



Original Article

Psychometric validation of the Chinese version of the M. D. Anderson Symptom Inventory—Head and Neck Module in patients with nasopharyngeal carcinoma



Wenli Xiao^a, Carmen W.H. Chan^b, Xin Shelley Wang^c, Jinnan Xiao^d, Marques S.N. Ng^{b,*},¹

^a School of Nursing, Guangzhou University of Chinese Medicine, Guangzhou, China

^b The Nethersole School of Nursing, The Chinese University of Hong Kong, Hong Kong SAR, China

^c Department of Symptom Research, The University of Texas M. D. Anderson Cancer Center, Houston, TX, USA

^d Xiangya School of Nursing, Central South University, Changsha, China

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ABSTRACT

Objective: The Chinese version of the M. D. Anderson Symptom Inventory—Head and Neck Module (MDASI-HN-C) has been linguistically validated. However, its psychometric properties have not been established yet. The purpose of the study was to psychometrically validate the MDASI-HN-C in patients with nasopharyngeal carcinoma (NPC).

Methods: 130 Chinese NPC patients who were undergoing radiotherapy (RT) participated in this cross-sectional study. The content, convergent, and construct validity of the MDASI-HN-C were examined. The reliability of the instrument was tested by examining the internal consistency and test–retest reliability.

Results: Cronbach's α coefficients ranged from 0.85 to 0.91 for the three subscales of the MDASI-HN-C. The 3-day test–retest reliability was acceptable with intraclass correlation coefficients (ICC) ranged from 0.52 to 0.71. The scale content validity index (S-CVI) was satisfactory (0.97). Subscale scores of the MDASI-HN-C were negatively correlated with the total score of the Chinese version of the Functional Assessment of Cancer Therapy—Head and Neck Scale (FACT-H&N-C) as hypothesized ($r = -0.484$ to -0.563 , all $P < 0.01$). Exploratory factor analysis (EFA) revealed two factors for the 13 core and another two for the nine HNC-specific items. Only one factor was generated for the six interference items.

Conclusions: The MDASI-HN-C shows desirable psychometric properties for evaluating symptom burden in NPC patients, which can be used in both clinical and research contexts.

Introduction

Nasopharyngeal carcinoma (NPC) is relatively uncommon with an incidence of 133,354 new cases worldwide, accounting for 0.7% of all sites in 2020.¹ However, it is endemic in eastern and south-eastern Asia, and 46.8% of new cases in the world occurs in China.^{1,2} Radiotherapy (RT) alone or combined with chemotherapy (CTX) are the main treatments, and the five-year overall survival rate of NPC patients can be as high as 70%–80%.^{3,4} However, symptoms associated with the disease and treatment such as taste change, xerostomia, sticky saliva, sore throat, and anorexia are still major problems, which may lead to treatment interruption and declined emotional well-being, functional performance, and quality of life (QOL).^{5–8} In addition, these symptoms can form

clusters that increase patients' symptom burden.^{9–12} Timely identification and monitoring of symptoms is critical to symptom management. Compared with assessing symptoms by clinicians, because using patient reported outcome instruments can elicit the patient experience directly, it is superior in both clinical and research contexts.¹³ Therefore, a psychometrically sound instrument is warranted to evaluate symptoms experienced by NPC patients.

There is currently no NPC-specific symptom assessment instrument. Given that NPC is one kind of head and neck cancers (HNCs), we looked for HNC-specific instruments instead to assess symptoms experienced by NPC patients. However, most of these HNC-specific instruments were designed to measure QOL, such as the European Organization for Research and Treatment of Cancer (EORTC) QOL Core Questionnaire

* Corresponding author.

E-mail address: marquesng@cuhk.edu.hk (MSN. Ng).

¹ Present address: The Chinese University of Hong Kong, Hong Kong SAR, China.

(QLQ-C30) and HNC module (QLQ-H&N 35),¹⁴ the Functional Assessment of Cancer Therapy—Head and Neck Scale (FACT-H&N),^{15,16} and the Head and Neck Cancer Inventory (HNCI).¹⁷ These QOL instruments often omit specific symptoms and the distress they cause.¹⁸

The Vanderbilt Head and Neck Symptom Survey (VHNSS) and the Head and Neck Symptom Checklist (HNCS) are instruments that focus on HNC-specific symptoms.^{19,20} However, the VHNSS and the HNCS were designed to assess only oral health outcomes and nutrition impact symptoms, respectively. Another two instruments found were the Head and Neck Distress Scale (HNDS) and the M. D. Anderson Symptom Inventory—Head and Neck Module (MDASI-HN),^{18,21} which were both developed by the University of Texas M. D. Anderson Cancer Center in 2006 and 2007, respectively. However, the HNDS has a long recall period of one month that affects its practicality. Unlike the HNCS and HNDS, the MDASI-HN is more comprehensive and assesses symptoms occurring in the last 24 h.

