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Translation and Validation of a Korean Version of the Xerostomia Inventory in Patients with Primary Sjögren's Syndrome

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This study was conducted to generate and validate a cross-culturally adapted Korean version of the xerostomia inventory (XI), an 11-item questionnaire designed to measure the severity of xerostomia. The original English version of the XI was translated into Korean according to the guidelines for cross-cultural adaptation of health-related quality-of-life measures. Among a prospective cohort of primary Sjögren's syndrome (pSS) in Korea, 194 patients were analyzed. Internal consistency was evaluated by using Cronbach's alpha, and test-retest reliability was obtained by using an intraclass correlation coefficient (ICC) analysis. Construct validity was investigated by performing a correlation analysis between XI total score and salivary flow rate (SFR). Cronbach's alpha for internal consistency was 0.868, and the ICC for test-retest reliability ranged from 0.48 to 0.827, with a median value of 0.72. Moderate negative correlations between XI score and stimulated SFR, unstimulated SFR, and differential (stimulated minus unstimulated) SFR were observed (Spearman's rho, ρ = -0.515, -0.447, and -0.482, respectively; $P < 0.001$). The correlation analysis between the visual analogue scale (VAS) score of overall dryness and SFR indicated a smaller ρ value (-0.235 [$P = 0.006$], -0.243 [$P = 0.002$], and -0.252 [$P = 0.003$], respectively), which supports that XI more accurately reflects the degree of xerostomia in the pSS patients. In conclusion, the Korean version of the XI is a reliable tool to estimate the severity of xerostomia in patients with pSS.

Keywords: Xerostomia Inventory; Sjögren's Syndrome, Cross-Cultural Adaptation

INTRODUCTION

Primary Sjögren's syndrome (pSS) is a systemic autoimmune disease characterized by lymphocytic infiltration of the exocrine glands, which results in dry mouth (xerostomia) and eyes (xerophthalmia) (1). The prevalence of pSS in Korea has not been reported. Worldwide, it varies according to the race and age of the subject population ranging from 0.03%-2.7% (2). The major manifestation of pSS is sicca symptom, but extraglandular manifestations such as interstitial lung disease (3), myelopathy (4), and renal involvement (5,6) have been reported. Diagnosis of pSS is made according to ECCG criteria (7), or American College of Rheumatology classification criteria (8). Despite advances in the understanding of pathogenesis of the disease, current treatment mainly targets for alleviating sicca symptoms with lack of targeted therapy.

Although oral dryness does not always correlate with systemic disease activity, the degree of xerostomia needs to be determined because it affects the quality of life of patients and can be managed with medications such as pilocarpine. Salivary flow rate (SFR), both resting and stimulated, is commonly determined as an objective tool to evaluate dryness. Nevertheless, only a weak association was observed between subjective dryness and SFR (9). Therefore, xerostomia is often evaluated by using the visual analogue scale (VAS) or questionnaires such as the xerostomia inventory (XI) and sicca symptom inventory.

The XI is a set of questions consisting of 11 items that address xerostomia symptoms in daily activities (10). The original English version of the XI was developed by Murray Thompson, an Australian dentist, in order to evaluate oral dryness. It performed well in various populations, including pSS patients (11) and aged populations (10). XI was translated into Spanish (12) and Portuguese (13), and its condensed version was translated into Chinese (14). For establishing a large prospective cohort of pSS in Korea, the XI was translated into Korean and a validation process was carried out.

Here, we describe the process of developing a validated Korean version of the XI (XI-K) to evaluate the degree of xerostomia in pSS patients. For this purpose, the internal consistency and reliability of the questionnaire was evaluated in patients from the Korean pSS registry (Korean Initiative of Sjögren's Syndrome [KISS]).

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MATERIALS AND METHODS

Study population

All of the patients with pSS in this study were participants registered in the KISS registry. The KISS was founded in 2013 with the aims of establishing a nationwide prospective cohort that contains overall clinical data and samples from patients with pSS and developing diagnostic and treatment tools for pSS. All data were collected and managed with the use of the Clinical Research and Trial Management System (Korea National Institutes of Health, Korea Centers for Disease Control and Prevention). Recruitment began in October 2013 in Seoul St. Mary's Hospital, a tertiary care university hospital and referral center in Seoul, Korea. By July 2015, the database included 224 pSS patients from Seoul St. Mary's hospital. Patients were diagnosed with pSS according to the American-European Consensus Group criteria for pSS (7) or the 2012 American College of Rheumatology criteria (8). Among the patients, 194 who completed the XI questionnaire were analyzed in this study. Resting SFR was obtained for 166 patients; and stimulated SFR, in 137 patients. Sixty-four patients were asked to answer the XI-K questionnaire again 2 weeks after the first round in order to investigate test-retest reliability.

