

Brief Methodological Report

Validation and Application of the Chinese Version of the M. D. Anderson Symptom Inventory Gastrointestinal Cancer Module (MDASI-GI-C)



Ren-wang Chen, PhD, Sheng-li Yang, PhD, Zhong-yu Xu, MD, Miao Peng, PhD, Meng-ni Chen, MD, Qiu-shuang Wang, MD, Jian Chang, MD, and Jian-li Hu, PhD

Cancer Center (R.-w.C., S.-l.Y., M.P., M.-n.C., Q.-s.W., J.C., J.-l.H.), Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan; and Department of Epidemiology and Biostatistics (Z.-y.X.), Huazhong University of Science and Technology, Wuhan, China

Abstract

Objectives. To validate and use the Chinese Version of the M. D. Anderson Symptom Inventory Gastrointestinal Cancer Module (MDASI-GI-C) to assess the symptom burden of Chinese-speaking patients with gastrointestinal cancer.

Methods. In total, 527 patients with postoperative or advanced digestive tract tumors were enrolled in the trial, who had definitive diagnoses and different treatments in our cancer center. MDASI-GI-C was administered to these patients between February and December 2017. The item-scale correlations and internal consistency were evaluated. Construct validity was established by factor analysis. Hierarchical cluster analysis was performed.

Results. Cronbach's alpha of the symptom severity and interference subscales was 0.842 and 0.859, respectively. Construct validity revealed a four-factor structure. Known-group validity was established by comparing the MDASI-GI-C scores between patients having different Karnofsky Performance Status scores (≤ 70 or > 70), which were observed to have significant differences. The overall mean subscale scores for the core and interference subscales were 1.63 ± 2.02 and 2.17 ± 2.34 , respectively. Fatigue, disturbed sleep, and lack of appetite had the highest scores for most serious symptoms. No significant differences in age, working status, and educational level were found.

Conclusions. MDASI-GI-C is a reliable and valid tool for assessing cancer-related symptoms in Chinese-speaking patients with digestive tract tumors, facilitates the understanding of the common symptoms of patients with digestive tract tumors, and enables timely management of these symptoms. Cognitive debriefing demonstrated that the patients found MDASI-GI-C to be an easy-to-use and understandable instrument. *J Pain Symptom Manage* 2019;57:820–827. © 2019 American Academy of Hospice and Palliative Medicine. Published by Elsevier Inc. All rights reserved.

Key Words

MDASI-GI-C, MDASI, digestive tract tumors, validation, application, Chinese version

Introduction

The modern anticancer treatment model has evolved from a simple assessment of tumor size to a comprehensive assessment model based on the holistic being of cancer patients, such as the tumor size, physical function, psychological symptoms, and social functions.^{1–3} Patients with tumor often suffer from

many physical and psychological symptoms, such as pain, fatigue, and depression. The number and severity of symptoms in the symptomatic group have a negative impact on the quality of life and functional status of patients.^{4–7} Among them, symptoms caused by cancer and anticancer therapy should be properly evaluated and treated, regardless of language or

Address correspondence to: Jian-li Hu, PhD, Cancer Center, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan 430022, China. E-mail: jl5199@126.com

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country.^{8–10} These symptoms greatly influence the patient's activities of daily living and may even cause the patient to change or neglect an active treatment plan.^{11,12} Digestive tract tumors are associated with unique symptoms affecting both patient survival and health-related quality of life.^{12–16} During the anti-cancer treatment and survival, gaining an understanding of the patient's experience requires assessment of symptoms.¹⁷

In the recent years, symptomatic cluster research has become one of the emerging research issues in identifying symptoms and managing cancer patients.^{18–20} Many scholars have been working on the tools for assessing these symptoms in cancer patients, which are both universal and specific. Assessment tools play an important role in assessing the symptoms of cancer patients. Although no specific tools are available, some tools are highly reliable and valid,^{21,22} such as the M. D. Anderson Symptom Inventory (MDASI). The MDASI can evaluate the manifestations and effects of some common cancer-related symptoms. Currently, specific modules for different cancers have been developed, which assess the severity and impact of multiple symptoms related to cancer and its treatment. A systematic review of 57 symptom assessment tools identified as appropriate for clinical use indicated that the MDASI has several advantages over the other tools.²² The MDASI was designed with different modules that can be further developed to various tumor types by adding specific items.^{23–29} Studies on the validation and application of the M. D. Anderson Symptom Inventory Gastrointestinal Cancer Module (MDASI-GI)²⁹ and its Chinese version have already been completed.³⁰ In our study, the Chinese version of the MDASI-GI (MDASI-GI-C) was translated and culturally adapted in the context of contemporary Chinese and evaluated to establish its reliability and validity.

