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Summated Xerostomia Inventory to detect both xerostomia and salivary gland hypofunction

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Abstract. – OBJECTIVE: This study aims to evaluate the diagnostic performance of the Summated Xerostomia Inventory (SXI-ID) questionnaire in detecting xerostomia and salivary gland hypofunction (SGH).

SUBJECTS AND METHODS: This diagnostic study first underwent a validity and reliability test. Participants were randomly sampled from the Geriatric Clinics of Dr. Hasan Sadikin Hospital, Bandung, Indonesia. The SXI-ID was generated through a forward-backward translation, after which its validity (item-total item correlations), internal consistency (Cronbach's alpha), and test-retest reliability (kappa statistic) were all assessed. The diagnostic performance of the SXI-ID in detecting SGH was evaluated using receiver operating characteristic (ROC) curve analysis.

RESULTS: A total of 60 participants (aged ≥60 years) were involved in this study, most of whom were female (75%). The internal consistency of the SXI-ID was acceptable (α = 0.823), and its test-retest reliability was perfect (K= 1.00). ROC analysis showed that an SXI-ID cut-off value > 11 could detect SGH with a sensitivity of 96.0%, a specificity of 100.0%, and an area under the curve of 0.985 ($p < 0.001$).

CONCLUSIONS: The SXI-ID questionnaire is a valid and reliable tool to detect xerostomia and SGH in older Indonesians, and a score of 11 or above is useful to identify those with a low salivary flow.

Key Words:
Reliability test, Salivary gland hypofunction, SXI questionnaire, Validity test, Xerostomia.

Introduction

Xerostomia is the subjective perception of dry mouth. It is assumed to be associated with low salivary flow, a condition known as salivary gland hypofunction (SGH)[1,2]. Xerostomia and SGH are conditions that may occur independently of each other, but the former is frequently a consequence of the latter. Over 25% of older adults experience xerostomia[3]. Although the proportion of parenchymal acinar cells in salivary glands decreases gradually with age, the prevalence of xerostomia increases[4], but the contribution of aging itself to the age gradient remains unclear[5,6]. The remaining reserve capacity of salivary glands in older adults is adequate to maintain function, unless exogenous factors (such as particular medications) stress this physiological state[4,7]. Multiple chronic degenerative diseases that commonly occur in older adults are also thought to be related with xerostomia through the side effects resulting from multiple pharmacological interventions (polypharmacy). The neurotransmitters are blocked in interacting with salivary gland membrane receptors, and this interferes with the ion transport pathways in acinar cells, reducing the quality and quantity of salivary secretions[4,8,9]. Xerostomia also reduces chewing ability. This results in dyskinesia and oral mandibular dystonia accompanied by chronic oral mucosal pain disorders that cause frailty syndrome in older adults consisting of chronic malnutrition, sarcopenia,

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loss of dependency, poor quality of life, increasing risk of falls, and even death[10-13]. Therefore, the early detection of xerostomia and SGH in older adults is vital to prevent this condition[14-16].

Measurements of xerostomia and SGH are based on subjective and objective assessments, respectively. Self-reported questionnaires used in the identification of xerostomia include the Xerostomia Inventory, the Xerostomia Questionnaire, the Groningen Radiotherapy-Induced Xerostomia, and the Summated Xerostomia Inventory (SXI)[17-20]. SGH is assessed based on objective measurements of salivary flow, also known as sialometry[21]. However, sialometry is time-consuming, and may be impractical for non-dental primary healthcare providers. Thus, the use of xerostomia questionnaires to detect SGH would be an attractive alternative if they could show that a particular range of scale values predicted SGH with acceptable accuracy.

The SXI is a globally used questionnaire that has been recently shown to be a valid tool to apply in the context of Indonesia[22], but its utility in detecting both xerostomia and SGH is yet to be determined. Accordingly, this study aims to test the validity and reliability of the Indonesian version of the Summated Xerostomia Inventory (SXI-ID) through a series of stages, starting with translation and cross-cultural adaptation, and then examining its performance in detecting SGH.