The XI questionnaire

The XI questionnaire consists of the following 11 items: "My mouth feels dry," "I have difficulty eating dry foods," "I get up at night to drink," "My mouth feels dry when eating a meal," "I sip liquids to aid in swallowing food," "I suck sweets or cough lollies to relieve dry mouth," "I have difficulties swallowing certain foods," "The skin of my face feels dry," "My eyes feel dry," "My lips feel dry," "The inside of my nose feels dry." The 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" (score 1), "hardly ever" (score 2), "occasionally" (score 3), "fairly often" (score 4), or "very often" (score 5). The sum of 11 scale scores makes the final score, which can range from 11 to 55 (Table 1). Higher scores depict greater severity in oral dryness.

Translation into Korean and cultural adaptation

The forward translation into Korean was performed by two independent rheumatologists whose native language was Korean. The two forward translations were compared, and one common version was developed by an expert panel that consisted of three rheumatologists. The common forward translation version was translated back into English by two independent translators whose native language was English. The two back-translations were discussed again by the expert panel and reviewed against the original XI. Finally, the pre-final version of the XI-K was developed (Table 1).

Statistical analyses

Internal consistency

Internal consistency of the XI-K was assessed by calculating Cronbach's alpha. Inter-item correlations were calculated, and correlations of each item and the total score (item-total correlation) were examined. We also investigated whether Cronbach's alpha was improved by removal of any item.

Test-retest reliability

After a 2-week interval, each patient was asked to answer the XI-K questionnaire again. Prescribed medications were kept unchanged during the 2 weeks. The procedure was identical to the first administration. The test-retest reliability of the XI-K total score and score for each question was determined by calculating ICCs (model: two-way randomization; type: absolute agreement) and 95% confidence intervals (CI). ICCs were interpreted as follows: ICC < 0.40 = poor reliability; ICC ≥ 0.40 but ≤ 0.75 = fair to good reliability; and ICC > 0.75 = excellent reliability.

Table 1. Original English and Korean versions of the xerostomia inventory

Xerostomia inventory in English (XI-E)	Xerostomia inventory in Korean (XI-K)
My mouth feels dry	내 입안은 건조합니다.
I have difficulty eating dry foods	나는 마른 음식을 먹는데 어려움이 있습니다.
I get up at night to drink	나는 밤에 자다가 물을 마시기 위해 일어납니다.
My mouth feels dry when eating a meal	나는 식사할 때 입안이 건조합니다.
I sip liquids to aid in swallowing food	나는 음식 삼키는 것이 수월하도록 액체류를 같이 마십니다.
I suck sweets or cough lollies to relieve dry mouth	나는 구강 건조 증상을 완화 시키기 위해 사탕이나 목 캔디를 먹습니다.
I have difficulties swallowing certain foods	나는 특정 음식을 삼키는 데 어려움이 있습니다.
The skin of my face feels dry	내 얼굴의 피부는 건조합니다.
My eyes feel dry	내 눈은 건조합니다.
My lips feel dry	내 입술은 건조합니다.
The inside of my nose feels dry	내 콧속은 건조합니다.
Scoring:	
Never (1), hardly ever (2), occasionally (3), fairly often (4), very often (5)	전혀 그렇지 않다 (1), 거의 대부분 그렇지 않다 (2), 가끔 그렇다 (3), 꽤 자주 그렇다 (4), 언제나 그렇다 (5)

Construct validity

To determine the construct validity of the XI-K questionnaire, aspects of the convergent validity were considered. Total XI-K scores were compared with the function of resting, stimulated, and differential (stimulated minus resting) SFRs, and a Spearman correlation analysis was performed.

Data analysis

Statistical analyses were performed by using the SAS version 9.0 software (SAS, Cary, NC, USA). Data were presented as medians (interquartile ranges [IQRs]). Spearman's correlations were used for correlation analyses. A $P < 0.05$ was considered to indicate statistical significance.

Ethics statement

This study was approved by the institutional review board of Seoul St. Mary's Hospital (KC13ONMI0646). Informed consent was obtained from all of the patients according to the principles of the Declaration of Helsinki.

RESULTS

Translation into Korean

The translation process went well without any difficulties. None of the patients complained of any difficulties in answering the XI-K questionnaire.