Methods

Instrument

The MDASI (consisting of 19 items: 13 core + six interference items) was translated into Chinese by Wang XS in 2004³⁰ and used directly. In addition, five GI-C items (diarrhea, bloating, constipation, difficulty swallowing, and change in taste) were developed using the standard translation/back-translation procedure that was used to create other validated versions of the MDASI-GI. First, a physician who spoke both English and Chinese translated MDASI-GI items as simply as possible into Chinese characters. A second translator who had not seen the original English items then back-translated the Chinese translation into English. Bilingual fluency was required of both translators. The items that had been back-translated into English

were then compared with the original items. If the back-translated items and the original items did not agree, the first translator offered a second translation after comparing the original items and their back-translations and a second back-translation was generated and compared with the original items once more. This translation/back-translation procedure was repeated until the translation was judged to be satisfactory.³⁰ The MDASI-GI-C questionnaire (including 13 core + five GI + six interference items) was explained item-by-item to the patients participating in the survey until they fully understood their meaning. The degree of all symptom scores (18) in the MDASI-GI-C is expressed as numbers from "0" to "10," representing from "not present" to "as bad as you can imagine." The degree rating of the MDASI-GI-C interference items (6) is represented by numbers from "0" to "10," representing from "did not interfere" to "interfered completely." The symptoms evaluated were all in the past 24 hours. In addition, patient demographics, disease stage, and Karnofsky Performance Status (KPS) were also recorded. The Short Form 36 Quality of Life Questionnaire (SF-36-C)³¹ was also completed along with the MDASI-GI-C questionnaire.

Participants

The inclusion criteria were as follows: inpatients at the Department of Abdominal Oncology, Cancer Center, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China, with clear pathological diagnosis, such as tumors, that is, gastric, colorectal, esophageal, pancreatic, and hepatobiliary cancer; underwent radiotherapy, chemotherapy, chemoradiotherapy, or palliative treatment; aged ≥ 18 years; and could understand and speak Chinese fluently. Exclusion criteria were as follows: impaired ability to listen, read, and understand because of mental disorders and refusal to participate in the research. A total of 534 patients with digestive tract tumors participated in the study and completed the MDASI-GI-C questionnaire. The final valid questionnaire was 527. The survey period was from February to December 2017.

Cognitive Debriefing

The first 20 patients who were randomly selected to complete the MDASI-GI-C participated in a cognitive interview conducted by study personnel regarding its ease of completion and comprehensibility. They were then queried on the appropriateness of each specific item, if any item was unclear or redundant, and if they had any other suggestions on potential improvement.

Interview

The survey was conducted by two experienced oncologists. They first introduced the purpose and

precautions of the survey to each participating patient and obtained their consent. Participants fully understood and completed the questionnaire independently. The completion time of each questionnaire was approximately 20–30 minutes.

Statistical Analyses

All statistical analyses were performed using the SPSS, version 18, statistical software. The MDASI-GI-C reliability and validity test method is as follows: The internal consistency test is obtained by calculating the Cronbach's α coefficient, which ranges from 0 to 1. The higher value indicates a smaller measurement error, indicating better reliability. In our study, construct validity was established using principal axis factor analysis with direct oblimin rotation, which was used with oblimin rotation to determine the final number of factors based on their eigenvalues, congruity, and clinical significance. The Kaiser-Meyer-Olkin (KMO) test confirmed sample adequacy, and a KMO value of >0.5 indicates an acceptable structural validity. In addition to the spindle factor analysis, known-group validation testing also show the construct validity, which was analyzed by comparing MDASI-GI-C symptom entries and interference entries for different tumor types and patient characteristics (age, physical status, working status, and educational level). Convergent validity was tested by calculating the correlation coefficient between the MDASI-GI-C and SF-36-C scores. Cluster analysis was used to investigate the association between symptom characteristics and the actual symptoms in Chinese patients with digestive tract cancer.

