Brief Methodological Report

Psychometric Validation of the M. D. Anderson Symptom Inventory—Head and Neck Module in the Spanish Language

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Abstract

Context. The assessment of cancer-related symptoms requires culturally adapted and psychometrically validated symptom assessment tools. The M. D. Anderson Symptom Inventory—Head and Neck Module (MDASI-HN) is a useful instrument for measuring symptom burden that was specifically developed for head and neck cancer patients.

Objectives. To validate the Spanish version of the MDASI-HN.

Methods. We evaluated the psychometric features of the MDASI-HN in patients with head and neck cancer. We evaluated the item-scale correlations and the internal consistency. We conducted principal axis factoring to identify the underlying dimensions as a measure of construct validity. The convergence/concurrent validity was assessed with the University of Washington Quality of Life Questionnaire for Head and Neck Patients, and known-group validity and test-retest reliability also were assessed.

Results. One hundred thirty patients were included. The mean ± SD age was 60.5 ± 13.6 years; 68% of patients were male, 42% had laryngeal tumors, and 45.9% had Stage III tumors. Forty-seven percent of the patients underwent surgery, 55% underwent radiotherapy, and 36% underwent chemotherapy. The global Cronbach alpha for the HN module was 0.81. The factor analysis identified two factors (Factor 1: speech, mucus, coughing, and constipation; Factor 2: teeth, taste, sores, swallowing, and skin). The correlation with the global score of the University of Washington Quality of Life was −0.68. The difference in the MDASI-HN scores according to Eastern Cooperative Oncology Group performance status was statistically significant (2.72 vs. 4.01, $P = 0.006$). The intraclass test-retest correlation was 0.62.

Conclusion. The Spanish version of the MDASI-HN is reliable and valid for evaluating cancer-related symptoms in head and neck cancer patients. J Pain Symptom Manage 2016;51:1055−1061. © *2016 American Academy of Hospice and Palliative Medicine. Published by Elsevier Inc. All rights reserved.*

Key Words

Head and neck cancer, symptoms, inventory, M. D. Anderson, quality of life

Introduction

Head and neck tumors are located in a body part that is closely related with the exterior aspect and functions of the superior aerodigestive tract and sense organs. Additionally, surgical treatment and the sequelae of chemoradiotherapy can worsen these aspects and function. Commonly, head and neck tumors produce many symptoms and disturbances in patients. In a recent study with 748 head and neck cancer patients, Hanna et al.[1] demonstrated that more than 30% of treatment-naïve patients reported moderate to severe symptoms related to sleep disturbances, distress, and fatigue. Gunn et al.[2] also demonstrated that specific symptoms related to tasting, swallowing, speech, and mucus in the throat can increase in

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Accepted for publication: December 23, 2015.

0885-3924/$ - see front matter
http://dx.doi.org/10.1016/j.jpainsymman.2015.12.320

frequency by three- to seven-fold after treatment. It is known that there is a high frequency of psychiatric disorders in head and neck cancer patients. The rate of anxiety and depression in patients with head and neck cancer is around 38% before treatment and increases to 44% after treatment.[3] Recently, Kam et al.[4] reported that the rate of suicide was three times higher in patients with head and neck tumors, with a statistically significant increase involving the larynx/hypopharynx location, exclusive treatment with radiotherapy, and advanced stage.

Unfortunately, Latin American studies of the symptom burden of head and neck cancer patients are scarce, and the majority of the available studies are related to palliative care.[5–7] Most studies only describe the symptoms in a generic manner and do not define the severity of each symptom, and such definitions are important tools for guiding the treatment and rehabilitation plan. Otherwise, many symptoms are included in quality of life (QOL) scales, but they only represent one domain in the entire instrument and do not allow for examination of the specific effects on daily life.

The recording of symptoms and their severities could help to modify the treatment plan; it also can help to introduce early measures to eliminate or decrease the burden of symptoms during chemoradiotherapy, which results in better adherence to treatment or in other cases, can serve to indicate any early recurrence after treatment.[8] However, to date, few instruments have approached the measurement of symptoms with a systematic methodology for assessing their intensity and effects on body function and community living,[9–12] and no instruments have been translated to and validated in the Spanish language.

