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Original Article

Psychometric validation of the Chinese version of the Edmonton-33 scale in patients with head and neck cancer

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ABSTRACT

Objective: This study aimed to translate the Edmonton-33 scale (E−33) into Chinese and evaluate its reliability and validity in patients with head and neck cancer (HNC).
Methods: In Phase 1, the E−33 was translated from English to Chinese using the Brislin double-back translation method. Content validity was evaluated by a panel of experts, and a pilot test was conducted with a small sample of HNC patients. In Phase 2, a cohort of 510 patients from Henan and Hubei provinces was recruited. Psychometric properties were assessed through item analysis; and reliability testing (including Cronbach's alpha, test-retest reliability, and split-half reliability), as well as construct validity (using exploratory and confirmatory factor analysis).
Results: The item-level content validity index (I–CVI) ranged from 0.833 to 1.000, and the scale-level content validity index (S–CVI/Ave) was 0.965. The Cronbach's alpha, the test-retest reliability coefficient, and the split-half reliability values were 0.922, 0.973, and 0.971, respectively. Four main factors were identified using exploratory factor analysis, explaining 77.07% of the total variance. Confirmatory factor analysis showed good fit indices: $\chi^2/df = 1.626$, RMSEA = 0.048, NFI = 0.936, RFI = 0.930, IFI = 0.974, TLI = 0.972, and CFI = 0.974.
Conclusions: The Chinese version of the Edmonton-33 scale (CE-33) demonstrated high reliability and validity, suggesting its potential as a valuable self-report tool for assessing functional outcomes in Chinese-speaking HNC patients.

Introduction

Head and neck cancer (HNC) is one of the most rapidly increasing cancers worldwide. Global cancer statistics indicate that HNC accounted for 4.8% of all cancer cases in 2020, with 932,000 new cases and 467,000 deaths worldwide.[1] In China, 103,000 new cases and 51,000 deaths were reported.[2] While diagnostic and treatment advancements have significantly improved cure rates and long-term survival for HNC patients,[3,4] the 1-year survival rate for HNC ranges from 70% to 92.6%.[5,6] The 5-year survival rate for HNC ranges from 45% to 79.3%.[4,5,7] HNC survivors face not only common challenges that cancer patients encounter, such as fear of death, pain, weight loss, self-image disorders, anxiety, depression, and other negative emotions, as well as social functioning issues,[8–10] but also unique head and neck dysfunctions, including swallowing and chewing difficulties, dysarthria, shoulder and neck dysfunctions, dry mouth, dyspnea, and altered taste and smell.[11,12] These issues significantly affect their recovery and quality of life.[13,14]

Patients with HNC often experience functional impairments due to both the tumor itself and its treatments. Functional outcomes assess the extent to which a patient can engage in various activities.[15] In HNC research, the selection of functional outcomes and measurement methods varies widely among research teams. This variability hinders the comparison and synthesis of results across studies with comparable interventions. The establishment of core functional endpoints ensures consistent measurement and reporting of outcomes, facilitating valid comparisons of treatments across different studies.[16–18] Metcalfe et al.[19] identified four key endpoints considered most important by patients with HNC, based on tumor site and disease progression: speech, dry mouth, swallowing, and mastication. Mendez et al.[20] obtained similar results in a study of patients with HNC through open-ended interviews and modified Delphi counseling. Swallowing, speech, dry mouth, and chewing were identified as the most important functional outcomes among HNC survivors and are core functions of the head and neck.[21] Riechelmann et al.[22] examined 681 individuals with HNC and found that 40% of

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participants experienced significant, long-lasting impairments in at least one area of functioning. Core dysfunction in HNC survivors causes both physical suffering and psychological trauma.[23] Their suicide risk is twice that of survivors of other cancers and persists for a prolonged period, severely affecting their quality of life.[24]

Given the wide range of challenges faced by HNC patients, it is crucial to assess their functional outcomes accurately.[25] These assessments are typically categorized into two main types: quality of life and symptom measurement scales, and functional outcome assessment tools tailored to specific HNC subgroups. The first category encompasses quality of life and symptom measurement scales designed for HNC patients, such as the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Head and Neck Cancer (EORTC QLQ–H&N35),[26] the University of Washington Quality of Life Questionnaire (UW–QOL),[27] the M. D. Anderson Symptom Inventory (MDASI–H&N),[28] and the Head and Neck Patient Symptom Checklist (HNSC).[29] These scales contain only one or a few items related to core functional outcomes in HNC, lacking the specificity needed for comprehensive evaluation. Furthermore, measures of quality of survival are influenced by psychological factors, response shifting, and social desirability bias, which may affect their accuracy in reflecting the extent of dysfunction and symptoms.[22,30–32] The second category includes functional outcome assessment tools for specific HNC subgroups, such as the Swallowing Outcome After Total Laryngectomy (SOAL)[33] and the Xerostomia Questionnaire (XQ).[34] These scales are primarily unidimensional and focus on specific functional outcomes. Therefore, the evaluation of functional status in one HNC subgroup may not be generalized to other subgroups. Furthermore, most existing scales were developed without patient input, which may limit their comprehensiveness.[35,36] Although many tools exist to assess functional outcomes in HNC patients, few focus on core functional outcomes from the patient's perspective.

Patient-reported outcomes (PROs) allow patients to report treatment-related functional status from the perspective of their feelings and interests.[37] This ensures sensitivity to the subjective assessment of symptoms and addresses the tendency of observers to underestimate the severity of patients' symptoms compared to patients' own experiences.[38] PROs offer invaluable insights by capturing the subjective experience of patients, often providing details that medical staff or family members might overlook. This is particularly critical for assessing the functional challenges faced by HNC survivors, as traditional clinical assessments may fail to fully capture the extent of dysfunction.[39] The assessment of HNC survivors facing severe dry mouth, swallowing, speech, and chewing dysfunction is highly subjective.[13,31]