Results

Cognitive Debriefing

The Chinese version of the instrument was administered to 20 patients with digestive tract cancer and was evaluated according to ease or difficulty in understanding and answering, using a scale of 1–5, 1 being very difficult to understand and to answer and 5 being very easy to understand and answer. Revisions, as well as back-translation, were made by the translators according to the recommendations of the participants. Results from the cognitive interview of the first 20 participants revealed that this was clear through in-person explanation.

Patient Characteristics

The mean \pm standard deviation age was 54.9 ± 11.2 years; the proportion of patients aged ≤ 60 years was 60.7%; the proportion of the male patients was 63%; the proportion of gastric cancer, colon, rectal, hepatobiliary, pancreatic, and esophageal cancer was 28.7%, 23.9%, 26.2%, 12.3%, 4.7%, and 4.2%, respectively; the proportion of patients with educational level of \leq grade 9 was 55.4%; the

proportion of patients with Stages III and IV cancer was 21.3% and 74.0%, respectively; and the proportion of patients before, during, and after treatment was 35.1%, 49.5%, and 15.4%, respectively (Table 1).

Internal Consistency

Internal consistency was established using the Cronbach's alpha coefficients. Generally, Cronbach's alpha values of >0.9 are generally rated as excellent, >0.8 as good, >0.7 as acceptable, and <0.6 as doubtful. In MDASI-GI-C, the total Cronbach's alpha coefficient for all symptom items (18) was 0.893, with the core items (13) having 0.821, the GI items (5) having 0.710, and the interference items (6) having 0.859. The results show that the scale has good internal consistency (Table 2).

Construct Validity

Construct validity was assessed using the principal axis factor analysis. MDASI-GI-C symptom items (18) generate four possible factors: Factor 1 contains all

Table 1
Main Demographic and Disease Characteristics (N = 527)

Patient Characteristics	n (%)
Age	
Mean \pm SD (yrs)	54.9 \pm 11.2
Range (yrs)	25–81
Age \leq 60 yrs	320 (60.7)
Age $>$ 60 yrs	207 (39.3)
Gender	
Male	332 (63.0)
Female	195 (37.0)
Marital status	
Married	498 (94.5)
Single (including divorced, widowed)	29 (5.5)
Education level	
Grade \leq 9	292 (55.4)
Grade $>$ 9	235 (44.6)
Employment status	
Employed	195 (37.0)
Retired or unemployed	192 (36.4)
Farmer	140 (26.6)
Cancer diagnosis	
Gastric	151 (28.7)
Colon	126 (23.9)
Rectal	138 (26.2)
Hepatobiliary	65 (12.3)
Pancreatic	25 (4.7)
Esophageal	22 (4.2)
Cancer stage	
I	0
II	25 (4.7)
III	112 (21.3)
IV	390 (74.0)
Current cancer treatment status	
Before treatment	185 (35.1)
In treatment	261 (49.5)
After treatment	81 (15.4)
KPS group	
Poor \leq 70	96 (18.2)
Good $>$ 70	431 (81.8)

SD = standard deviation; KPS = Karnofsky Performance Status. Data are presented as median (range) or absolute frequency (%).

Table 2
Internal Consistency Reliability of MDASI-GI-C

Symptom	Cronbach's α	Total Cronbach's α if Item Deleted
Severity (18)	0.842	
Core items (13)	0.821	
Pain		0.880
Fatigue		0.881
Nausea		0.885
Disturbed sleep		0.883
Distress		0.880
Shortness of breath		0.885
Difficulty remembering		0.888
Lack of appetite		0.880
Drowsiness		0.883
Dry mouth		0.886
Sadness		0.881
Vomiting		0.887
Numbness		0.890
GI-specific items (5)	0.710	
Constipation		0.887
Diarrhea		0.883
Difficulty swallowing		0.880
Change in taste		0.886
Bloating		0.889
Interference items (6)	0.859	
Activity		0.878
Mood		0.879
Work		0.883
Relations with others		0.882
Walking		0.879
Enjoyment of life		0.878

MDASI-GI-C = Chinese version of M. D. Anderson Symptom Inventory Gastrointestinal Module; GI-specific = Gastrointestinal Module-specific.

physical symptoms (lack of appetite, pain, change in taste, disturbed sleep, drowsiness, sadness, distress, fatigue, dry mouth, shortness of breath, bloating, and difficulty swallowing); Factor 2 represents upper gastrointestinal symptoms (vomiting and nausea); Factor 3 is associated with neurological symptoms (numbness and memory loss); and Factor 4 represents lower gastrointestinal symptoms (constipation and diarrhea). These data are suitable for the factor analysis because the sample has a KMO value of 0.784, with eigenvalues of 5.03, 1.62, 1.46, and 1.26, accounting for 27.9%, 9.0%, 8.1%, and 7.0%, respectively (Table 3).