Table 2. Demographic characteristics and salivary flow rates of the subjects

Variables	Values
No. of patients	194
Age, yr	54 (46.75-60)
Female	193 (99.5%)
Resting salivary flow rate, mL/min	0.02 (0-0.08)
Stimulated salivary flow rate, mL/min	0.5 (0.2-1.1)

Characteristics of the subjects

All of the patients enrolled in our registry were patients with pSS, meeting the 2012 American College of Rheumatology classification or 2002 American-European Consensus Group criteria for pSS. Among the 194 patients, 193 were women, and the median age was 53 (14) years (Table 2). The resting and stimulated SFRs were 0.02 (0.06) and 0.5 (0.9) mL/min, respectively. The median total XI score of the subjects was 36 (13).

Internal consistency

Cronbach's alpha for the 11 questions was 0.868, showing good internal consistency, as values higher than 0.80 are considered desirable (15). The mean inter-item correlation coefficient was 0.37, and the average item-total correlation coefficient was 0.654. In addition, Cronbach's alpha was obtained after the item was removed, indicating that internal consistency did not improve significantly even after any item removal (Table 3).

Test-retest reliability

To test the reliability of the inventory, ICC analysis was performed with values obtained at 2-week intervals. The ICC analysis result demonstrated that the test-retest reliability was good, with

Table 3. Item-total correlations and Cronbach's alpha when the item was removed

Items	ITC	α_c
My mouth feels dry	0.739	0.852
I have difficulty eating dry foods	0.819	0.842
I get up at night to drink	0.550	0.864
My mouth feels dry when eating a meal	0.835	0.840
I sip liquids to aid in swallowing food	0.831	0.840
I suck sweets or cough lollies to relieve dry mouth	0.536	0.866
I have difficulties swallowing certain foods	0.755	0.848
The skin of my face feels dry	0.519	0.866
My eyes feel dry	0.473	0.867
My lips feel dry	0.645	0.858
The inside of my nose feels dry	0.492	0.868

ITC, inter-total correlation; α_c, Cronbach's alpha when the item was removed.

Table 4. Mean scores and standard deviations of both administrations of the XI-K questionnaire and intraclass correlation coefficients

Questions of XI-K	First round (n = 194)		Second round (n = 65)			95% CI	
	Median	IQR	Median	IQR	ICC	Min	Max
My mouth feels dry	4	3.75-5	4	3-5	0.708	0.562	0.811
I have difficulty eating dry foods	4	3-5	4	3-5	0.672	0.514	0.786
I get up at night to drink	3	1-4	3	2-3	0.740	0.606	0.833
My mouth feels dry when eating a meal	3	2-4	3	2-4	0.776	0.657	0.858
I sip liquids to aid in swallowing food	3	2-5	3	3-4	0.785	0.669	0.863
I suck sweets or cough lollies to relieve dry mouth	2	1-3.25	3	1-3.5	0.812	0.71	0.881
I have difficulty swallowing certain foods	3	2-4	3	2-4	0.733	0.596	0.828
The skin of my face feels dry	3.5	3-4	3	2.5-4	0.630	0.457	0.757
My eyes feel dry	4	3-5	4	3-5	0.720	0.579	0.82
My lips feel dry	4	3-5	4	3-5	0.694	0.544	0.801
The inside of my nose feels dry	3	2-4	3	2-4	0.480	0.271	0.647
Total	37	30-44	38	30-42	0.827	0.732	0.891

XI-K, Korean version of the XI; CI, confidence intervals; IQR, interquartile ranges; ICC, intraclass correlation coefficients.

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the ICC ranging from 0.48 to 0.812 (Table 4).

Construct validity

To demonstrate construct validity, the correlation between the total XI-K scores and the resting, stimulated, and differential (stimulated minus resting) SFRs was evaluated. The results showed that Spearman's rho was -0.447 for resting SFR, -0.515 for stimulated SFR, and -0.482 for differential SFR ($P < 0.001$; Fig. 1). The construct validity of the XI was originally evaluated by using the single standard question, "How often does your mouth feel dry?", with the following response options: never, occasionally, frequently, and always (10,16). The question was also administered in our study subjects. Spearman's correlation coefficient was 0.772 ($P < 0.001$). We also checked the correlation between XI score and simple VAS score for dryness. The results showed that Spearman's rho was 0.492 ($P < 0.001$), which showed a moderate positive correlation.