The E-33, a 33-item Likert–type scale developed by Mendez et al.,[20] was officially published in *JAMA Otolaryngology-Head & Neck Surgery*. This patient-centered instrument emphasizes active patient involvement, ensuring that the functional domains it measures align with patients' priorities. Specifically, the scale evaluates core functional outcomes in patients with HNC, including swallowing, speech, xerostomia, and chewing. The E-33 has been translated into Finnish, and ethical approval was obtained for the study in Turku University Hospital. Studies have shown that the E-33 scores correlate strongly with several other relevant measures: the swallowing scores of the MD Anderson Dysphagia Inventory ($r = 0.77$), the EORTC QLQ–H&N35 ($r = -0.73$), and the modified barium swallow test ($r = -0.60$). Additionally, there are strong correlations with the Speech Handicap Index scores ($r = -0.64$), word intelligibility scores ($r = 0.61$), and sentence intelligibility scores ($r = 0.55$). Furthermore, moderate to strong correlations were observed between the E-33 and the EORTC QLQ–H&N35 in the dry mouth ($r = -0.54$) and chewing ($r = -0.45$) domains.[20]

Despite its established reliability and validity in Western populations, the E-33 scale has yet to be adapted and validated for Chinese HNC patients, creating a gap in its applicability in non-Western contexts. In conclusion, this study aims to fill a crucial gap in the existing literature by translating the E-33 scale into Chinese and assessing its psychometric properties. By validating the scale for Chinese HNC patients, this research contributes to more accurate and culturally appropriate functional outcome assessments, improving the management of HNC survivors.

Methods

Study design

This study had two phases. In Phase 1, the Edmonton-33 scale was translated into Chinese using the Brislin double-back translation method,[40] followed by content validity assessment and a pilot test with HNC patients. In Phase 2, the psychometric properties of the CE-33 were evaluated in 510 HNC patients from Henan and Hubei provinces. Reliability was assessed using Cronbach's alpha, test-retest, and split-half methods. Exploratory and confirmatory factor analyses were conducted to confirm validity.

Phase 1: translation and content validation

Forward translation: The scale was translated into Chinese with permission from Professor Hadi Seikaly. Two native Chinese speakers fluent in English independently translated the English version of the E-33 into Chinese. Both translators held degrees in oncology and were familiar with HNC–related terminology. The second translator was a graduate student specializing in nursing. After reviewing the two Chinese versions, the researchers (authors) collaborated with the two translators to consolidate them into a unified version.

Back translation: Two bilingual academics, who had not previously seen the scale, independently translated the CE-33 back into English. To reach consensus, the two back-translated versions were compared, and the discrepancies between them were discussed. After back-translation, the scale was virtually identical to the original version.

Cultural adaptation: Six experts—two clinical medical doctors, two nursing professors, and two senior nurses—participated in the cultural adaptation of the scale based on the concept of cultural adaptation.[41] The criteria for inclusion of experts were: the research focus is on clinical nursing, medical treatment, management, and scientific research in head and neck cancer; a bachelor's degree or higher; more than 10 years of work experience; and an intermediate or higher title. Six experts thoroughly reviewed and compared the original, translated, and back-translated versions of the E-33. They engaged in detailed discussions until consensus was reached. It was agreed that the E-33 and CE-33 were conceptually equivalent in terms of semantics, idiomatic expressions, rhetoric, and underlying concepts.

Content validity: Six experts in cultural adaptation evaluated the significance of each item and its relevance to the corresponding content. Based on their evaluations, the content validity index for each item, dimension, and the total scale was calculated. The I– CVI was calculated as the ratio of experts scoring an item 3 or 4 to the total number of experts.[42] The average I–CVI for each item is referred to as the S–CVI/Ave (*average*). Content validity was considered good if the S–CVI/Ave was 0.9 or higher.

Pilot testing: A pilot test of the CE-33 was conducted with 20 HNC patients. Participants completed the scale independently, followed by cognitive interviews to evaluate clarity, item comprehension, and overall acceptability.

Phase 2: psychometric testing

Participants. This was a cross-sectional study. Patients diagnosed with HNC were recruited from two general hospitals in Wuhan and Zhengzhou between December 2023 and June 2024. Inclusion criteria were: (a) diagnosis of HNC (oral cavity, oropharynx, hypopharynx, or laryngeal); (b) age 18 or older; and (c) no history of mental illness with the ability to comprehend the scale items. Exclusion criteria included: (a) patients who had other malignant tumors; and (b) those with evidence of disease recurrence.

The study followed the Kendall criteria, which recommend a sample size of 5–10 times the number of items for exploratory factor analysis (EFA);[43] a minimum of 200 participants for confirmatory factor analysis (CFA);[44] and

an estimated sample size of 402–583, considering a 10% dropout rate for the 33 items on the E-33 scale. A total of 510 HNC patients participated in the survey. For the patient flow chart, please refer to Fig. 1.

Study instruments

General demographic attributes. A survey was developed to collect demographic data, including medical history, primary tumor site, pathological stage, treatment, age, education level, sex, occupation, and marital status.

The CE-33. The scale consists of 33 items across four dimensions: swallowing (11 items), speech (10 items), xerostomia (7 items), and chewing (5 items). Each item can be rated on a scale from 1 to 5, with response options including "Strongly Agree," "Agree," "Neutral," "Disagree," and "Strongly Disagree." Respondents may also choose "Not Applicable." Each domain was assigned a score between 0 and 100. A linear transformation was applied to each domain, yielding a score ranging from 0 to 100, with higher scores indicating better functioning (Appendix A).

Data collection

Three team members distributed the surveys using a convenience sampling method. Investigators were uniformly trained to administer the questionnaires to patients using standardized language. After obtaining consent from the relevant hospitals and departments, investigators were introduced to patients by the head nurse or nurse in charge. After obtaining patient consent, the investigators distributed the questionnaires. Participants completed the questionnaires independently after receiving an explanation of the survey's purpose and significance. When patients had poor vision or difficulty holding a pen, investigators completed the questionnaires based on the participant's responses. Thirty participants were randomly selected for a follow-up survey 14 days later to assess the questionnaire's retest reliability.

Statistical analysis

Statistical analyses were conducted using AMOS 24.0 and SPSS 25.0. Data were double-checked before being entered. Continuous variables were described using the mean and standard deviation, while categorical variables were described using frequencies and percentages. The normality of the data distributions was assessed by examining the skewness and kurtosis values, which ranged from −2 to 2.[45]

Item analysis

Item analysis was conducted to evaluate the suitability and reliability of the scale. Three methods were used to assess the questionnaire items.

