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ORIGINAL ARTICLE

Validation of the Chinese version of the Head and Neck Patient Symptom Checklist for measuring nutrition impact symptoms during radiotherapy in patients with head and neck cancer

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Abstract

Purpose The Head and Neck Patient Symptom Checklist (HNSC) is a valid tool for measuring nutrition impact symptoms (NIS) specific to head and neck cancer (HNC) patients. This study aimed to translate the HNSC into Chinese and to evaluate its psychometric properties in Chinese HNC patients treated with radiotherapy.

Methods The HNSC was translated into Chinese following standard forward- and back-translation procedures. Three instruments, the Chinese version of HNSC, the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30, and Patient-Generated Subjective Global Assessment (PG-SGA), were answered by 116 HNC patients, of whom 11 were submitted to the test–retest in 3–7 days. The criterion and convergent validities were confirmed by measuring the relations of the HNSC score with the PG-SGA and EORTC QLQ-C30, respectively. The discriminant validity was evaluated through known group analysis. Reliability was evaluated by means of Cronbach's alpha and test–retest using the correlation coefficient.

Results Criterion validity was 0.767 for intensity dimension and 0.795 for interference dimension, respectively. Convergent validity was confirmed by the significant correlations between the HHSC score and most domains of QLQ-C30. The comparison among the groups demonstrated good discriminant validity. The Cronbach's alpha was 0.787 for intensity dimension and 0.797 for interference dimension, respectively. The test–retest reliability was 0.845 for intensity dimension and 0.883 for interference dimension, respectively.

Conclusions The Chinese version of HNSC demonstrated favorable validity and reliability. It can be used in identification of NIS and development of symptom management program in HNC patients in China.

Keywords Head and neck cancer · Nutrition impact symptom · Head and Neck Patient Symptom Checklist · Reliability · Validity

Introduction

Head and neck cancers (HNCs) include tumors which are located in the lips, oral cavity, oropharynx, nasopharynx, hypopharynx, larynx, nasal cavity and paranasal sinuses, thyroid gland, and salivary glands. In China, the number of new cases and deaths for cancers of lip, oral cavity, and pharynx in 2015 was approximately 108,700 and 56,200, respectively [1]. Therapeutic options for patients with HNC include radiotherapy, surgery and/or chemotherapy, among which radiotherapy is the most commonly used treatment [2, 3]. However, it also contributes to remarkable adverse symptoms and impaired functions [4, 5].

Nutrition deficiency frequently occurred in HNC patients because the special site of tumor can cause a variety of symptoms such as mouth sore, pain, xerostomia, dysphagia, loss of appetite, and difficulty chewing, which are known as nutrition impact symptoms (NIS) [6, 7]. Subsequent treatment with radiotherapy either alone or combined with chemotherapy or surgery can result in substantial toxicities which often impose further nutritional challenges. Previous studies have shown that oral symptom burden had great impact on oral energy and protein intake [8]. Multiple symptoms presented by patients undergoing radiotherapy/chemoradiation are also

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significant indicators to predict the weight loss [9]. Weight loss is very common in HNC patients and approximately 71% of patients had 5% weight loss from baseline to posttreatment [10]. It has been demonstrated that weight loss during radiotherapy is an important prognostic indicator for 5-year survival rate in HNC patients [11]. In conclusion, these NIS can affect food intake and thereby lead to weight loss and eventually poor survival in HNC patients. Therefore, it is essential to manage these symptoms.

To develop effective management to these NIS in HNC patients, the first step for clinical staff is to perform an accurate assessment of them. Currently, multiple instruments are available to evaluate the symptoms of HNC, such as Vanderbilt Head and Neck Symptom Survey version 2.0 (VHNSS 2.0) [12], the M. D. Anderson Symptom Inventory-Head and Neck module (MDASI-HN) [13], as well as the Head and Neck patient Symptom Checklist (HNSC) [14]. Among these instruments, the HNSC is specifically developed for the assessment of symptoms which are related to reduced food intake in HNC patients. Patients are asked to assess the severity of each symptom and its interference with dietary intake. It has been demonstrated that HNSC is a valid instrument used to detect these NIS that significantly affect dietary intake in patients with HNC [14].

HNSC was developed in English. In this study, we aimed to translate the HNSC into Chinese and to evaluate its psychometric properties in Chinese population.