The most recently developed instrument for assessing cancer patients' symptoms is the M. D. Anderson Symptom Inventory (MDASI). This scale was developed by Cleeland et al. who evaluated symptoms in more than 500 patients according to a validated methodology to obtain a list of 13 cardinal symptoms (pain, fatigue, nausea, disturbed sleep, distress, shortness of breath, remembering, lack of appetite, drowsiness, dry mouth, sadness, vomiting, and numbness) and six evaluations of the effects of symptoms on daily life (general activity, mood, work, relations with other people, walking, and enjoyment of life). Each symptom item is rated on a scale of 0 (not at all) to 10 (as bad as you can imagine), and each of the six interference items is rated on a scale of 0 (does not interfere) to 10 (completely interferes). A symptom composite score (average of the 13 symptoms) and an interference composite score (average of the six items) are calculated. The instrument measures two factors, one related to general symptoms and other to gastrointestinal symptoms. The authors demonstrated a high reliability (Cronbach $\alpha > 0.85$) and sensitivity,[13] and this instrument has been validated in many languages.[14–21] However, in the development of this instrument, the authors found that some groups of patients rated other types of specific symptoms that were related to the characteristics of the tumor and its treatment. This effect culminated in the development of specific modules that were added to the MDASI. In 2007, Rosenthal et al.[22] developed the Head and Neck module (MDASI-HN), which includes symptoms such as mucus in the mouth/throat, difficulty swallowing, choking or coughing, difficulty with speech, skin pain, constipation, problems with tasting, mouth/throat sores, and problems with teeth or gums. Testing with 205 patients revealed psychometric properties (two factors and high reliability [Cronbach $\alpha > 0.88$]) that were similar to those of the basic MDASI. The MDASI-HN has been validated in other languages[23] and offers advantages, such as the inclusion of interference items and being easy to complete. Currently, there is an official version of the MDASI-HN in the Spanish language, which implies a linguistic validation using a forward-backward translation process by independent native translators and an iterative process of translations until agreement was reached. However, we were unable to find a psychometric validation of the instrument, which has impeded its routine use in Latin America. The aim of this study was to make language adjustments and psychometrically validate the MDASI-HN in the Latin American Spanish language.

Methods

This study used a multicenter, cross-sectional design to validate the MDASI-HN instrument. This study was approved by the Ethics in Research Committee of the Hospital Pablo Tobon Uribe. Informed consent was obtained for the inclusion of patients in the study. The inclusion criteria were as follows: adult patients with histologically confirmed head and neck tumors who were seen in the head and neck units of the Hospital Pablo Tobon Uribe, Medellin, the Hospital Universitario de Caldas, Manizales, and the Hospital Mederi, Bogota at any clinical stage or treatment phase; tumor location in the larynx, oral cavity, paranasal sinus or salivary gland; and Spanish was the native language. Patients with physical impairments that prevented reading, hearing, or understanding the scale, those for whom the last treatment date was more than five years ago, and those who did not consent to participate were excluded.

The official Spanish version of the MDASI-HN was obtained from the M. D. Anderson Cancer Center with authorization. This instrument has 22 questions that assess symptom severity on a 0 (not at all) to 10 (as bad as you can imagine) scale, and six questions

that assess symptom interference with daily life within the last 24 hours using a numeric rating scale ranging from 0 to 10. The final score is calculated by summing the scores for each question.

First, we designed an assessment of the general language of the instrument including the ease of reading and understanding the questions. In a second phase, we asked candidates to complete the Spanish-validated versions of the University of Washington Quality of Life Questionnaire for Head and Neck Patients (UW-QOL)[24] and the MDASI-HN. The UW-QOL is a scale for which higher scores represent better QOL. We also obtained demographic, disease stage and Eastern Cooperative Oncology Group (ECOG) performance status information from the clinical charts. For the test-retest analysis, randomly selected patients completed the MDASI-HN instrument for a second time. We assisted the patients who could not read the instrument to obtain the information.