Subjects and Methods

This validity, reliability and diagnostic study was conducted at the Geriatric Clinics of Dr. Hasan Sadikin Hospital, Bandung, Indonesia. Ethical approval was obtained from the Hospital's Ethics Committee (LB.04.01/A05/EC/282/IX/2017).

The participants were randomly sampled from patients presenting at the clinic. Those who agreed with the investigator's explanation signed a statement of consent to participate in this study. The participants were older adults (age ≥ 60 years), without cognitive impairment (MMSE test > 24), severe general weakness, or clinical signs of dehydration (defined as the absence of thirst and dry axilla).

The study was conducted in two phases (**Supplementary Figure 1**). Phase 1 involved the adaptation process for the instrument, as well as validity and reliability testing. The adaptation process comprised (1) translation, which was the process of translating the SXI questionnaire from English to Indonesian by two certified language translators, and vice versa; (2) synthesis or modification, which is the process of merging the two into one unified translation; (3) back-translation, which is the process of re-translating from Indonesian to English by two translators, certified by the National Accreditation Authority for Translators and Interpreters; and (4) a final review by a committee of oral medicine experts and geriatricians. Furthermore, validity testing was conducted on the initial questionnaire. This involved calculating the correlation between the instrument item scores and the total score, known as the Corrected Item-Total Correlation. A questionnaire item is deemed valid when the validity coefficient (r) is greater than or equal to the value of the r table. The instrument's reliability was also determined in two ways. This test was carried out by testing the internal consistency, and then calculating the Cronbach's alpha reliability coefficient and test-retest reliability by checking the *p*-value using the Kappa Coefficient Agreement analysis. An alpha value ≥0.6 indicates good reliability and agreement.

Phase 2 involved a diagnostic study to validate the SXI-ID questionnaire against SGH, based on the American Dental Association (ADA) criterion of an unstimulated whole salivary flow rate of <0.1 ml/min and a stimulated whole salivary flow rate of 0.7 ml/min or less. The resulting unstimulated and stimulated whole saliva flow rates were cross tabulated to arrive at a kappa coefficient. Receiver operating characteristic (ROC) curve analysis and sensitivity and specificity assessments were also carried out. An area under the curve (AUC) value of > 80% reflects the validity of the SXI-ID questionnaire to detect SGH.

Statistical Analysis

The validity test was carried out by calculating the value of the inter-item correlation coefficient (r count ≥ r table), whereas the reliability test was carried out by calculating Cronbach's alpha ($\alpha \geq 0.6$), followed by the Kappa Coefficient Agreement analysis. The concurrent validity of the SXI-ID was determined by comparing the mean scale scores across the ordinal response categories of a standard single-item xerostomia question: "How often does your mouth feel dry?" The response options were "Never," "Sometimes," "Often," or "Always."

Cut-off values and sensitivity and specificity values for detecting SGH were obtained through ROC curve analysis using MedCalc 15.2 software.

Results

The translation and adaptation processes for the SXI-ID were carried out during the initial phase of this study. The outcome after translation, synthesis, back-translation, and a final review of the questionnaire is summarized in **Supplementary Table I.**

The validity test was carried out by conducting interviews with 30 respondents using the SXI questionnaire. The sample comprised 17 females (56.7%) and 13 males (43.3%), with ages ranging from 60 to 85 years (mean 73; SD 6). In the second phase of the study, a total of 60 participants fulfilled the inclusion criteria after two were excluded because of an MMSE score < 24 (Table I). The sociodemographic characteristics of the 60 participants are summarized in Table I. Most participants were female. The prevalence of SGH based on the unstimulated and stimulated salivary flow tests was 41.7% and 63.3%, respectively.