Methods

Participants

Adult patients were selected from two tertiary hospitals in Beijing between March and August in 2017. The inclusion criteria were as follows: (i) diagnosed as head and neck cancer through pathological evaluation; (ii) undergoing radiotherapy; and (iii) be willing to participate. Patients were excluded if they had other cancers, had tube-feeding or total parenteral nutrition, or had cognitive or mental problems.

The smallest sample size required for testing the validity of an instrument ranges from 3 to 20 times the number of its items [15]. As the HNSC includes 17 items, about 51 to 340 patients are needed. To estimate the sample size, known group analysis which was used to evaluate the discriminant validity should also be considered. Therefore, a pilot study was conducted for measuring the mean score of HNSC in 40 HNC patients who were receiving radiotherapy either alone or combined with chemotherapy or surgery. We calculated the sample size according to different known groups, including groups with concurrent chemotherapy versus no chemotherapy and groups who had received ≤ 10 fractions versus > 10 fractions [16–18]. It was found that the sample size calculated by groups with concurrent chemotherapy versus no chemotherapy was larger than that calculated by groups who had received ≤ 10 fractions versus > 10 fractions. The calculation process is as follows. The standard deviation of the HNSC score in all 40 patients (for intensity dimension of HNSC) was 9.28. We assumed an equal standard deviation in different groups. According to the groups with concurrent chemotherapy versus no chemotherapy, the mean scores of HNSC in each group were 42.28 and 37.05, respectively. With $\alpha = 0.05$, two-tailed and a power of 80%, we needed 50 patients in each group, which meant a total of 100 patients. Considering the absence of the sample, it is recommended to increase the sample size by 10 to 20%. So, we should invite 110 to 120 patients to participate in our study, which also meets the sample size of 51 to 340 patients calculated earlier.

Instruments

NHSC

The HNSC, a tool targeted for the HNC patients, is used for the assessment of NIS related to decreased food intake. It was developed in 2013 and includes 17 symptoms (pain, anxiety, dry mouth, loss of appetite, constipation, feeling full, depression, thick saliva, diarrhea, sore mouth, lack of energy, nausea, difficulty chewing, altered smell, vomiting, difficulty swallowing, and taste changes) [14]. These items were chosen according to a comprehensive review of the literature and clinical experience. Patients are asked to rate the intensity of each symptom and the degree of each symptom's interference with dietary intake. Both intensity and interference dimensions of each symptom are assessed using a five-point Likert scale ranging from "1 = not at all" to "5 = a lot." The total score by adding all 17 items is between 17 and 85 for each dimension. A higher total score indicates more severe intensity or interference of the symptoms.

PG-SGA

Patient-Generated Subjective Global Assessment (PG-SGA) is a specialized and feasible tool developed for cancer patients. It has great diagnostic value in detection of patients who may develop malnutrition or are malnourished [19–21]. And it has been considered as a standard for assessment of nutrition status in cancer patients by Oncology Nutrition Dietetic Practice Group of the American Dietetic Association [19]. It consists of two sections. The first section is self-rated by patients and includes information on four aspects (weight, food intake, symptoms, and activity). In the second section, clinician needs to complete three aspects (disease-related nutrient demands, metabolic stress, and a physical assessment). A total score is obtained by adding seven aspects of the instrument. The higher the score, the worse the nutritional status.

EORTC QLQ-C30

European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 is a questionnaire evaluating cancer-specific quality of life [22]. It comprises 30 items, including five functional subscales (physical, role, emotional, cognitive, and social functioning), an overall health subscale, three symptom subscales (fatigue, nausea and vomiting, pain), six individual items related to symptoms that are frequently occurred in patients with tumors (diarrhea, constipation, insomnia, poor appetite, dyspnea, and financial difficulties). Scores are between 0 and 100, where a high score in functional subscales and overall health subscale represents a high level of functioning or a high QoL; however, a high score in symptom subscales/items indicates that the symptom is more severe. The EORTC provided us with the Chinese version of QLQ-C30 and authorized our use of it.

Translation process

After obtaining authorization via email from the original author, Dr. Catherine Kubrak, standardized forward- and back-translation procedures were performed [23]. Firstly, two Chinese individuals independently complete the translation procedures from English into Chinese, and both have master's degree in nursing and proficient mastery of English. Afterwards, the two translators discussed the inconsistencies of two translated versions, and finally synthesized them into a unified Chinese version after reaching an agreement. Finally, a researcher specialized in nursing who was unknown the original version and has a good mastery of Chinese–English translation was responsible for the back-translation. At last, the English back-translated version was compared with the original version for conceptual consistency by the three translators.