Critical ratio (CR): The scale's overall scores were divided into two categories: the top 27% in the high category and the bottom 27% in the low category. Statistically significant discrimination was indicated by a CR < 3 and $P < 0.05$, suggesting that the corresponding items should be retained.[46]

Correlation coefficient: An item was considered highly homogeneous with the overall scale if it had a correlation coefficient of 0.4 or higher and $P < 0$ 0.05.[46]

Reliability test: An item was deleted if its removal resulted in a significantly higher Cronbach's alpha for the scale.[46]

Construct validity

EFA: The Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy was greater than 0.8, while Bartlett's test was significant ($P < 0.05$); this indicates that the data are suitable for conducting EFA. Principal component analysis with maximum variance orthogonal rotation was used to extract common factors without restricting the number of factors. The assessment criteria were as follows: factors with eigenvalues > 1 were retained; the cumulative explained variance should exceed 50%; each factor should have ≥ 3 items; and the factor loading of each item on its primary factor should be > 0.4, with loadings on other factors < 0.4. These criteria align with the use of a scree plot to determine the optimal number of factors.[47]

CFA: The proposed factor structure was validated through CFA. The model fit indices were estimated and assessed using the maximum likelihood method. Several metrics were used to evaluate model fit, including the ratio of chi-square to degrees of freedom (χ^2/df), root mean square error of approximation (RMSEA), Normed Fit Index (NFI), Relative Fit Index (RFI), Incremental Fit Index (IFI), Tucker–Lewis Index (TLI), and Comparative Fit Index (CFI). Model fit was considered acceptable when the following criteria were met: $\chi^2/df < 3.0$, RMSEA $<$ 0.05, NFI > 0.90, RFI > 0.90, IFI > 0.90, TLI > 0.90, and CFI > 0.90.[48]

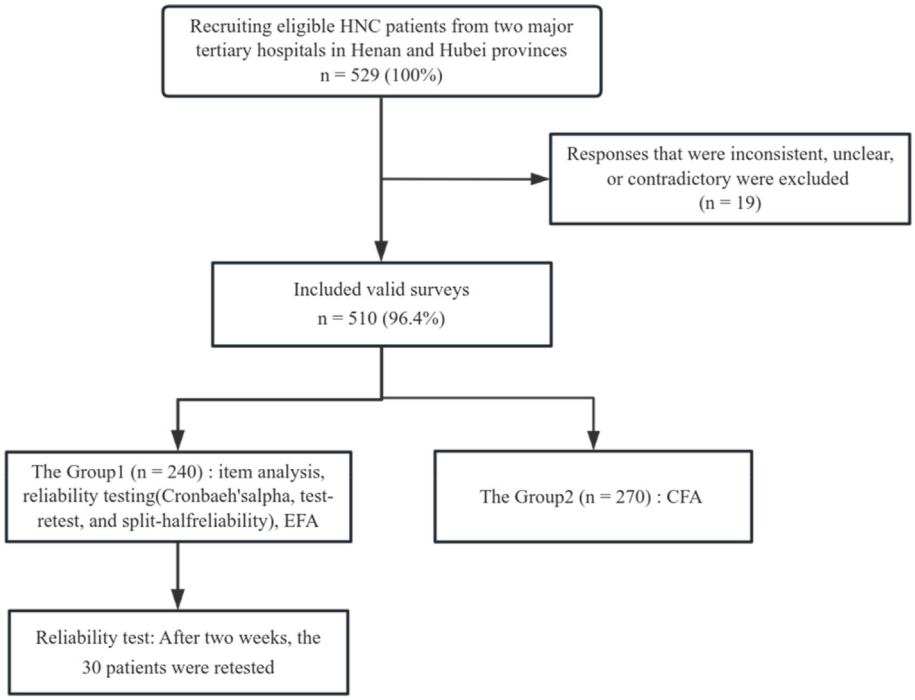

Fig. 1. Patient flow chart. HNC, Head and neck cancer; EFA, Exploratory factor analysis; CFA, Confirmatory factor analysis.

Reliability analysis

Internal consistency reliability refers to the degree of consistency among scale items, with a value generally greater than 0.8.[49]

Retest reliability is the stability of the scale; after two weeks, the 30 patients were retested, and the correlation between retest values should generally be > 0.7.[50]

Split-half reliability divides the questionnaire into two halves based on odd and even items, and calculates the correlation between the scores of the two groups. The split-half reliability coefficient should generally be greater than 0.7.[51]

Results

Phase 1: translation and content validation

The specialists' ages ranged from 39 to 60 years (51.50 ± 7.54 years), with 14–41 years of experience (27.5 ± 9.59 years). The team included one chief physician, one deputy chief physician, two chief nurses, one deputy chief nurse, and one head nurse. In terms of academic credentials, one held a Ph.D., three held master's degrees, and two held bachelor's degrees. Two specialized in clinical medicine, two in clinical nursing, one in nursing research, and one in nursing management. The initial version of the E-33 was culturally adapted for use in China. One key modification involved changing "hard candy" to "lollipop" in item 25 to better reflect Chinese preferences. HNC patients often face difficulties such as swallowing issues and oral mucosal pain during treatment. Hard candies typically require more chewing or take a long time to dissolve in the mouth. In contrast, lollipops, which can be licked instead of chewed, provide an effective alternative by stimulating saliva production, thereby alleviating dry mouth. This change was supported by a portion of the expert panel, which included one clinical medical doctor and two nurses, during the cultural adaptation process. They agreed that lollipops were more culturally appropriate and practical for Chinese patients. The I–CVI at the item level ranged from 0.833 to 1.000, and the S–CVI /Ave was 0.965. A pilot test showed that the CE-33 questionnaire was clear, easy to understand, and took approximately three minutes to complete. All 20 patients found the scale easy to comprehend, with no difficulties in answering the items.

Phase 2: psychometric testing of CE-33

Participant characteristics

A total of 529 surveys were completed. Responses that were inconsistent, unclear, or contradictory were excluded from the sample. Ultimately, a response rate of 96.4% was achieved, with 510 valid surveys collected. The 510 valid surveys were randomly divided into two groups: the EFA group ($n = 240$) and the CFA group ($n = 270$).

A total of 215 (42.16%) questionnaires were completed by participants from Zhengzhou, and 295 (57.84%) by participants from Wuhan. The sample included 345 (67.65%) males and 165 (32.35%) females, with ages ranging from 28 to 89 years. A detailed description of the participants' demographic characteristics is presented in Table 1.

Item analysis

The CR approach revealed significant differences between the low and high groups ($P < 0.001$). The CR values ranged from 5.056 to 13.365. The correlation coefficients between the items and the total scale ranged from 0.418 to 0.640. Removing any item did not result in an increase in the Cronbach's alpha coefficient for the overall questionnaire. Detailed information is shown in Table 2.