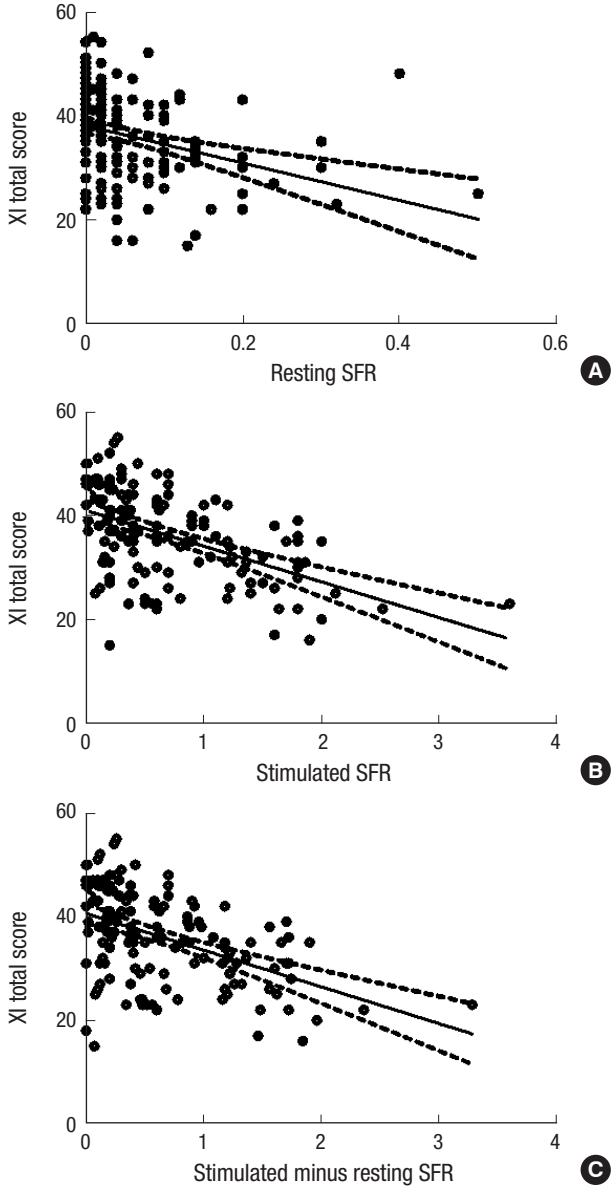

Fig. 1. Spearman's correlation between the Xerostomia inventory (XI) total scores and salivary flow rate (SFR)s. The correlations between XI total scores and the resting (**A**), stimulated (**B**), and differential (stimulated minus resting) (**C**) SFRs were analyzed. The dotted lines depict 95% confidence intervals.

DISCUSSION

The present study demonstrated the process of developing a Korean version of the XI. The XI-K questionnaire was administered to a well-characterized pSS cohort in Korea and showed excellent reliability in terms of internal consistency, test-retest reliability, and construct validity.

The XI was originally developed to evaluate xerostomia in the Austrian elderly (10). Later, it was applied to patients who received radiotherapy for head and neck cancer (16) and diabetic patients (17). It was also used in pSS patients whose sicca symptoms needed to be evaluated (11,18). As mentioned, the Portuguese and Spanish versions of the XI were already developed and validated in pSS populations. We also verified that the performance of the XI was excellent in Korean pSS patients, reflecting the degree of oral dryness appropriately.

To evaluate construct validity, we investigated the correlation between XI score and SFR. We observed only a weak association between the SFRs and subjective symptoms. However, the lack of an objective standard led us to use SFR as standard. Indeed, the SFRs correlated well with the XI total scores. The best correlation was observed with the stimulated SFRs. This may result from the fact that 4 items in the XI deal with hyposalivation during food ingestion, which is more related to stimulated SFR rather than resting SFR. XI total score also correlated well with the original standard question and simple VAS score for dryness, as mentioned. Therefore, the construct validity of XI-K could be considered good. Of note, the negative correlation between the VAS scores for dryness and SFRs was weaker than that between the XI-K scores and SFRs, supporting the appropriateness of using the relatively lengthy XI-K questionnaire rather than the simple VAS of dryness to evaluate subjective severity of xerostomia in pSS patients.

Our study has several limitations. First, not all of the patients answered the second round-questionnaire, and test-retest reliability was tested in a relatively small number of subjects. Second, the subjects in our study only included pSS patients, and whether the tool will work well in non-PSS populations with sicca symptoms remains unclear. On the other hand, the strength of the present study is that our data were based on a relatively large number of pSS subjects enrolled in a prospective cohort.

In conclusion, the Korean version of the XI is a reliable tool to estimate the severity of xerostomia in pSS patients.

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DISCLOSURE

The authors have no potential conflicts of interest to disclose.

AUTHOR CONTRIBUTION

Conception and design of the study: Park SH, Lee J. Data acquisition: Park SH, Kwok SK, Lee J, Koh JH. Statistical analysis and preparation of the manuscript: Lee J. Review and final approval of the manuscript: all authors.

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