Statistical Analysis

For the psychometric validation, we used principal axis factor analysis with oblimin rotation to identify the underlying dimensions as measures of construct validity and to provide evidence as to whether the instrument reproduced the same factor-loading pattern observed for the original English MDASI-HN.[25] Bartlett's test of sphericity for intercorrelation and the Kaiser-Meyer-Olkin measure of sampling adequacy for factor analysis were used to test the assumptions of the determinant of the correlation matrix. A reliability test involving Cronbach alpha and the item-total correlation were performed. For convergent/concurrent validity, we selected the Spanish-validated version of the UW-QOL,[24] and for the known-group validity, we used the ECOG performance status and the Classification of Malignant Tumors by the Union for the International Cancer Control-American Joint Committee on Cancer (TNM) stage. Scores were compared using Spearman correlation coefficients. For test-retest reliability, we administered the instrument two weeks after the first completion and used the intraclass correlation coefficient.

A sample size of 110 patients was calculated using the Bonnet formula[26] with the following parameters: a Type I error of 0.05, power of 80%, a Cronbach α estimate of 0.8, and a scale of 28 items. A test-retest analysis was planned in a subsample of 18 patients. We used a consecutive nonrandom sampling method in each center.

The categorical variables are presented as percentages and ranges, and the continuous variables are shown as mean and SD. For the analysis, some continuous variables were categorized. For these analyses, we set the significance level to $P < 0.05$. We used Stata, version 9.1, statistical software (StataCorp, College Station, TX) for all analyses.

Table 1
Sample Characteristics

Characteristic	Number (%)
Male	88 (67.7)
Marital status	
Married	53 (40.8)
Single	27 (20.8)
Widowed	10 (7.7)
Divorced	10 (7.7)
Other	27 (20.8)
No data	3 (2.3)
Education level	
None	13 (10)
Elementary	54 (41.5)
Secondary	42 (32.3)
University	12 (9.2)
No data	9 (6.9)
Employment status	
Unemployed	52 (40)
Employed	16 (12.3)
Self-employment	25 (19.2)
Retired	27 (20.8)
No data	10 (7.7)

Results

Patient Characteristics

We interviewed 130 consecutive patients. The demographic data of the sample are summarized in Table 1, and the clinical and treatment characteristics are summarized in Table 2. The mean ± SD age was 60.5 ± 13.6 years (median 62, range 15–87). Most of the patients were men and were married. Seventy-nine percent had low or medium educational levels, and 40% were unemployed. The most common tumor location was the larynx, and 74% of the tumors were in TNM Stage III/IV. More than one-third of the sample had undergone tracheostomy or gastrostomy, and 43% had active disease at the time of the interview.

Description of Symptoms

The mean score for the basic and head and neck subscales were 2.51 ± 2.15 (median 2.15, range 0–9.53) and 3.04 ± 2.37 (2.55, 0–10), respectively. The symptom score and prevalence of moderate to severe intensity symptoms (score ≥5) are displayed in Table 3. Among the core items, the most prevalent moderate to severe items (frequencies greater than 40%) were dry mouth, sadness and distress, and among the head and neck items, the most prevalent moderate to severe items were difficulty with voice/speech, difficulty with swallowing/chewing and mucus in the mouth/throat. The less prevalent symptoms included vomiting and mouth and throat sores.

Internal Consistency Reliability

The global Cronbach alpha for the core items was 0.87, and for the HN module, this value was 0.81 (Table 4).

Table 2
Clinical and Treatment Characteristics

Characteristic	*n* (%)
Tumor location	
Oral cavity	25 (19.2)
Oropharynx	28 (21.5)
Larynx	54 (41.5)
Salivary gland	12 (9.2)
Other	11 (8.4)
T stage	
T1	8 (6.2)
T2	30 (23.1)
T3	39 (30)
T4	45 (34.6)
Unknown	8 (6.2)
N stage	
N0	45 (34.6)
N1	24 (18.5)
N2	42 (32.3)
N3	10 (7.7)
Unknown	9 (6.9)
M stage	
M0	118 (90.8)
M1	3 (2.3)
Unknown	9 (6.9)
Treatment	
Exclusive surgery	22 (16.9)
Exclusive radiotherapy	3 (2.3)
Exclusive chemoradiotherapy	30 (23.1)
Surgery + radiotherapy	23 (17.7)
Surgery + chemoradiotherapy	16 (12.3)
Palliative treatment	36 (27.7)
Tracheostomy at interview	49 (37.7)
Gastrostomy/nasogastric tube at interview	41 (31.5)
Laryngectomy	21 (16.2)
Vital stage at interview	
Alive without disease	73 (56.2)
Alive with disease	57 (43.8)
ECOG status	
0	59 (45.4)
1	34 (26.2)
2	26 (20)
≥3	11 (8.5)

ECOG = Eastern Cooperative Oncology Group.