The construct validity test using the Corrected Item-Total Correlation yielded an R-value of > 0.361 from the first question (Q1) to the fifth (Q5) (Table II). The correlation coefficient (r = 0.813) between the SXI-ID questionnaire and the Global Question demonstrated a strong, positive agreement between those tools. Examination of the concurrent validity of the SXI-ID involved comparing mean SXI-ID

Table I. Baseline characteristics of the study participants.

Variable	n=60
Mean age (years) ± SD	70 ± 6
Age Group (n, %)	
60-69	31 (51.7)
70-79	24 (40.0)
≥80	5 (8.3)
Education, n (%)	
Junior High School	1 (1.7)
High School	45 (75.0)
Diploma	10 (16.7)
Bachelor	4 (6.7)
Median MMSE (Range)	27 (25-28)
Median SXI (Range)	9 (5-23)
Median Unstimulated Whole Salivary Flow Rate (Range)	0.3 (0.0-1.4)
SXI-ID score 5-11, median (IQR)	0.36 (0.35-0.48)
SXI-ID score >11, median (IQR)	0.20 (0.17-0.24)
Diagnosis of SGH based on Unstimulated Whole Salivary Flow Rate, n (%)	
SGH	25 (41.7)
Non-SGH	35 (58.3)
Median Stimulated Whole Salivary Flow Rate (Range)	0.6 (0.3-2.0)
SXI-ID score 5-11, median (IQR)	0.66 (0.61-0.78)
SXI-ID score >11, median (IQR)	0.50 (0.47-0.56)
Diagnosis of SGH based on Stimulated Whole Salivary Flow Rate, n (%)	
SGH	38 (63.3)
Non-SGH	22 (36.7)

MMSE, Mini-Mental Status Examination; SD, Standard Deviation; SGH, Salivary Gland Hypofunction; SXI, Summated Xerostomia Inventory.

Table II. Corrected Item-Total Correlation of the Indonesian Summated Xerostomia Inventory (SXI-ID).

Question	Coefficient Correlation (r_{count})	Coefficient Correlation (r_{table})	Validity
Q1	0.707	0.361	Valid
Q2	0.621	0.361	Valid
Q3	0.629	0.361	Valid
Q4	0.484	0.361	Valid
Q5	0.659	0.361	Valid

Table III. Mean total SXI-ID scores by responses to the standard xerostomia question.

Standard Question	Mean (SD) SXI	Median (range) SXI	*p*
Never	7.7 (2.6)	7 (5 to 15)	<0.001*
Occasionally	10.5 (0.7)	10.5 (10 to 11)	
Frequently	15.3 (1.6)	15.0 (13 to 17)	
Always	-	-	

*Kruskal-Wallis test

scores across the ordinal response categories of the global dry mouth question (Table III). This showed a consistent and statistically significant gradient across the response categories, although no one reported "Always" for dry mouth. The kappa coefficient and Cronbach alpha value for the SXI-ID was 1.000 and 0.823, respectively.

ROC analysis was performed (Table IV), and the diagnosis of SGH using the SXI-ID had an AUC value of 0.985 ($p < 0.001$). The questionnaire was found to have 96% sensitivity and 100% specificity at a cut-off value > 11 (Figure 1).

Table V and **Supplementary Table II** present data on the degree of concordance between SGH determined from the stimulated and unstimulated salivary flow rates. Although almost two-thirds of the participants were "cases," only 65.7% (25 of 38) were identified by both approaches. However, Figure 2 shows a strong correlation between the unstimulated and stimulated salivary flow rates, with r = 0.845.

Discussion

This study confirmed that the SXI-ID has acceptable validity and reliability in detecting xerostomia in older people. This is consistent with the findings by Wimardhani et al[22] and from other versions of the SXI in various countries[20,23,24]. Besides, this study showed that a cut-off value > 11 on the SXI-ID can be used to diagnose SGH (**Supplementary Table III**), with high sensitivity (96%) and specificity (100%).