A pilot study was conducted to test Chinese version's clarity in expression and understanding in meaning. The pilot study included eight HNC patients who were undergoing radiotherapy and voluntarily signed the written informed consent. These patients were characterized by a wide range of socio-demography and clinical features. They were asked to fill out the Chinese version of the HNSC according to their own symptoms. After completing the instrument, they were interviewed whether each translated symptom was easy to be understood, and whether they got confused when filling out the instrument. They stated that the instrument was acceptable and easy to be understood. Thereafter, the final Chinese version was established.

Validation process

Three indicators including criterion validity, convergent validity, and discriminant validity were used to assess the validity of the HNSC. The criterion validity was confirmed by measuring the relation of the HNSC score with the PG-SGA score. PG-SGA is a valid and reliable assessment tool. It has been recommended for use in detection of malnutrition among cancer patients by several oncology practice societies, including the Oncology Nursing Society [19, 24]. So, we used it as the gold standard for assessing nutritional status in HNC patients. We assumed that both intensity and interference dimension scores of HNSC would be positively correlated with the score of PG-SGA.

For convergent validity, scores of both dimensions of HNSC were considered to be correlated with scores of subscales/items of QLQ-C30. We hypothesized that the HNSC was negatively correlated with the QLQ-C30 global QoL, physical functioning, role functioning, emotional functioning, cognitive functioning, and social functioning subscales, but positively correlated with fatigue, dyspnea, insomnia, nausea and vomiting, pain, poor appetite, constipation, diarrhea, and financial difficulties subscales/items of QLQ-C30.

For discriminant validity, known groups analysis was performed to compare the mean (standard deviation) symptom burden as measured by the HNSC to test whether this instrument could differentiate between patient groups. Patients with concurrent chemotherapy might present higher symptom scores induced by both radiotherapy and chemotherapy. It is generally recognized that radiation-induced symptoms such as oral mucositis and taste impairment often become much more serious during the third week and will likely last for the rest of the period [16–18]. So, we chose the count of ten fractions as the cutoff point which means that the patients have finished 2 weeks of radiotherapy. So, in this study, it was primarily hypothesized that those who had concurrent chemotherapy versus no chemotherapy, and those who had received ≤ 10 fractions versus > 10 fractions would all differ regarding the score of the instrument.

The internal reliability for the 17 NIS on the HNSC was assessed by calculating the Cronbach's alpha. Stability of the HNSC was measured by test–retest method. Eleven patients in total accomplished the second assessment of the HNSC 3~7 days after the first investigation.

Statistical analysis

Descriptive statistics was used for analysis of demographic and clinical variables. Means (± standard deviation) and frequency or percentage were used to express continuous variables and categorical variables, respectively. The correlations between the scores of HNSC and PG-SGA were evaluated using Pearson's correlation coefficients, while the correlations between HNSC score and the subscales/items of QLQ-C30 were calculated by

Spearman's correlation coefficients due to the non-normal distribution of the data. Two-sample/group *t* test for independent samples was performed to compare HNSC scores between different groups of patients regarding concurrent chemotherapy. Rank test of non-parametric test was used to compare HNSC scores between groups of patients regarding the count of received fractions. The internal consistency was assessed by calculating the Cronbach's alpha. Spearman correlation coefficient was used to assess the test–retest reliability because the first and second data were both non-normally distributed. A Spearman correlation coefficient equal to or greater than 0.7 was considered to be acceptable [25, 26]. All statistical analyses used a significant level of 0.05 (two-sided). SPSS statistical software (version 16.0) was used to perform all statistical analyses.

Ethical statement

Biomedical Ethics Committee of Peking University (IRB00001052-17002) approved all the procedures of the study, and all participants involved in the study voluntarily signed informed consent forms.

Results

Patient characteristics and descriptive analysis of HNSC

A total of 116 patients were invited to participate in the study. The average age of all 116 patients was 55.1 ± 13.5 (median 56.0; range 18~80) years. All patients received intensity-modulated radiotherapy. Doses of 1.8–2.2 Gy per fraction, 5 days a week, were delivered over 4–7 weeks to patients. The mean count of received fractions when the patient was investigated was 17.4 ± 5.9 (median 16; range 6~33). Other demographic and clinical features of the participants are shown in Table 1.