Construct validity

EFA. The 33 items were analyzed using EFA. The KMO score was 0.922, and Bartlett's test of sphericity yielded a value of 9341.122 (528 degrees of freedom, $P < 0.001$). Table 3 shows that four factors with eigenvalues

Table 1
Clinical and demographic details ($N = 510$).

Characteristics	*n* (%)
Sex	
Male	345 (67.65)
Female	165 (32.35)
Age (years, mean ± SD)	60.50 ± 10.93
Education level	
Elementary and lower	143 (28.04)
Junior high school	156 (30.59)
Senior high school	151 (29.61)
College and above	60 (11.76)
Occupation	
Agriculture	165 (32.35)
Employee	144 (28.24)
Retired	86 (16.86)
Other	115 (22.55)
Marital status	
Married	462 (90.59)
Other	48 (9.41)
Primary tumor site	
Oral cavity	122 (23.92)
Oropharyngeal	82 (16.08)
Hypopharyngeal	112 (21.96)
Larynx	194 (38.04)
Stage	
Early	240 (47.06)
Advanced	270 (52.94)
Treatment	
Operation	112 (21.96)
Radiotherapy	84 (16.47)
Chemotherapy	79 (15.49)
Combined treatment	205 (40.20)
Other	30 (5.88)

Table 2
Findings of the CE-33 item evaluation.

Item	Critical ratio	Correlation coefficient	Cronbach's α if deleted
1	5.056	0.434	0.921
2	8.007	0.525	0.920
3	8.436	0.517	0.920
4	10.129	0.566	0.919
5	9.050	0.556	0.919
6	7.654	0.491	0.920
7	9.623	0.572	0.919
8	9.421	0.547	0.920
9	10.368	0.607	0.919
10	9.418	0.568	0.919
11	10.910	0.616	0.919
12	6.901	0.501	0.920
13	10.394	0.589	0.919
14	8.463	0.519	0.920
15	9.365	0.572	0.919
16	9.666	0.601	0.919
17	9.095	0.570	0.919
18	8.350	0.539	0.920
19	7.663	0.520	0.920
20	9.306	0.537	0.920
21	8.432	0.504	0.920
22	9.633	0.541	0.920
23	9.513	0.576	0.919
24	11.188	0.608	0.919
25	9.238	0.548	0.920
26	13.365	0.640	0.918
27	10.609	0.587	0.919
28	10.655	0.602	0.919
29	6.470	0.418	0.922
30	8.001	0.468	0.921
31	6.730	0.425	0.922
32	7.251	0.464	0.921
33	8.698	0.493	0.921

CE-33, Chinese version of the Edmonton-33 scale.

Table 3
EFA result of the CE-33 ($n = 240$).

Factor	Items	Factor loadings			
		1	2	3	4
Swallowing	1. I Can swallow normally	**0.590**	0.242	−0.083	0.039
	2. Swallowing takes a lot of effort	**0.812**	0.122	0.030	−0.035
	3. It takes me longer to eat than others because of swallowing problems	**0.793**	0.175	−0.036	−0.010
	4. I Cough or choke when I try to drink liquids	**0.855**	0.212	−0.023	−0.035
	5. I Limit my food intake because of difficulty swallowing	**0.876**	0.148	−0.003	−0.034
	6. I Can maintain my weight by eating	**0.654**	0.222	0.019	0.001
	7. Food or liquid comes out of my mouth	**0.855**	0.192	0.009	−0.034
	8. Food or liquid comes out of my nose	**0.816**	0.137	0.033	−0.001
	9. I Have to plan ahead to eat because of swallowing problems	**0.887**	0.196	0.006	0.012
	10. I Avoid certain types of food because of swallowing problems	**0.890**	0.208	−0.022	−0.079
	11. I Cough or choke when I eat solid food	**0.913**	0.187	0.039	−0.040
Speech	12. I Can speak normally	0.249	**0.570**	0.086	0.053
	13. My speech sounds “nasal”	0.176	**0.619**	0.270	0.087
	14. I Avoid using the phone because of the speech problem	0.137	**0.751**	0.126	−0.041
	15. I Find certain words difficult to pronounce	0.219	**0.852**	0.015	−0.005
	16. My speech sounds slurred	0.206	**0.897**	0.057	−0.034
	17. When speaking face to face, people ask me to repeat myself	0.205	**0.863**	0.027	−0.027
	18. It takes me longer to talk because of speech problems	0.169	**0.901**	−0.006	−0.067
	19. I Speak with great effort	0.210	**0.867**	−0.047	−0.075
	20. My voice makes it difficult for people to hear me	0.192	**0.886**	0.003	−0.099
	21. My voice sounds creaky and dry	0.240	**0.848**	−0.016	−0.185
Dry mouth	22. My mouth feels dry	−0.035	0.031	**0.858**	0.247
	23. I Have trouble eating dry food because of dry mouth	0.042	0.040	**0.869**	0.197
	24. Because of dry mouth, I have to take a sip of liquid to help me swallow my food	0.001	0.086	**0.893**	0.249
	25. I Use lollipops, gum, or other products to relieve dry mouth	−0.059	0.042	**0.882**	0.259
	26. My saliva is very sticky	0.022	0.139	**0.866**	0.271
	27. I Always carry liquids with me because of dry mouth	−0.007	0.057	**0.916**	0.213
	28. Dry mouth makes it difficult for me to speak	0.004	0.063	**0.918**	0.228
Chewing	29. I Can chew normally	−0.031	−0.076	0.289	**0.878**
	30. I Have difficulty chewing hard food because of my teeth, mouth, or dentures	−0.046	−0.045	0.372	**0.876**
	31. I Take longer to eat than others because of chewing problems	−0.028	−0.109	0.343	**0.865**
	32. It's hard for me to open my mouth wide enough to eat	−0.046	−0.065	0.377	**0.888**
	33. I Have difficulty moving food with my tongue	−0.009	−0.052	0.394	**0.870**
Eigenvalue		**7.795**	**7.071**	**6.251**	**4.316**
Variance contribution (%)		**23.621**	**21.428**	**18.944**	**13.078**

EFA, Exploratory factor analysis; CE-33, Chinese version of the Edmonton-33 scale.

greater than 1 were extracted, explaining 77.07% of the variance in questionnaire responses.

CFA. The CFA results are shown in Fig. 2. The initial model was revised based on the fit statistics. The data before and after correction are presented in Table 4.