The English version of the MDASI-HN was developed in two steps. First, Cleeland and colleagues developed the original MDASI with two subscales, including 13 core items for assessing the severity of generic cancer related symptoms and six interference items for evaluating the influence of symptoms on daily living activities.²² The 13 core items measure two underlying constructs: (1) a factor comprising pain, fatigue, disturbed sleep, feeling of being distressed, shortness of breath, feeling drowsy, having a dry mouth, feeling sad, problem with remembering things, and numbness or tingling; and (2) a factor comprising nausea and vomiting. The symptom lack of appetite loads on both of these constructs.²² The MDASI has been widely used and validated in various languages, including Chinese.²³ Second, another subscale containing nine HNC-specific items for measuring the severity of symptoms associated with HNC was developed.¹⁸ These three subscales formed the 28-item MDASI-HN. The nine HNC-specific items measure two underlying constructs: (1) a factor comprising mouth/throat sores, problem with tasting food, constipation, problem with teeth or gums, and skin pain/burning/rash; and (2) a factor comprising difficulty with voice/speech, choking/coughing, difficulty swallowing/chewing, and problem with mucus.¹⁸ Because of its comprehensiveness, ease of understanding, promptness, and brevity, the MDASI-HN is considered as the most appropriate instrument to assess symptom burden in NPC patients.^{18,24}

To date, the Filipino, Spanish, and Italian versions of MDASI-HN have been psychometrically validated.^{25–27} The Chinese version of the MDASI-HN (MDASI-HN-C) (Appendix 1) has been translated by the M. D. Anderson Cancer Center and demonstrated good adaptation to the Chinese context. However, while its psychometric properties have not been evaluated, its routine use in clinical and research settings in China is hindered. Therefore, the aim of the study was to psychometrically validate the MDASI-HN-C by examining its reliability and validity in patients with NPC.

Methods

Study design and patient recruitment

This study adopted a cross-sectional design. It was conducted in the NPC department of Sun Yat-sen University Cancer Center, Guangzhou, China. The inclusion criteria were: (1) first-treated Chinese NPC patients; (2) undergoing RT at the time; (3) 18 years old or above; and (4) able to communicate in Mandarin or Cantonese. Patients who had been diagnosed with psychiatric morbidity or other types of cancer were excluded.

Instruments

Sociodemographic and clinical data questionnaires were constructed to collect information such as gender, age, educational level, marital status, occupational status, weight loss during treatment, stage of disease, number of times RT received, and type of CTX. The data were reported by the participants or retrieved from the medical records.

The MDASI-HN-C contains 28 items in three subscales, namely: core symptoms (13 items), HNC-specific symptoms (9 items) and symptom interference (6 items). All items are rated based on a 0–10 scale to measure symptom severity or interference over the last 24 h, with 0 indicating “not present” or “did not interfere” and 10 “as bad as you can imagine” or “interfered completely.” It takes approximately 5 min to complete the questionnaire. The Cronbach's α coefficients range from 0.83 to 0.92 for the three subscales.¹⁸

The 39-item FACT-H&N (version 4) was used to establish the construct validity of the MDASI-HN-C. The English version of the FACT-H&N is a validated HNC-specific QOL instrument consisting of five domains,^{15,16} namely: physical well-being (7 items), social/family well-being (7 items), emotional well-being (6 items), functional well-being (7 items) and HNC-specific concerns (12 items) in the past seven days based on a 0–4 scale (0 = not at all; 1 = a little bit; 2 = somewhat; 3 = quite a bit; 4 = very much). The Chinese version of the FACT-H&N (FACT-H&N-C) had been used on NPC patients with acceptable internal consistency (Cronbach's $\alpha = 0.75$).²⁸

Data collection

After obtaining ethical approval, eligible patients were approached consecutively. A signed information sheet and consent form was obtained from each participant. The whole questionnaire was completed mainly by patients themselves and the researcher was available if any assistance was needed. Based on the experience of previous studies,^{29–31} the MDASI-HN-C was administered again three days later with a convenient subsample to evaluate the test–retest reliability of the instrument. A total of 66 participants could be reached in wards by the researcher to complete the second questionnaire.