The cut-off value of > 11 on the SXI-ID was selected based on examination using an unstimulated whole salivary flow rate. This value is considered useful because the findings with the kappa cross-tabulation (categorical) and the correlation (numeric) between unstimulated and stimulated flow rates are concordant.

This study, however, did not analyse factors that influence the occurrence of xerostomia, such as medication use, smoking, and chronic disease. As the participants in this study were older people, the SXI-ID cut-off value may not apply to the general population. However, this research has several advantages. First, an external validation test was carried out by performing a diagnostic test with sialometry as a gold standard for SGH. Two methods were involved, namely, stimulated, and unstimulated whole salivary flow rates. Both provided acceptable accuracy and agreement. The validity of the findings was also further strengthened by the magnitude of the correlation between the SXI-ID and the Global Question. In addition, an external reliability test was conducted with an analysis of the reliability between the assessments using the SXI-ID in the first and second weeks.

Table IV. The best SXI-ID cut-off value (threshold) for diagnosing Salivary Gland Hypofunction using the unstimulated and stimulated whole salivary flow rates.

Variable	AUC (95% CI)	*p*-value	Cut-off	Diagnostic Value (95% CI)
SXI-ID Score (Unstimulated whole salivary flow rates)	0.98 (0.91 - 1.0)	<0.001	>11	Sensitivity: 96% (79.6% - 99.9%) Specificity: 100% (90% - 100%) PPV: 100% (85.8% - 100%) NPV: 97.2% (85.5% - 99.9%)
SXI-ID Score (Stimulated whole salivary flow rates)	0.84 (0.72 - 0.92)	<0.001	>10	Sensitivity: 65.8% (48.6% - 80.4%) Spesifisitas: 100% (84.6% - 100%) PPV: 100% (86.3% - 100%) NPV: 62.9% (44.9% - 78.5%)

CI, Confidence Interval; NPV, Negative Predictive Value; PPV, Positive Predictive Value; SGH, Salivary Gland Hypofunction.

Table V. Concordance between salivary gland hypofunction estimates determined using unstimulated flow and stimulated flow rates (brackets contain total percentages unless otherwise indicated).

		Stimulated flow < 0.7 ml/min		
		No	Yes	
Unstimulated flow < 0.1 ml/min	No	22 (36.7)	13 (21.7)	35 (58.3)[a]
	Yes	0 (0.0)	25 (41.7)	25 (41.7)[a]
		22 (36.7)[b]	38 (63.3)[b]	60 (100.0)

[a]Column percent; [b]Row percent.

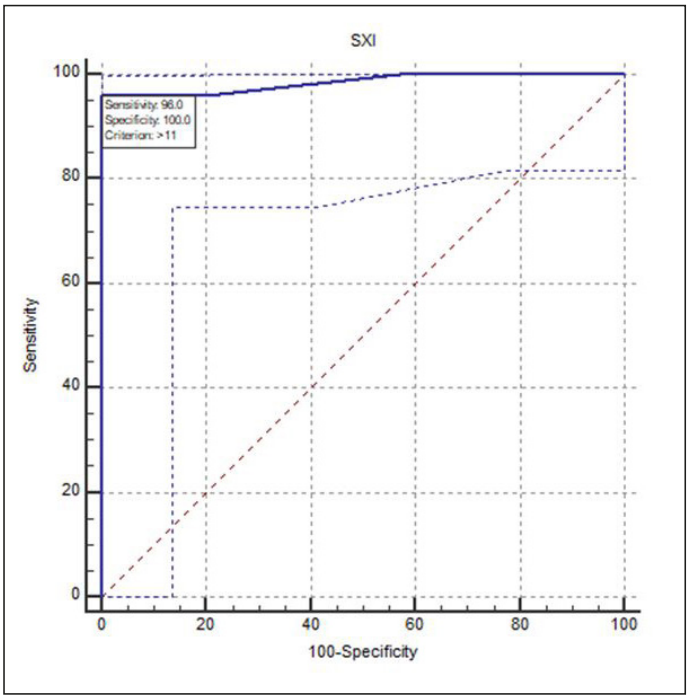

Figure 1. Receiving Operating Curve (ROC) analysis for sensitivity and specificity of SXI-ID in diagnosing Salivary Gland Hypofunction using the unstimulated whole salivary flow rates.