Known-Group Validity

Known-group validity analysis showed no significant difference in patients of different ages (≥ 60 and < 60 years), different working conditions (on-the-job, retired or unemployed, or farmers), and different educational levels ($> \text{grade } 9$ and $\leq \text{grade } 9$) ($P \geq 0.05$). However, patients with KPS of > 70 had significantly lower MDASI-GI-C scores (24 items) than those with KPS of ≤ 70 ($P < 0.05$).

Correlation Coefficients

The correlation coefficient was shown by the aggregation validity test between the score of each item in the MDASI-GI-C and their corresponding item in

Table 3
Construct Validity of the M. D. Anderson Symptom Inventory: Baseline Factor Loadings of the Core Symptom Items ($N = 527$)

Symptom	Factor 1	Factor 2	Factor 3	Factor 4
Lack of appetite	.697	.288	-.220	-.158
Pain	.676	-.113	.082	-.072
Change in taste	.669	.255	-.143	-.108
Disturbed sleep	.641	-.282	.137	-.027
Drowsiness	.663	-.237	.152	-.089
Sadness	.607	-.382	-.495	.366
Distress	.604	-.427	-.487	.337
Fatigue	.596	-.026	-.140	-.234
Dry mouth	.509	-.030	.379	-.021
Shortness of breath	.466	-.144	.321	.138
Bloating	.428	-.223	.075	-.415
Difficulty swallowing	.372	.131	.341	.314
Vomiting	.468	.675	-.191	.067
Nausea	.546	.641	-.145	.026
Numbness	.291	-.001	.444	.221
Difficulty remembering	.358	.039	.430	.145
Constipation	.371	-.126	.058	-.640
Diarrhea	.274	.139	.180	.370

Kaiser-Meyer-Olkin (KMO) 0.784.

Values in bold indicate that they belong to the same factor.

SF-36-C. The SF-36-C scale consists of eight parts: bodily pain, vitality, mental health, physical functioning, general health perceptions, physical role functioning, social role functioning, and emotional role functioning. The average score for all MDASI-GI-C items was found to be significantly consistent with the mean score for symptoms in the SF-36-C scale.

Cluster Analysis

The correlation between symptoms was explored using cluster analysis, and the relative distance between symptom groups is shown in Figure 1. Symptoms that were previously related (left side of the figure) were more relevant than the symptoms that were connected later (right side of the figure). As shown in Figure 1, nausea and vomiting, sadness and depression, changes in taste and lack of appetite, and dysphagia and shortness of breath were highly correlated.

Clinical Application of MDASI-GI-C

All symptoms in the MDASI-GI-C scale with 0–10 classification were classified into mild (0–3), moderate (4–6), and severe (7–10) based on the score. The overall mean scores for all symptom items (18) and interference items (6) were 1.63 ± 2.02 and 2.17 ± 2.34 , respectively. The most severe symptoms reported were fatigue (2.91 ± 2.57), disturbed sleep (2.62 ± 2.52), and lack of appetite (2.37 ± 2.61). The mildest symptoms reported were difficulty swallowing (0.51 ± 1.46) and vomiting (0.70 ± 1.52). Among the three most serious symptoms, the proportion of patients with severe scores (7–10) was 11.8% for fatigue, 12.0% for disturbed sleep, and 9.9% for