Data analysis

Descriptive statistics such as the mean, standard deviation (SD) and frequency (%) were used to describe the study sample. Inferential statistics such as the intraclass correlation, Pearson product–moment correlation, as well as confirmatory (CFA) and exploratory (EFA) factor analyses were used to evaluate the reliability and validity of the MDASI-HN-C. While the LISREL 8.8 (Scientific Software International Inc., Skokie, IL) was used to conduct the CFA, other statistical tests were conducted using SPSS 21.0 (IBM Corp., Armonk, NY). A P -value < 0.05 indicates statistically significant results.

Content validity was examined by calculating the content validity index (CVI) including item CVI (I-CVI) and scale CVI (S-CVI).³² An expert panel with expertise in NPC treatment and care, including two oncologists, two oncology nurses and one academic researcher, was established to evaluate the content validity of the MDASI-HN-C on a scale ranging from 1 to 4 (1 = not relevant; 2 = somewhat relevant; 3 = quite relevant; 4 = highly relevant). The I-CVI equals the number giving a rating of 3 or 4 divided by the number of raters, while the S-CVI is computed by averaging all I-CVIs. A minimum value of 0.8 for the I-CVI and 0.9 for the S-CVI are considered acceptable.³²

To examine the convergent validity, the Pearson product–moment correlation was used to determine the correlation of the MDASI-HN-C and the FACT-H&N-C based on the hypothesis that the symptom burden and QOL are negatively correlated.¹⁸ A correlation coefficient between 0.1 and 0.29, 0.3 and 0.49, and 0.5 and 1.0 represents small, medium, and large effect size, respectively.³³

CFA was conducted based on the 2-factor structure of core symptoms and the 2-factor structure of HNC-specific symptoms suggested by the instrument developers.^{18,22} Robust diagonally weighted least-squares method was applied. The following parameters were used to determine model fitness: degree of freedom ratio ($\chi^2/df \leq 3$), root-mean-square error of approximation (RMSEA ≤ 0.08), standardized root-mean-square residual (SRMR ≤ 0.1), adjusted goodness-of-fit index (AGFI ≥ 0.9), comparative fit index (CFI ≥ 0.9) and non-normed fit index

(NNFI \geq 0.95).³⁴ As the data did not fit the structures well, EFA was then performed using principle axis factor analysis with oblimin rotation to examine the factor structures of the 13 core and nine HNC-specific items separately. Since the instrument developers did not examine the factor structure of the six interference items, only EFA was conducted for this subscale.^{18,22} Kaiser's criterion was adopted and only factors with an eigenvalue greater than 1.0 were retained. A cut-off value of 0.3 for factor loading was chosen to determine which items belonged to a certain factor.³⁵

The reliability of the MDASI-HN-C was evaluated by examining the instrument's internal consistency and test–retest reliability. Internal consistency was determined by the Cronbach's α coefficient and item-to-total correlation. A minimum value of 0.7 for Cronbach's α and 0.4 for item-to-total correlation were adopted.^{36,37} Intraclass correlation coefficient (ICC) was used to evaluate the 3-day test–retest reliability. An ICC below 0.4 represents poor reliability, between 0.4 and 0.75 represents fair to good reliability, and above 0.75 represents excellent reliability.³⁸

Ethical considerations

The study was approved by the Survey and Behavioural Research Ethics Committee of the Chinese University of Hong Kong.

Results

Characteristics of participants

A total of 130 patients with NPC participated in the study. The sociodemographic and clinical characteristics of the sample are presented in Table 1. The mean \pm SD age was 43.22 \pm 9.75 years (range 18–65). Most of the participants were male (72.3%), married (91.5%), employed (59.2%) and had received junior high or above levels of education (86.9%). The mean \pm SD weight loss was 5.13 \pm 3.58 kg. 87.7% of participants were in a stage III or IV of the disease according to the 7th edition of the tumour node metastasis (TNM) classification. The average number of RT treatments received by participants were 21.48 \pm 4.80 (mean \pm SD) and majority of them (97.7%) received the treatment of

Table 1
Sociodemographic and clinical characteristics of participants (n = 130).