Reliability analysis

Cronbach's alpha values for the overall questionnaire and for the swallowing, speech, dry mouth, and chewing subscales were 0.922, 0.957, 0.952, 0.970, and 0.972, respectively. The overall scale and its subscales demonstrated retest reliability values of 0.973, 0.911, 0.914, 0.946, and 0.918, respectively. Split-half reliabilities for the overall scale and its subscales were 0.971, 0.961, 0.919, 0.979, and 0.972, respectively.

Discussion

This study presents the first systematic translation and cultural adaptation of the E-33 scale into Chinese. In item 25, “hard candy” was changed to “lollipop”, based on expert recommendations. This change was made to better align with Chinese linguistic preferences and to ensure clinical appropriateness for patients with oral dysfunction. Patients with HNC often experience significant challenges such as swallowing difficulties (55.6% to 98.5%), pain (89.2% to 95.7%), and oral mucosal discomfort (81.2% to 89.1%) during the late stages of radiotherapy.[52,53] These symptoms make it difficult to consume hard or solid foods, such as hard candies, which require significant chewing or longer to dissolve.[54] In contrast, lollipops, which can be licked instead of chewed, provide a suitable alternative by stimulating saliva production and alleviating dry mouth.

To date, there is no PRO measure specifically designed to assess core functional outcomes in patients with HNC exists in China.[36,55] Existing tools like the SOAL[33] and the XQ[34] provide valuable insights into specific areas, but they are largely unidimensional and fail to address the full range of functional issues experienced by HNC patients. The functional outcome scale developed by Zhang et al. for patients after partial laryngectomy contains 21 items across three domains: swallowing, articulation, and respiratory function.[56] This scale has a Cronbach's α coefficient of 0.928.[56] However, it focuses primarily on laryngeal function and is only applicable to patients who have undergone partial laryngectomy following laryngeal cancer. Although these scales were developed with input from patients, they predominantly emphasize functional status and do not necessarily apply to the broader HNC population. Further research is needed to determine their applicability to all HNC patients. In contrast, the E-33 scale comprehensively addresses core functional outcomes across four key areas of concern for HNC patients. Therefore, there is a pressing need for a comprehensive, multidimensional PRO measure tailored specifically to Chinese HNC patients.

The CE-33 demonstrated strong discriminant validity, with item CR values ranging from 5.056 to 13.365, which are above the typical range. Modest to substantial positive correlations were observed between individual item scores and the total scale score. Cronbach's alpha did not improve by removing any items, suggesting that all items contribute meaningfully to the scale's internal consistency.

Validity refers to the extent to which the assessment tool accurately reflects the construct it is intended to measure. The scale's reliability was assessed through content and structural evaluations. I–CVI and S–CVI/

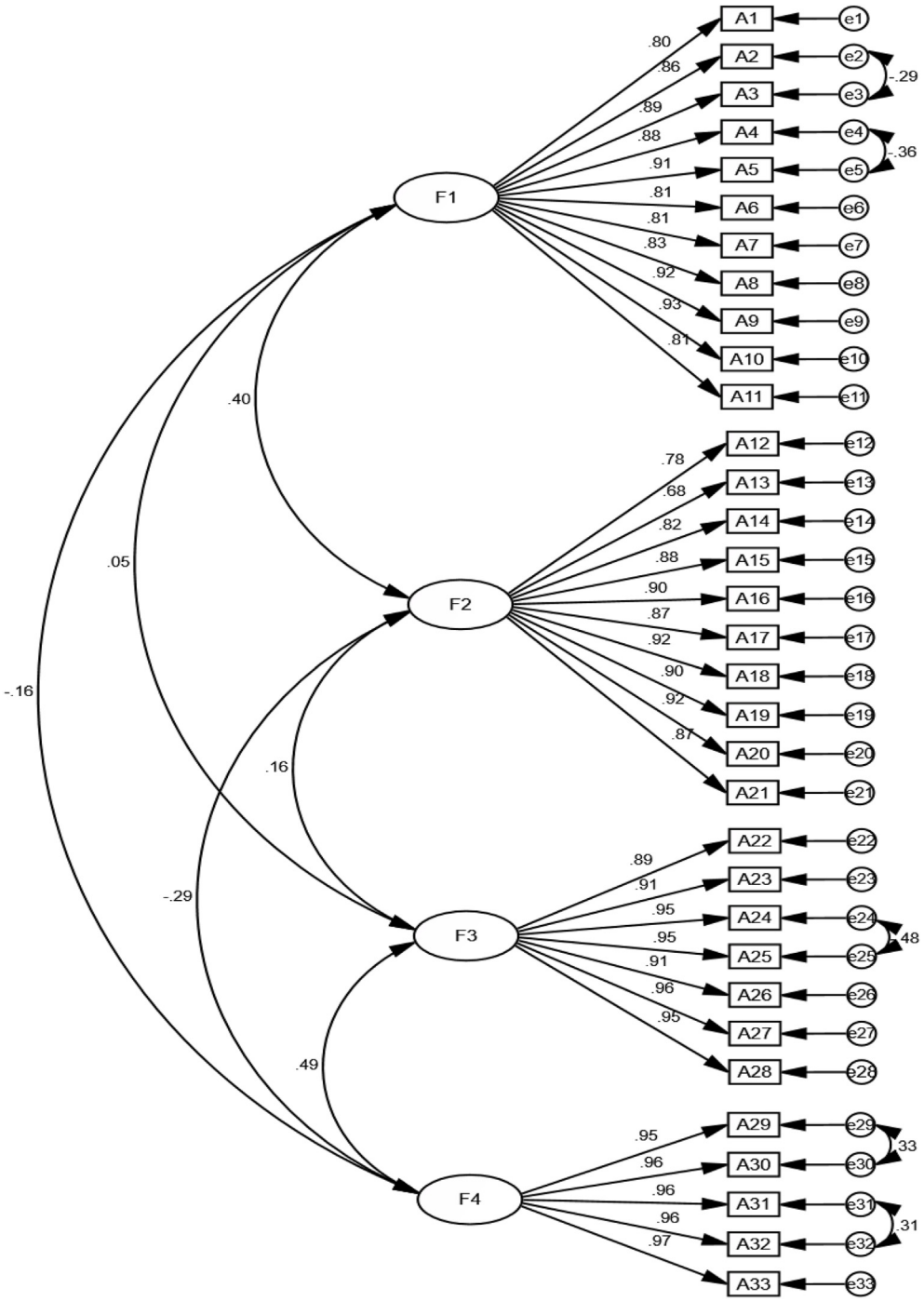

Fig. 2. A standardized four-factor framework of the CE-33 ($n = 270$). CE-33, Chinese version of the Edmonton-33 scale.