According to the scoring manual of the HNSC, the mean intensity score of HNSC was 38.9 ± 9.2 (median 38.0; range 20~60) and the mean interference score of HNSC was 32.1 ± 9.3 (median 31.0; range 17~62).

Table 1 Participants' demographic and clinical characteristics ($n = 116$)

Groups	Frequency (%)
Gender	
Male	92 (79.3)
Female	24 (20.7)
Tumor location	
Nasopharynx	30 (25.9)
Oropharynx/hypopharynx	16 (13.8)
Larynx	9 (7.8)
Lip and oral cavity	16 (13.8)
Salivary gland	11 (9.5)
Other	34 (29.3)
Tumor stage	
I	7 (6.0)
II	11 (9.5)
III	39 (33.6)
IV	49 (42.2)
Unknown	10 (8.6)
Surgery before radiation	
Yes	59 (50.9)
No	57 (49.1)
Concurrent chemotherapy	
Yes	52 (44.8)
No	64 (55.2)

Validity of the HNSC

Criterion validity

The Pearson correlation coefficient between the HNSC score and the PG-SGA score was 0.767 ($p < 0.001$) for intensity dimension and 0.795 ($p < 0.001$) for interference dimension, respectively.

Convergent validity

The relations between HNSC score and EORTC QLQ-C30 subscales/items are shown in Table 2. The HNSC intensity score was negatively correlated with global QoL, physical functioning, role functioning, emotional functioning, cognitive functioning, and social functioning subscales/items, and positively correlated with fatigue, nausea and vomiting, pain, insomnia, appetite loss, and constipation subscales/items of the QLQ-C30. As for the HNSC interference score, the same results were obtained except for the subscale of emotional functioning which was not correlated with the HNSC interference score significantly.

Discriminant validity

Table 3 reveals the capability of the HNSC score to distinguish between different groups of patients concerning the nutrition impact symptoms.

Reliability of the HNSC

Internal consistency

The reliability Cronbach's alpha was 0.787 for intensity dimension and 0.797 for interference dimension, respectively.

Table 2 The convergent validity of the HNSC score ($n = 89$)

Dimensions of EORTC QLQ-C30	Total intensity score of HNSC		Total interference score of HNSC	
	r	*p*	*r*	*p*
Global QoL	− 0.552	< 0.001	− 0.416	< 0.001
Physical functioning	− 0.469	< 0.001	− 0.365	< 0.001
Role functioning	− 0.408	< 0.001	− 0.434	< 0.001
Emotional functioning	− 0.257	0.015	− 0.174	0.102
Cognitive functioning	− 0.290	0.006	− 0.277	0.009
Social functioning	− 0.378	< 0.001	− 0.438	< 0.001
Fatigue	0.577	< 0.001	0.539	< 0.001
Nausea and vomiting	0.342	0.001	0.354	0.001
Pain	0.605	< 0.001	0.615	< 0.001
Dyspnea	0.146	0.172	0.090	0.402
Insomnia	0.388	< 0.001	0.366	< 0.001
Appetite loss	0.470	< 0.001	0.386	< 0.001
Constipation	0.465	< 0.001	0.249	0.019
Diarrhea	0.026	0.812	0.098	0.361
Financial difficulties	0.080	0.456	− 0.024	0.822

EORTC QLQ-C30 European Organization for Research and Treatment of Cancer QLQ-C30, *HNSC* Head and Neck Patient Symptom Checklist

Test–retest reproducibility

Eleven patients accomplished the second investigation after a mean interval of 3~7 days. The Spearman correlation coefficient of the total score was 0.845 ($p < 0.001$) for intensity dimension and 0.883 ($p < 0.001$) for interference dimension, respectively.

Discussion

Weight loss which is very common in cancer patients is usually caused by two key aspects: increased energy expenditure and reduced dietary intake [27]. In HNC patients who are undergoing radiotherapy, reduced dietary intake is especially prominent due to the severe symptoms experienced by them [8, 28]. These symptoms are known as NIS which will severely compromise nutritional status and eventually result in poor survival of the patients [29]. Therefore, it is necessary to assess the NIS in these patients. This will provide clinicians a scientific basis for developing specific interventions to manage these symptoms and then improve the outcome of the patients.