Characteristics	Mean (SD)	n (%)
Gender		
Male		94 (72.3)
Female		36 (27.7)
Age (years)	43.22 (9.75)	
Educational level		
Primary		17 (13.1)
Junior high		39 (30.0)
Senior high		39 (30.0)
Tertiary or above		35 (26.9)
Marital status		
Single or widowed		11 (8.5)
Married		119 (91.5)
Occupational status		
Unemployed		53 (40.8)
Employed		77 (59.2)
Weight loss (kg)	5.13 (3.58)	
Clinical stage		
I		1 (0.8)
II		15 (11.5)
III		74 (56.9)
IV		40 (30.8)
Number of times of RT	21.48 (4.80)	
Type of CTX		
No CTX		3 (2.3)
Neoadjuvant		5 (3.8)
Concurrent		58 (44.6)
Neoadjuvant + concurrent		64 (49.2)

Abbreviations: CTX, Chemotherapy; RT, Radiotherapy; SD, Standard deviation.

CTX. Detailed information on characteristics of this sample has also been reported in our previous publication.⁹

Validity of the MDASI-HN-C

The I-CVI of one item (item 6: shortness of breath) was computed as 0.60. Another two items (item 7: problem with remembering things and item 13: numbness or tingling) had an I-CVI of 0.80. The I-CVI for the remaining 25 items was 1.00. The S-CVI of the MDASI-HN-C was 0.97, indicating satisfactory content validity.

The three subscale scores of the MDASI-HN-C correlated negatively with the total score of the FACT-H&N-C ($r_{\text{core}} = -0.496$, $r_{\text{HNC-specific}} = -0.484$, $r_{\text{interference}} = -0.563$; all $P < 0.01$) and three domain scores, namely: physical ($r_{\text{core}} = -0.679$, $r_{\text{HNC-specific}} = -0.596$, $r_{\text{interference}} = -0.723$; all $P < 0.01$), emotional ($r_{\text{core}} = -0.373$, $r_{\text{HNC-specific}} = -0.321$, $r_{\text{interference}} = -0.466$; all $P < 0.01$) and HNC-specific ($r_{\text{core}} = -0.356$, $r_{\text{HNC-specific}} = -0.453$, $r_{\text{interference}} = -0.359$; all $P < 0.01$), with medium to large effect size. The functional domain of the FACT-H&N-C were negative correlated with the core and interference subscale scores of the MDASI-HN-C only with small effect size ($r_{\text{core}} = -0.202$, $P < 0.05$; $r_{\text{interference}} = -0.296$, $P < 0.01$). No statistically significant correlations were found between any of the three subscale scores of the MDASI-HN-C and the social/family domain. Details of the associations between the MDASI-HN-C and the FACT-H&N-C are provided in Table 2. The significant negative correlation coefficients indicated that more severe symptom burden was related to poorer QOL. This result suggests the good convergent validity of the instrument.

The results of the CFA indicate that the 2-factor structure of the MDASI-HN-C core symptoms ($\chi^2 = 142.8$, $df = 63$, $P < 0.001$; RMSEA = 0.101; SRMR = 0.064; CFI = 0.95; NNFI = 0.94; AGFI = 0.78) was not satisfactorily fitted by the data. Regarding the MDASI-HN-C HNC-specific symptoms, our data did not fit the 2-factor structure ($\chi^2 = 72.5$, $df = 26$, $P < 0.001$; RMSEA = 0.118; SRMR = 0.067; CFI = 0.94; NNFI = 0.92; AGFI = 0.81). In the EFA, we identified two factors for both two subscales but with different constituting items comparing with the findings of the instrument developers.^{18,22} Specifically, for the 13 core items, principle axis factor analysis revealed two factors, explaining 47.25% and 8.79% of the variance respectively. Factor 1 comprised 11 items (general symptoms): feeling drowsy, shortness of breath, feeling of being distressed, feeling sad, numbness or tingling, disturbed sleep, fatigue, problem with remembering things, pain, lack of appetite and having a dry mouth. Factor 2 consisted of two items (gastrointestinal symptoms): nausea and vomiting. For the nine HNC-specific items, another two factors, explaining 47.65% and 11.48% of the variance respectively. Factor 3 covered six items (nutrition impact symptoms): problem with mucus, mouth/throat sores, difficulty swallowing/chewing, problem with tasting food, problem with teeth or gums and constipation. Factor 4 covered three items (social interaction impact symptoms): choking/coughing, difficulty with voice/speech and skin pain/burning/rash. For the six interference items, only one factor was generated, explaining 63.65% of the variance. The patterns of factor loadings are shown in Table 3.