Ave values exceeded the acceptable thresholds.[57] Exploratory factor analysis identified a four-factor structure explaining 77.07% of total variance. Notably, the factor loadings in the CE-33 (all > 0.4) were higher than those in the E-33 (all > 0.3), which may be due to better cultural and linguistic adaptation in the translated version. However, further validation is needed to confirm these findings.[58] CFA demonstrated that the CE-33 provided a satisfactory fit for clinical settings.[59] Therefore, the test exhibits adequate reliability for individuals with HNC.

Table 4
Evaluation of fit of the CE-33 model.

Fit index	χ^2/df	RMSEA	NFI	RFI	IFI	TLI	CFI
Initial model	1.855	0.056	0.926	0.921	0.965	0.962	0.965
Modified model	1.626	0.048	0.936	0.930	0.974	0.972	0.974
Standard	< 3	< 0.05	> 0.9	> 0.9	> 0.9	> 0.9	> 0.9

RMSEA, root mean square error of approximation; NFI, Normed Fit Index; RFI, Relative Fit Index; IFI, Incremental Fit Index; TLI, Tucker–Lewis Index; CFI, Comparative Fit Index.

Consistency refers to a scale's stability over time and its reliability across different contexts.[60] The consistency of the CE-33 was assessed using three metrics: Cronbach's alpha coefficient, split-half reliability, and test-retest reliability. The Cronbach's alpha for the entire scale was 0.922, with values for each dimension ranging from 0.919 to 0.979, indicating high internal consistency. The split-half and test-retest reliability scores were 0.971 and 0.973, respectively, further demonstrating the scale's reliability and stability.

Implications for nursing practice

This study shows that the CE-33 can assist nurses in assessing the functional outcomes of Chinese patients with HNC. As a core functional assessment tool, the CE-33 offers high comparability, which aids in cross-study comparisons and analyses. This is crucial for evaluating the effects of different treatments and improving the consistency of study results. The scale was developed with careful consideration of patients' opinions and needs. PROs help nurses identify symptoms that may be overlooked by traditional methods. This makes the assessment more patient-centered, reflecting the actual distress of the patients and enhancing the clinical application value.

Limitations

This study has several limitations. First, its cross-sectional design lacked longitudinal follow-up data, restricting the ability to assess long-term functional changes in HNC patients. Second, the use of convenience sampling may have introduced selection bias, potentially limiting the generalizability of the findings. Third, the lack of an external validation cohort constrains the applicability of post-transitional scales across diverse clinical settings. Fourth, the study did not conduct a calibration validation analysis. To enhance external validity and minimize potential bias, future research should adopt more rigorous sampling methods, include a larger and more representative sample, and incorporate a longitudinal design. Additionally, comparing the CE-33 scale with standardized scales will further validate its use.

Conclusions

This study demonstrates that the CE-33 for patients with HNC is reliable and effective, making it suitable for evaluating functional outcomes. This tool could assist health care practitioners in assessing patients' functional status and developing effective rehabilitation programs.

CRediT authorship contribution statement

YMZ: Investigation, Data curation, Writing–Original Draft. **MZ**: Data curation. **YL**: Conceptualization. **LC**: Investigation, Data curation. **SLG**: Data curation. **LZ**: Investigation, Data curation. All authors had full access to all the data in the study, and the corresponding author had final responsibility for the decision to submit for publication. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Ethics statement

The study was approved by the Institutional Review Board of the Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology (Approval No. TJ-IRB20231216) and was conducted in accordance with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. All participants provided written informed consent.

Data availability statement

The data that support the findings of this study are available from the corresponding author, YL, upon reasonable request.

Declaration of generative AI and AI-assisted technologies in the writing process

No AI tools/services were used during the preparation of this work.

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Declaration of competing interest

The authors declare no conflict of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.apjon.2025.100685.

References

1. Sung H, Ferlay J, Siegel RL, et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin*. 2021;71(3):209–249. https://doi.org/10.3322/caac.21660.
2. Cao W, Chen H, Yu Y, Li N, Chen W. Changing profiles of cancer burden worldwide and in China: a secondary analysis of the global cancer statistics 2020. *Chin Med J (Engl)*. 2021;134(7):783–791. https://doi.org/10.1097/CM9.0000000000001474.
3. Chow LQM. Head and neck cancer. *N Engl J Med*. 2020;382(1):60–72. https://doi.org/10.1056/NEJMra1715715.
4. León X, Orús C, Casasayas M, Neumann E, Holgado A, Quer M. Trends in disease-specific survival of head and neck squamous cell carcinoma patients treated in a single institution over a 30-year period. *Oral Oncol*. 2021;115:105184. https://doi.org/10.1016/j.oraloncology.2021.105184.
5. Johansen J, Grau Eriksen J. Trends in cancer of the head and neck in the elderly in Denmark, 1980–2012. *Acta Oncol*. 2016;55(suppl 1):13–18. https://doi.org/10.3109/0284186X.2015.1114672.
6. Mayor S. Survival rates with head and neck cancers vary widely, audit finds. *BMJ*. 2015;351:h4758. https://doi.org/10.1136/bmj.h4758.
7. Zanoni DK, Montero PH, Migliacci JC, et al. Survival outcomes after treatment of cancer of the oral cavity (1985–2015). *Oral Oncol*. 2019;90:115–121. https://doi.org/10.1016/j.oraloncology.2019.02.001.
8. Yang T, Cheng XW, Zheng XD, Fu ML, Yang Y, Wang YX. Meta-synthesis of qualitative research on disease experience and needs in patients with head and neck cancer. *Nurs J*. 2024;39(1):47–51. https://doi.org/10.3870/j.issn.1001-4152.2024.01.047.
9. Chang YLHB. Effects of a return to work program on the health and barriers to returning to work in head and neck cancer patients: a randomized controlled trial. *Asia-Pac J Oncol Nurs*. 2023;10(12):100320. https://doi.org/10.1016/j.apjon.2023.100320.
10. Lan HZ, Wang M, Xu JQ, Zhang SY, He XF. Summary of best evidence for enteral nutrition support management in home care for patients with head and neck cancer undergoing radiotherapy. *Nurs J*. 2024;39(12):107–111. https://doi.org/10.3870/j.issn.1001-4152.2024.12.107, 115.
11. Parke SC, Langelier DM, Cheng JT, Kline-Quiroz C, Stubblefield MD. State of rehabilitation research in the head and neck cancer population: functional impact vs. impairment-focused outcomes. *Curr Oncol Rep*. 2022;24(4):517–532. https://doi.org/10.1007/s11912-022-01227-x.
12. Zhang YM, Liu Y, Wang YY, Zhang HR, Zhou M. Meta-synthesis of qualitative research on the disease experience and needs of patients with head and neck cancer. *Nurs J*. 2023;30(15):52–57. https://doi.org/10.16460/j.issn1008-9969.2023.15.052.
13. Iwanaga K, Ishibashi Y, Maki K, et al. Two-year evolution of quality of life following radiotherapy and/or chemotherapy in patients with head and neck cancer. *Asia-Pac J Oncol Nurs*. 2023;10(11):100301. https://doi.org/10.1016/j.apjon.2023.100301.
14. Taylor KJ, Amdal CD, Bjordal K, et al. Long-term health-related quality of life in head and neck cancer survivors: a large multinational study. *Int J Cancer*. 2024;154(10):1772–1785. https://doi.org/10.1002/ijc.34861.
15. Ringash J, Bernstein LJ, Cella D, et al. Outcomes toolbox for head and neck cancer research. *Head Neck*. 2015;37(3):425–439. https://doi.org/10.1002/hed.23561.
16. Waters AM, Tudur Smith C, Young B, Jones TM. The consensus study: protocol for a mixed methods study to establish which outcomes should be included in a core outcome set for oropharyngeal cancer. *Trials*. 2014;15(1):168. https://doi.org/10.1186/1745-6215-15-168.
17. Allen D, Hickson L, Ferguson M. Defining a patient-centred core outcome domain set for the assessment of hearing rehabilitation with clients and professionals. *Front Neurosci*. 2022;16:787607. https://doi.org/10.3389/fnins.2022.787607.