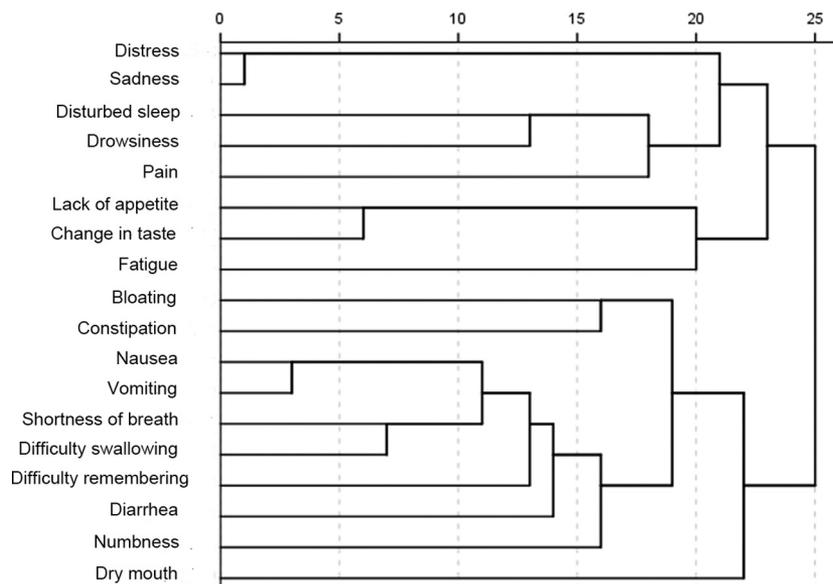


Fig. 1. Hierarchical clustering analysis with dendrogram showing relative distances between item clusters. Clusters were formed based on the distance between symptom ratings, which was calculated using squared Euclidian distances. Symptoms that join together earlier (toward the left side of the figure) are more similar than symptoms that join together later (toward the right side of the figure).

lack of appetite. The three most serious items in the interference item were “work” (3.38 ± 2.86), “walking” (2.39 ± 2.68), and “mood” (2.35 ± 2.54); among them, the proportion of patients with severe scores (7–10) for work accounted for 18.0%, walking 10.1%, and mood 9.1% (Table 4). The most severe symptoms according to disease group were compared. The first three most severe symptoms of gastric cancer were similar with those for all diseases. The first three most severe symptoms of colorectal cancer and hepatobiliary cancer were also similar, that is, fatigue, disturbed sleep, and distress; however, the first three most severe symptoms of pancreatic cancer were fatigue, disturbed sleep, and pain (Table 5).

Discussion

The presence, severity, and impact of cancer in a patient’s daily life, such as during the diagnosis, treatment, and follow-up, should be assessed.^{7,32,33} In this study, the effectiveness of the MDASI-GI-C module was evaluated. The results of the study showed its good reliability and validity in assessing the burden of symptoms. Several previous studies have validated other MDASI modules in other languages,^{23,26,28,34–36} such as Chinese Version of the M. D. Anderson Symptom Inventory Spine Tumor Module³⁷ and the M. D. Anderson Symptom Inventory Head and Neck Module in Spanish.²⁶

In this study, the KMO value of the construct validity test is 0.874, which is much higher than 0.5, indicating that the scale has good construct validity; however, we

obtained four factors in the factor analysis, which are different from the two factors obtained by XS Wang et al. reported by MDASI-GI.²⁹ This reason for this variation should be explored in further research.

Table 4
Mean and Percentage of Patients With Moderate and/or Severe Scores for Each Item (N = 527)

Symptom	Mean Score	Score ≤ 3 (%)	Score > 6 (%)	SD
Severity				
Fatigue	2.91	63.8	11.8	2.57
Disturbed sleep	2.62	67.1	12.0	2.52
Lack of appetite	2.37	73.6	9.9	2.61
Distress	2.27	73.2	8.3	2.47
Sadness	2.22	74.6	8.2	2.45
Change in taste	2.06	77.4	8.5	2.48
Drowsiness	1.97	79.3	3.6	2.10
Pain	1.88	77.2	8.3	2.56
Dry mouth	1.85	81.2	8.3	2.46
Bloating	1.47	84.3	6.3	2.28
Difficulty remembering	1.40	86.0	2.7	1.91
Nausea	1.25	87.7	3.6	1.98
Numbness	1.18	86.7	4.9	2.10
Constipation	0.95	91.5	4.2	2.00
Diarrhea	0.91	90.5	3.6	1.93
Shortness of breath	0.82	92.8	2.1	1.63
Vomiting	0.70	93.7	1.7	1.52
Difficulty swallowing	0.51	95.1	1.7	1.46
Interference items				
Work	3.38	57.1	18.0	2.86
Walking	2.39	70.2	10.1	2.68
Mood	2.35	75.5	9.1	2.54
Enjoyment of life	2.06	73.8	8.0	2.57
Activity	1.87	82.0	5.1	2.26
Relations with others	0.96	90.7	3.0	1.91

SD = standard deviation.

Data are presented as median (range) or absolute frequency (%).