Reliability of the MDASI-HN-C

The Cronbach's α coefficients for the three subscales and their underlying constructs ranged from 0.74 to 0.91, which indicated satisfactory internal consistency. The item-to-total correlation coefficients ranged from 0.40 to 0.82, providing further evidence for the items' homogeneity. The three-day test–retest reliability of the MDASI-HN-C was also acceptable, with ICC ranging from 0.48 to 0.71, which represented fair to good reliability (Table 4).

Discussion

The MDASI has been widely used to assess symptom burden in various cancer patients and the MDASI-HN was developed and validated

Table 2
Correlation between the MDASI-HN-C and the FACT-H&N-C.

MDASI-HN-C domains	Correlation with FACT-H&N-C (r)					
	Physical	Social/family	Emotional	Functional	HNC-specific	Total
Core	-0.679**	0.028	-0.373**	-0.202*	-0.356**	-0.496**
HNC-specific	-0.596**	-0.036	-0.321**	-0.150	-0.453**	-0.484**
Interference	-0.723**	0.052	-0.466**	-0.296**	-0.359**	-0.563**

Abbreviations: FACT-H&N-C, Chinese version of the Functional Assessment of Cancer Therapy—Head and Neck Scale; HNC, Head and neck cancer; M, Mean; MDASI-HN-C, Chinese version of the M. D. Anderson Symptom Inventory—Head and Neck Module; SD, Standard deviation.

*P < 0.05; **P < 0.01.

Table 3
Exploratory factor analysis of the MDASI-HN-C.

MDASI-HN-C domains	Factor loadings				
	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
Core					
Feeling drowsy	0.833	0.084			
Shortness of breath	0.799	0.104			
Feeling of being distressed	0.797	0.052			
Feeling sad	0.714	0.059			
Numbness or tingling	0.596	0.018			
Disturbed sleep	0.530	-0.163			
Fatigue	0.527	-0.227			
Problem with remembering things	0.510	-0.106			
Pain	0.490	-0.072			
Lack of appetite	0.479	-0.280			
Having a dry mouth	0.322	-0.276			
Nausea	0.009	-0.925			
Vomiting	0.057	-0.853			
HNC-specific					
Problem with mucus			0.878	-0.025	
Mouth/throat sores			0.694	0.162	
Difficulty swallowing/chewing			0.576	0.239	
Problem with tasting food			0.571	-0.109	
Problem with teeth or gums			0.436	0.148	
Constipation			0.374	0.260	
Choking/coughing			-0.023	0.750	
Difficulty with voice/speech			0.073	0.736	
Skin pain/burning/rash			0.033	0.551	
Interference					
Enjoyment of life					0.820
General activity					0.818
Mood					0.803
Work					0.762
Walking					0.668
Relations with other people					0.625

Abbreviations: HNC, Head and neck cancer; MDASI-HN-C, Chinese version of the M. D. Anderson Symptom Inventory—Head and Neck Module. Major loadings (> 0.3 or < -0.3) in each factor are bolded.

later especially for HNC patients.^{18,22} As an instrument designed to measure symptoms and with advantages of comprehensiveness, ease of understanding, promptness, and brevity, it is considered to be the most appropriate instrument for assessing symptom burden in NPC patients. Although the MDASI-HN has been translated into Chinese and validated linguistically, its psychometric properties have not previously been examined. Therefore, this study psychometrically validated the MDASI-HN-C in Chinese NPC patients who were undergoing RT.

Except for item 6 “shortness of breath,” the I-CVI of all other items was above the suggested satisfactory value of 0.8. Two experts gave item 6 a rating of 2, indicating that the item is “somewhat relevant” to NPC patients. Although they pointed out that the prevalence of “shortness of

Table 4
Internal consistency and three-day test–retest reliability of the MDASI-HN-C.