In our study, patients who were undergoing radiotherapy were involved. As radiotherapy usually lasts 4 to 7 weeks, patients were in different stages, from the beginning to the end of the radiotherapy. The mean count of received fractions when the patient was investigated was 17.4 (range 6~33). In general, the demographic and clinical features of the participants can be regarded as representatives for study population.

Regarding the criterion validity, the instrument was positively correlated with the PG-SGA which is well known a gold standard for assessing nutritional status among cancer patients [19]. It meant that patients with more severe nutrition impact symptoms would probably have bad nutritional status. By using this instrument, we

Table 3 The discriminant validity of the HNSC score ($n = 116$)

Groups	Total intensity score of HNSC			Total interference score of HNSC		
	Mean ± SD	*t/z*	*p*	Mean ± SD	*t/z*	*p*
Concurrent chemotherapy		2.566	0.012		2.401	0.018
No ($n = 64$)	36.98 ± 9.27			30.28 ± 9.87		
Yes ($n = 52$)	41.31 ± 8.71			34.37 ± 8.08		
The count of received fractions		2.156	0.031		2.747	0.006
≤ 10 ($n = 10$)	32.30 ± 10.81			24.40 ± 8.06		
> 10 ($n = 106$)	39.55 ± 8.89			32.84 ± 9.11		

HNSC Head and Neck Patient Symptom Checklist can identify the individuals who are at high risk to develop substantial impairments of nutrition.

Convergent validity was verified by exploration of the correlation between HNSC score and EORTC QLQ-C30, which is widely used instrument for measuring QoL [22]. Table 2 shows significant correlations between the two dimensions of HNSC and most subscales/items of QLQ-C30 except for three items including dyspnea, diarrhea, and financial difficulties. Since these three items rarely occur in HNC patients, no significant correlation was found between the score of HNSC and these items. For HNSC intensity score, correlation coefficients higher than 0.4 have been confirmed in global QoL, physical functioning, role functioning, fatigue, pain, appetite loss, and constipation subscales/items, with the highest correlation being 0.605 (pain subscale). For HNSC interference score, correlation coefficients higher than 0.4 have been confirmed in global QoL, role functioning, social functioning, fatigue, and pain subscales/items, with the highest correlation being 0.615 (pain subscale). From this result, we can see that pain was the most disturbing symptom among HNC patients who were receiving radiotherapy. The results indicate that the Chinese version of HNSC has good convergent validity.

The capability to discriminate between different patient groups is essential for an instrument to be considered valid. Known factors including concurrent chemotherapy and the count of received fractions may affect the symptom burden in HNC patients. It was supposed that patients with concurrent chemotherapy may present higher symptom scores, because the symptoms induced by radiotherapy might become more serious by chemotherapy, which has been demonstrated by several studies [16, 30]. As symptom severity is significantly correlated with radiation dose to oral cavity [31], we assumed that symptom burden will increase along with the radiation due to the growing radiation dose delivered to patients. Previous studies have demonstrated that radiation-induced symptoms such as oral mucositis and taste impairment often become much more serious during the third week and will likely last for the rest of the period [16–18]. The HNSC had a good discriminant validity, as it could detect differences between those who underwent/did not undergo concurrent chemotherapy, and those who had received ≤ 10 fractions and > 10 fractions.

The internal reliability for the 17 NIS on the HNSC was assessed by calculating the Cronbach's alpha, which was 0.787 for intensity dimension and 0.797 for interference dimension, respectively. Eleven patients were recruited to determine the test–retest reliability. It was considered that 3~7 days was reasonable interval between two tests for symptom assessment. The Spearman correlation coefficient was 0.845 for intensity dimension and 0.883 for interference dimension, which were both higher than the acceptable level of 0.7, showing that the HNSC has a good stability.

Conclusion

The study has demonstrated that the Chinese version of HNSC presents a good feasibility and adequate criterion validity, convergent validity, and discriminant validity and has acceptable internal consistency and test–retest reproducibility. It is a valid and reliable instrument. It has great value for clinicians to detect the NIS among HNC patients who undergo exclusive or combined radiotherapy, thus allowing the development and implementation of intervention project for managing these symptoms.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Data The corresponding author has full control of all primary data and agrees to allow the journal to review the data if requested.

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