Tenho dificuldade em comer alimentos secos	.9	.88	.95	.77
I have difficulties swallowing certain foods | Tenho dificuldade em engolir certos alimentos	.87	.80	.91	.77
My lips feel dry | Sinto os lábios secos	.81	.72	.87	.63
Total score	.93	.90	.96	n/a

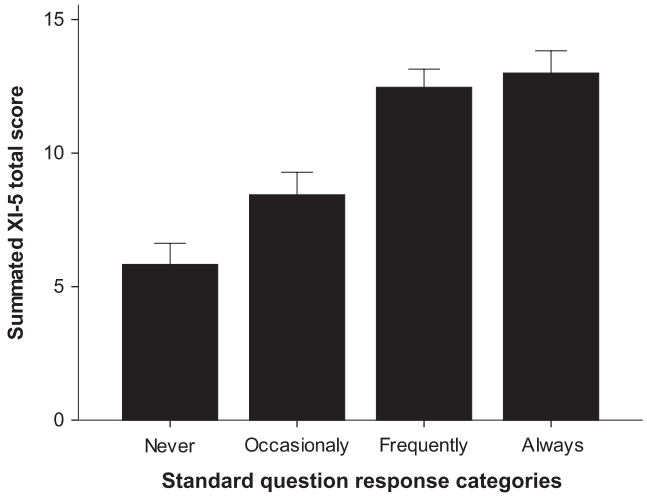

FIGURE 1 Mean +/- Standard Deviation shortened Xerostomia Inventory scores by standard question response categories and standard deviation

the nonsmoking population. Moreover, this was a pretest study, and a more comprehensive study should be designed to confirm these findings.

A major strength of this study was the double administration of the questionnaire with a separate time interval, thus enabling the first assessment of the test-retest reliability of the SXI. Intraclass correlation scores ranged from 79% to 93% with a two-week interval indicating excellent test-retest reliability for the SXI-PL. This results were similar or even elevated when compared to other studies.[15] This is an important finding as the test-retest reliability of any questionnaire is a critical characteristic. Moreover, the mean Cronbach's α value of .85 obtained in this study suggests that the 5 questions in the XI-5-PL are measuring the same construct and have good internal consistency. Similar findings have been obtained in other studies.[14-17,22,32] Positive correlations between all items were found, with a mean interitem correlation of .52, which is desirable according to Clark and Watson,[28] who consider values of .40-.50 to be required for scales tapping narrow characteristics as Xerostomia. Similar values were found in other studies[15-17] although higher than in others.[32]

Strong correlations (.63-.77) were also found when comparing an item and the rest of the scale (item-total correlation), all well above the recommended threshold (.3) for including an item in a scale; these finding are consistent with those of other studies.[15-17] Additionally, removing 1 or more items resulted in lower Cronbach's α values, reflecting the contribution of each item to the overall internal consistency of the inventory. Finally, there was also a significant positive and strong correlation between the single-item question and total score, fulfilling the criteria for independent validation as proposed in previous studies.[17]

The Portuguese language is spoken by more than 200 million people worldwide. The validation of a simpler and reliable Xerostomia questionnaire should therefore be considered as a valuable tool for clinical use. These findings are more important than ever because of increasing population longevity and the associated increase in numbers of older people with multimorbidity and polypharmacy. Monitoring and treating their dry mouth symptoms will be an important aspect of their health care.

Within the limitations of this study, we can conclude that the XI-5-PL has excellent psychometric properties and can be used successfully as a tool to measure Xerostomia of patients with hyposalivation.

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CONFLICT OF INTEREST

There is no conflict to interest to disclose.

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