MDASI-HN-C domains	Cronbach's α (n = 130)	Corrected item-to-total correlation (n = 130)	ICC (n = 66)
Core	0.91	0.51–0.70	0.63
General symptoms	0.89	0.48–0.74	0.66
Gastrointestinal symptoms	0.90	0.82	0.48
HNC-specific	0.85	0.40–0.71	0.71
Nutrition impact symptoms	0.82	0.46–0.73	0.70
Social interaction impact symptoms	0.74	0.50–0.62	0.65
Interference	0.88	0.59–0.76	0.52

Abbreviations: HNC, Head and neck cancer; ICC, Intraclass correlation coefficient; MDASI-HN-C, Chinese version of the M. D. Anderson Symptom Inventory—Head and Neck Module.

breath” in NPC patients during treatment is not high, they suggested retaining this item as it does occur in a certain number of NPC patients. Therefore, we decided to keep the item 6 in the instrument to be further validated by patients.

Negative associations were found between the symptom burden and the total score of QOL, which was consistent with the findings from the validation studies of other versions.^{18,25–27} For the domains of QOL, all subscale scores of the MDASI-HN-C were significantly correlated with them, except for the social/family and functional domains. No statistically significant correlations were found between the MDASI-HN-C and the social/family domain, which might be explained by the relatively strong and stable family support in the context of Chinese culture.^{39,40} In addition, there was no statistically significant correlation between the HNC-specific subscale of the MDASI-HN-C and the functional domain, which might attribute to the general functions the domain mainly measures, such as work, sleep, and life satisfaction.⁹

Factor analyses were performed to examine the internal structure of symptoms in the MDASI-HN-C. The researcher conducted CFA and EFA for the two subscales separately in order to follow the strategy adopted by the instrument developers, as well as for empirical reasons.^{18,22} Two factors were identified when examining the internal structure of the 13 core symptoms. This result was in line with some previous studies.^{23,29} Similar to the original English and translated Spanish versions,^{18,26} the nine HNC-specific symptoms generated two factors. However, items within each factor among these three language versions were not identical, which may be caused by different populations included in these studies.

The MDASI-HN-C demonstrated satisfactory internal consistency with high Cronbach's α coefficients, which was consistent with the original, Filipino and Spanish versions of the instrument.^{18,25,26} The internal consistency was further supported by the item-to-total correlation lying within a range of 0.40–0.82. As for test–retest reliability, the ICC for the three subscales and their underlying constructs was only moderately high. One possible explanation is that patients' symptoms change from day to day. In fact, the MDASI-HN-C was designed to measure symptoms on a daily basis (i.e., having a recall period of 24 h). Thus, the stability of the MDASI-HN-C was considered as acceptable.

By examining the content validity, convergent validity, construct validity, internal consistency, and test–retest reliability of the MDASI-HN-C in this study, its psychometric properties have been established. In addition to its strengths mentioned above, the validated MDASI-HN-C is the most suitable and practical instrument to assess symptom burden in Chinese NPC patients. Symptom management is always the key content of care for patients with cancer and symptom identification and monitoring are important links of management.⁴¹ The MDASI-HN-C can not only assess the symptom severity but also the interference of symptom on daily living. Therefore, it can help clinicians to quickly and comprehensively assess patients' symptom burden and monitor its longitudinal changes, so as to provide evidence for the formulation and evaluation of medical and nursing decisions. Besides, the MDASI-HN-C can also be used in a variety of research contexts regarding patient reported outcomes, such as research on symptom clusters in which multiple symptoms need to be evaluated simultaneously.

Limitations

Firstly, because this study was conducted in a single hospital in southern China, its generalizability may be affected. Secondly, symptoms were evaluated at a single time point in this cross-sectional study and the instrument's sensitivity to changes is not known. Thirdly, except for the 22 symptoms contained in the instrument, we did not explore other symptoms. Therefore, there is a possibility that some NPC-specific symptoms, such as visual and auditory problems, are neglected.

Conclusions

To conclude, the MDASI-HN-C shows desirable psychometric properties for evaluating symptom burden in Chinese NPC patients. It can help clinicians to have a better understanding of the symptoms experienced by NPC patients. In addition, the MDASI-HN-C can be used in patient reported outcome research, especially in studies which assessments of multiple concurrent symptoms. Future multi-centre, longitudinal studies that explore more NPC-specific symptoms for further validation of the instrument in patients with NPC are recommended.

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Declaration of competing interest

None declared.

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Supplementary material

To access the supplementary material accompanying this article, visit the online version of the *Asia-Pacific Journal of Oncology Nursing* at <http://doi.org/10.1016/j.apjon.2021.12.014>.

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