Table 5
Symptom Profiles: MDASI-GI-C Mean Severity (Standard Deviation) Across KPS and Disease Groups (N = 527, Except as Noted)

MDASI-GI Items	KPS			Most Severe Symptoms by Disease Group			
	All (N = 527)	≤70 (n = 96)	>70 (n = 431)	Gastric (n = 151)	Colorectal (n = 264)	Hepatobiliary (n = 65)	Pancreatic (n = 25)
Core							
Fatigue	2.91 ± 2.57	3.91 ± 2.57	2.05 ± 2.42	3.29 ± 2.54	2.65 ± 2.48	2.78 ± 2.80	3.53 ± 2.26
Disturbed sleep	2.62 ± 2.52	3.68 ± 2.67	1.93 ± 1.98	2.30 ± 2.72	2.39 ± 2.51	2.83 ± 2.99	3.50 ± 2.88
Lack of appetite	2.37 ± 2.61	3.46 ± 2.66	1.92 ± 1.87	2.66 ± 2.73	2.13 ± 2.55	2.23 ± 2.70	3.03 ± 2.43
Distress	2.27 ± 2.47	2.93 ± 2.71	1.78 ± 2.09	1.95 ± 2.33	2.31 ± 2.43	2.55 ± 2.82	2.44 ± 2.68
Sadness	2.22 ± 2.45	3.16 ± 2.88	1.65 ± 2.01	2.02 ± 2.39	2.28 ± 2.46	2.48 ± 2.85	1.97 ± 2.07
Drowsiness	1.97 ± 2.10	2.73 ± 2.42	1.69 ± 1.90	1.98 ± 2.14	1.74 ± 1.92	2.12 ± 2.24	2.25 ± 2.17
Pain	1.88 ± 2.56	2.59 ± 2.66	1.57 ± 2.07	1.61 ± 2.53	1.68 ± 2.33	2.16 ± 2.56	3.34 ± 3.11
Dry mouth	1.85 ± 2.46	2.48 ± 2.57	1.54 ± 2.34	1.48 ± 2.13	1.97 ± 2.57	2.51 ± 2.50	1.69 ± 2.30
Difficulty remembering	1.40 ± 1.91	2.02 ± 2.22	1.18 ± 1.60	1.42 ± 1.88	1.48 ± 2.01	1.31 ± 1.58	1.28 ± 1.75
Nausea	1.25 ± 1.98	1.91 ± 2.19	1.08 ± 1.69	1.35 ± 2.09	1.18 ± 1.88	2.10 ± 2.16	1.41 ± 2.19
Numbness	1.18 ± 2.10	1.82 ± 2.63	0.88 ± 1.67	1.40 ± 2.19	1.27 ± 2.20	1.31 ± 1.72	0.84 ± 1.64
Shortness of breath	0.82 ± 1.63	1.37 ± 1.92	0.65 ± 1.33	0.90 ± 1.77	0.75 ± 1.45	0.77 ± 1.73	0.78 ± 1.75
Vomiting	0.70 ± 1.52	1.32 ± 1.68	0.54 ± 1.22	0.85 ± 1.72	0.63 ± 1.40	0.68 ± 1.89	0.69 ± 1.29
GI module							
Change in taste	2.06 ± 2.48	2.92 ± 2.83	1.51 ± 1.91	2.48 ± 2.77	1.77 ± 2.31	1.69 ± 2.36	3.06 ± 2.73
Bloating	1.47 ± 2.28	1.97 ± 2.60	1.02 ± 1.73	1.65 ± 2.33	1.38 ± 2.23	1.53 ± 2.57	1.88 ± 2.65
Constipation	0.95 ± 2.00	1.52 ± 2.52	0.72 ± 1.67	1.14 ± 2.33	0.84 ± 1.88	0.95 ± 1.83	1.37 ± 2.04
Diarrhea	0.91 ± 1.93	1.48 ± 2.12	0.68 ± 1.33	0.63 ± 1.60	1.12 ± 2.07	0.74 ± 1.16	1.56 ± 2.77
Difficulty swallowing	0.51 ± 1.46	0.86 ± 1.67	0.42 ± 1.34	0.80 ± 1.77	0.27 ± 0.98	0.14 ± 0.47	0.56 ± 1.17
Interference items							
Work	3.38 ± 2.86	4.56 ± 3.03	2.62 ± 2.61	3.62 ± 2.84	3.16 ± 2.89	3.19 ± 2.85	4.06 ± 2.30
Walking	2.39 ± 2.68	3.32 ± 2.97	1.77 ± 1.89	2.60 ± 2.69	2.19 ± 2.66	2.32 ± 3.03	2.81 ± 2.46
Mood	2.35 ± 2.54	3.06 ± 2.73	1.88 ± 2.25	2.32 ± 2.59	2.22 ± 2.41	2.17 ± 2.78	2.59 ± 2.84
Enjoyment of life	2.06 ± 2.57	2.82 ± 2.69	1.70 ± 1.83	2.32 ± 2.61	1.63 ± 2.33	1.92 ± 3.06	2.22 ± 2.19
Activity	1.87 ± 2.26	2.53 ± 2.54	1.59 ± 1.63	1.95 ± 2.31	1.70 ± 2.11	1.75 ± 2.38	2.38 ± 2.55
Relations with others	0.96 ± 1.91	1.72 ± 2.36	0.73 ± 1.68	1.06 ± 2.05	0.78 ± 1.68	0.72 ± 2.26	1.16 ± 2.09