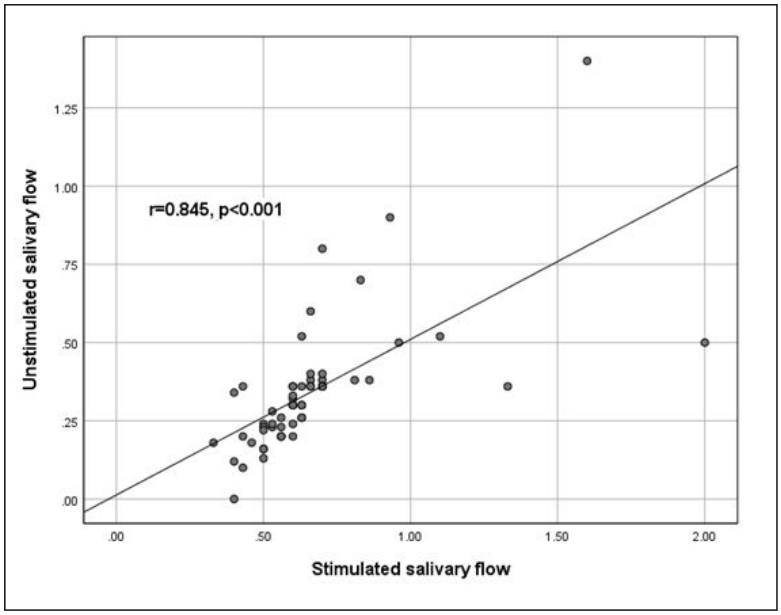

Figure 2. Scatter plot of unstimulated salivary flow against stimulated salivary flow.

Conclusions

To the best of our knowledge, no prior study has determined a cut-off SXI-ID value to identify SGH in older people using sialometry, as recommended by the ADA[21,25]. Based on the findings obtained, the SXI-ID can be applied by non-dental healthcare providers in geriatric clinics and primary care to identify likely cases of SGH in older people who would benefit from further investigation of their salivary flow rates. The earlier detection of xerostomia and faster diagnosis of SGH in the elderly using this approach should prove beneficial for disease prevention, thus improving the overall quality of life of older people.

The SXI-ID shows good validity, reliability, and diagnostic performance in detecting xerostomia with SGH in older adults.

Authors' Contribution

Study concept and design: Lazuardhi Dwipa, Tenny Setiani, Rita Wardhani.
Acquisition of data: Rita Wardhani.
Analysis and interpretation of data: Lazuardhi Dwipa, Tenny Setiani, Rita Wardhani, Evan Susandi.
Drafting of the manuscript: Lazuardhi Dwipa, Rita Wardhani, Irna, Ian Huang, Valentine Natasya Moenardi, Yuni Susanti Pratiwi, William Murray Thomson.
Critical revision of the manuscript for important intellectual content: Irna, Yuni Susanti Pratiwi, William Murray Thomson.

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Conflict of Interest

The authors report no conflict of interest.

Data Availability

The data that support the findings of this study are openly available through google drive in the shared folder under "Research data of SXI-ID" at:
https://drive.google.com/drive/u/1/folders/1cVPG_srVh-0dgI3HVkN-ZEBtfNURN9YiQ

Ethics Approval

This validity, reliability and diagnostic study was conducted at the Geriatric Clinics of Dr. Hasan Sadikin Hospital, Bandung, Indonesia. Ethical approval was obtained from the Hospital's Ethics Committee (LB.04.01/A05/EC/282/IX/2017).

Informed Consent

Those who agreed with the investigator's explanation signed a statement of consent to participate in this study.

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