18. List M, Bilir S. Functional outcomes in head and neck cancer. *Semin Radiat Oncol*. 2004;14(2):178–189. https://doi.org/10.1053/j.semradonc.2003.12.008.
19. Metcalfe CW, Lowe D, Rogers SN. What patients consider important: temporal variations by early and late stage oral, oropharyngeal, and laryngeal subsites. *J Craniomaxillofac Surg*. 2014;42(5):641–647. https://doi.org/10.1016/j.jcms.2013.09.008.
20. Mendez A, Seikaly H, Eurich D, et al. Development of a patient-centered functional outcomes questionnaire in head and neck cancer. *JAMA Otolaryngol Head Neck Surg*. 2020;146(5):437. https://doi.org/10.1001/jamaoto.2019.4788.
21. Rogers SN, Heseltine N, Flexen J, Winstanley HR, Cole-Hawkins H, Kanatas A. Structured review of papers reporting specific functions in patients with cancer of the head and neck: 2006–2013. *Br J Oral Maxillofac Surg*. 2016;54:e45–e51. https://doi.org/10.1016/j.bjoms.2016.02.012.
22. Riechelmann H, Dejaco D, Steinbichler TB, et al. Functional outcomes in head and neck cancer patients. *Cancers*. 2022;14(9):2135. https://doi.org/10.3390/cancers14092135.
23. Lane C, Higgins RC, Goyal N. Psychological survivorship in head and neck cancer. *Semin Plast Surg*. 2023;37(1):46–52. https://doi.org/10.1055/s-0042-1759798.
24. Nugent SM, Morasco BJ, Handley R, et al. Risk of suicidal self-directed violence among US veteran survivors of head and neck cancer. *JAMA Otolaryngol Head Neck Surg*. 2021;147(11):981–989. https://doi.org/10.1001/jamaoto.2021.2625.
25. Ren J, Lü D, Liu SX. Research progress on swallowing function assessment after treatment of head and neck malignant tumors. *Chin J Clin Otolaryngol Head Neck Surg*. 2020;34(9):861–864.
26. Bjordal K, Hammerlid E, Ahlner-Elmqvist M, et al. Quality of life in head and neck cancer patients: validation of the European organization for research and treatment of cancer quality of life questionnaire-H&N35. *J Clin Oncol*. 1999;17(3):1008. https://doi.org/10.1200/JCO.1999.17.3.1008.
27. Hassan SJ, Weymuller EA. Assessment of quality of life in head and neck cancer patients. *Head Neck*. 1993;15(6):485–496. https://doi.org/10.1002/hed.2880150603.
28. Rosenthal DI, Mendoza TR, Chambers MS, et al. Measuring head and neck cancer symptom burden: the development and validation of the M. D. Anderson symptom inventory, head and neck module. *Head Neck*. 2007;29(10):923–931. https://doi.org/10.1002/hed.20602.
29. Schmidt KN, Olson K, Kubrak C, Parliament M, Ghosh S. Validation of the Head and Neck Patient Symptom Checklist as a nutrition impact symptom assessment tool for head and neck cancer patients. *Support Care Cancer*. 2013;21(1):27–34. https://doi.org/10.1007/s00520-012-1483-y.
30. Dunne S, Mooney O, Coffey L, et al. Psychological variables associated with quality of life following primary treatment for head and neck cancer: a systematic review of the literature from 2004 to 2015. *Psychooncology*. 2017;26(2):149–160. https://doi.org/10.1002/pon.4109.
31. Ilie G, Bradfield J, Moodie L, et al. The role of response-shift in studies assessing quality of life outcomes among cancer patients: a systematic review. *Front Oncol*. 2019;9:783. https://doi.org/10.3389/fonc.2019.00783.
32. Kirsh E, Naunheim M, Holman A, Kammer R, Varvares M, Goldsmith T. Patient-reported versus physiologic swallowing outcomes in patients with head and neck cancer after chemoradiation. *Laryngoscope*. 2019;129(9):2059–2064. https://doi.org/10.1002/lary.27610.
33. Govender R, Lee MT, Davies TC, et al. Development and preliminary validation of a patient-reported outcome measure for swallowing after total laryngectomy (SOAL questionnaire). *Clin Otolaryngol*. 2012;37(6):452–459. https://doi.org/10.1111/coa.12036.
34. Eisbruch A, Kim HM, Terrell JE, Marsh LH, Dawson LA, Ship JA. Xerostomia and its predictors following parotid-sparing irradiation of head-and-neck cancer. *Int J Radiat Oncol Biol Phys*. 2001;50(3):695–704. https://doi.org/10.1016/S0360-3016(01)01512-7.
35. Xia J, Zeng Y, Zhao X, Hou L. Psychological intervention for negative emotion and quality of life of patients with head and neck cancer (HNC): a meta-analysis. *Shang Hai Kou Qiang Yi Xue*. 2022;31(3):330–336.
36. Zhang YM, Liu Y, Wang YY, Zhang HR, Zhou M. Progress in the research on patient-reported outcomes in laryngeal cancer patients. *Gen Nurs*. 2022;20(25):3507–3510. https://doi.org/10.12104/j.issn.1674-4748.2022.25.013.
37. US Department of Health and Human Services. Guidance for industry: patient-reported outcome measures: use in medical product development to support labeling claims: Draft guidance. *Health Qual Life Outcome*. 2006;4:79. https://doi.org/10.1186/1477-7525-4-79. et al.