MDASI-GI-C = Chinese version of M. D. Anderson Symptom Inventory Gastrointestinal Module; KPS, Karnofsky Performance Status. Values in bold represent the three most serious symptoms in the corresponding tumor.

Our study showed that the scale is greatly correlated with SF-36-C and supports the scale in measuring its associated specific symptoms. Previous studies have shown that symptom measurement is more informative than SF-36-C measurement because specific scales are more sensitive to symptom changes.^{31,36,38}

The average score obtained from the core symptoms was different from the distribution reported by XS Wang et al.²⁹ Wang's study showed that the core symptoms of MDASI and the severity of GI-specific symptoms were higher in patients with gastric cancer than in those with digestive tract cancer, but this was not observed in our study. In their initial study, the authors described fatigue, drowsiness, and pain as the three most severe symptoms in general; however, in our group, the three most serious symptoms were fatigue, disturbed sleep, and lack of appetite, suggesting that psychological symptoms are more pronounced in our population. This result may be related to the high proportion of advanced tumor staging in our subjects. In this study, the proportion of Stage III and Stage IV cancers was 21.3% and 74.0%, respectively.

Furthermore, the calculation of symptom states for different physical states and different diseases was performed. The first three most severe symptoms of gastric, colorectal, liver, and pancreatic cancers were

found to be different, which would provide guidance for individualized interventions in these patients in the future. Several studies also showed that multiple intervention modes could be used to determine the patients' quality of life and functional status, such as cognitive behavioral interventions, decompression therapy, psychological education therapy, and acupuncture therapy. They could change the patient's symptom group, especially for gastrointestinal symptoms, fatigue, sleep, and anxiety, among others.³⁹⁻⁴¹ Among the patients participating in the study, the highest concentration of symptoms was psychological. This indicates that clinicians should pay more attention on the mental health of patients with digestive tract cancer.

The validation of this instrument has several clinical and research uses. First, it offers an objective method to evaluate symptoms in Chinese-speaking patients with digestive tract cancer. Nearly 1.4 billion people who speak Chinese live in China, but their knowledge on symptom burden is unknown. Second, it provides a more reliable tool to evaluate symptoms when therapeutic or palliative treatments are evaluated in clinical trials. Third, it can be used to monitor the deterioration of patients' status during treatment to design therapeutic strategies to mitigate them. Finally, it

provides a standardized form to measure symptoms in clinical settings to avoid subjective assessments between physicians.

This study has some limitations. First, our patients were from one cancer center only. Second, the results only revealed the symptoms at a single point in the patients' lives because of the design. In the future, we will expand the sample and conduct multicenter research to validate our data and provide more clinically meaningful and valuable results.

In conclusion, cognitive debriefing demonstrated that the patients found MDASI-GI-C to be an easy-to-use and understandable instrument. Our study demonstrated the validity and reliability of MDASI-GI-C in assessing patients with digestive tract cancer in Chinese-speaking countries. The use of this instrument could objectively measure the symptoms to adjust the treatment and management of sequelae during follow-up.

Disclosures and Acknowledgments

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Ethical approval: This study was approved by the Ethics in Research Committee of Tongji Medical College, Huazhong University of Science and Technology, P.R. China. Informed consent was obtained for the inclusion of patients in the study.

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