38. Steen-Olsen EB, Stormoen DR, Kristensen CA, Vogelius IR, Hollander-Mieritz C, Pappot H. Patient-reported outcome during radiotherapy for head and neck cancer: the use of different PRO questionnaires. *Eur Arch Otorhinolaryngol*. 2022;279(8):4199–4206. https://doi.org/10.1007/s00405-022-07364-0.
39. Basch E, Torda P, Adams K. Standards for patient-reported outcome-based performance measures. *JAMA*. 2013;310(2):139–140. https://doi.org/10.1001/jama.2013.6855.
40. Jones PS, Lee JW, Phillips LR, Zhang XE, Jaceldo KB. An adaptation of Brislin's translation model for cross-cultural research. *Nurs Res*. 2001;50(5):300–304. https://doi.org/10.1097/00006199-200109000-00008.
41. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. *Spine*. 2000;25(24):3186–3191. https://doi.org/10.1097/00007632-200012150-00014.
42. Shi JC, Mo XQ, Sun ZQ. Application of content validity index in scale development. *J Cent South Univ (Med Sci)*. 2012;37:152–155.
43. Wolf EJ, Harrington KM, Clark SL, Miller MW. Sample size requirements for structural equation models. *Educ Psychol Meas*. 2013;73(6):913–934. https://doi.org/10.1177/0013164413495237.
44. Cheng N, Zhao Y, Li X, He X, Wang A. Translation and validation study of the Chinese version of the service user technology acceptability questionnaire. *Asia-Pac J Oncol Nurs*. 2023;10(6):100239. https://doi.org/10.1016/j.apjon.2023.100239.
45. Hahs-Vaughn DL, Hahs-Vaughn LR. *An Introduction to Statistical Concepts*. 4th ed. New York, NY: Routledge; 2020.
46. Wu ML. *Questionnaire Statistical Analysis Practice — SPSS Operation and Application*. Chongqing, China: Chongqing University Press; 2010.
47. Gaskin CJ, Happell B. On exploratory factor analysis: a review of recent evidence, an assessment of current practice, and recommendations for future use. *Int J Nurs Stud*. 2014;51(3):511–521. https://doi.org/10.1016/j.ijnurstu.2013.10.005.
48. Rong TS. *AMOS and Research Methods*. Chongqing, China: Chongqing University Press; 2010.
49. Streiner DL. Starting at the beginning: an introduction to coefficient alpha and internal consistency. *J Pers Assess*. 2003;80(1):99–103. https://doi.org/10.1207/S15327752JPA8001_18.
50. Xia W, Yan M, Jiang W, et al. Psychometric validation of the modified Chinese version of the personalized psychological flexibility index in patients with cancer. *Asia-Pac J Oncol Nurs*. 2023;10(6):100240. https://doi.org/10.1016/j.apjon.2023.100240.
51. Zhao FR, Zhou TC, Zhang JY, Qian CQ, Liu GP. The application and prospects of reliability and validity evaluation of scales (questionnaires) in the medical field of China. *Chin J Integr Med*. 2014;29(7):2280–2283.
52. Wang YJ, Lu Q, Jin SL, Pang D, Yang P, Cao YW. Research progress on oropharyngeal symptom management during radiotherapy for patients with head and neck cancer. *Chin Nurs Manag*. 2021;21(6):936–940.
53. Nathan CO, Asarkar AA, Entezami P, et al. Current management of xerostomia in head and neck cancer patients. *Am J Otolaryngol*. 2023;44:103867. https://doi.org/10.1016/j.amjoto.2023.103867.
54. Yang C, Zhu Y, Zhang J, Xu J, Wu H, Yang Y. Food texture modification in head and neck cancer patients: a scoping review. *Int J Oral Maxillofac Surg*. 2024. https://doi.org/10.1016/j.ijom.2024.11.004.
55. Mendez AI, Wihlidal JGJ, Eurich DT, Nichols AC, MacNeil SD, Seikaly HR. Validity of functional patient-reported outcomes in head and neck oncology: a systematic review. *Oral Oncol*. 2022;125:105701. https://doi.org/10.1016/j.oraloncology.2021.105701.
56. Zhang YM, Liu Y, Wang YY, Zhang HR, Zhou M. Development and psychometric testing of the functional outcomes reporting scale for patients after partial laryngectomy. *Nurs J*. 2023;38(23):43–46. https://doi.org/10.3870/j.issn.1001-4152.2023.23.043.
57. Almanasreh E, Moles R, Chen TF. Evaluation of methods used for estimating content validity. *Res Soc Adm Pharm*. 2019;15(2):214–221. https://doi.org/10.1016/j.sapharm.2018.03.066.
58. Tang R, Wan D, Leng C, et al. Cross-cultural adaptation and validation of the Central Sensitization Inventory among Chinese patients with chronic non-specific low back pain. *J Pain Res*. 2024;17:4263–4276. https://doi.org/10.2147/JPR.S499700.
59. Zhang Z. Structural equation modeling in the context of clinical research. *Ann Transl Med*. 2017;5:102. https://doi.org/10.21037/atm.2016.09.25.
60. Zeng Y, Li H. Psychometric evaluation of nursing interns' consciousness of rights scale in clinical practice. *BMC Nurs*. 2023;22. https://doi.org/10.1186/s12912-023-01622-0.