Table 3
Symptom Severities and Prevalences

MDASI-HN Item	Mean ± SD	Median (Range)	% of score ≥5
Core items			
Pain	2.8 ± 3.48	1 (0–10)	28.5
Fatigue	2.62 ± 3.19	1 (0–10)	27.9
Nausea	1.1 ± 2.64	0 (0–10)	13.1
Disturbed sleep	2.73 ± 3.80	0 (0–10)	30.0
Distress	3.72 ± 3.97	2 (0–10)	44.2
Shortness of breath	2.16 ± 3.42	0 (0–10)	23.1
Difficulty remembering	1.73 ± 2.81	0 (0–10)	18.5
Lack of appetite	2.34 ± 3.22	0 (0–10)	29.3
Drowsiness	2.53 ± 3.36	0.5 (0–10)	26.9
Dry mouth	3.99 ± 3.99	3.5 (0–10)	47.7
Sadness	4.0 ± 4.1	3 (0–10)	45.4
Vomiting	0.5 ± 1.82	0 (0–10)	3.9
Numbness	2.32 ± 3.21	0 (0–10)	23.8
Head and neck items			
Mucus in mouth/throat	4.03 ± 3.90	3 (0–10)	43.8
Difficulty swallowing/ chewing	4.21 ± 4.17	3 (0–10)	45.7
Choking	2.71 ± 3.45	0 (0–10)	31.0
Difficulty with voice/ speech	4.53 ± 4.13	4 (0–10)	47.7
Skin pain/burning/ rash	2.12 ± 3.24	0 (0–10)	23.4
Constipation	2.6 ± 3.176	0 (0–10)	26.9
Problem tasting food	3.32 ± 4.0	0 (0–10)	38.5
Mouth/throat sores	1.13 ± 2.75	0 (0–10)	11.6
Problem with teeth/gums	2.84 ± 4.05	0 (0–10)	27.1

MDASI-HN = M. D. Anderson Symptom Inventory–Head and Neck Module.

Construct Validity

The factor analysis evaluated core symptoms and head and neck subscales independently, considering that they have been designed and validated in specific studies. Factor analysis of the core symptom subscale revealed a two-factor solution using a Kaiser criterion >1. The two factors explained 95% of the variability. However, this solution differed from those reported in previous MDASI module and language validations. The distributions of these two factors were as follows: Factor 1—fatigue, shortness of breath, remembering, emesis, nausea, lack of appetite, dry mouth, and drowsiness and Factor 2: distress, sadness, disturbed sleep, and pain (Table 5). The diagnostic tests were acceptable (the Kaiser-Meyer-Olkin value was 0.85, and the Bartlett sphericity test yielded a $P < 0.001$).

Factor analysis of the head and neck symptom subscale revealed a one-factor solution using a Kaiser criterion >1, which explained 94% of the variability. For comparison with the original matrix of the MDASI-HN study, we selected two factors. The distributions of these two factors were as follows: Factor 1—speech, mucus, coughing, constipation, swallowing, and skin; and Factor 2—teeth, taste, and sores (Table 5). The diagnostic tests were acceptable (the Kaiser-Meyer-Olkin value was 0.81, and a Bartlett sphericity test yielded a $P < 0.001$).

Concurrent Validity

The concurrent validity was assessed by comparing the correlations between the MDASI-HN scores and the global UW-QOL and between the physical and social subscale scores (rho = −0.68; −0.57; and −0.67, respectively). The symptom scales of the MDASI-HN exhibited good correlations with the UW-QOL global score and a better correlation with the physical subscore. For the known-group validity, the patients with poor ECOG scores (ECOG ≥2) exhibited significantly higher symptom scores than the patients with good ECOG scores (2.72 vs. 4.01, $P = 0.006$). The patients with T3–T4 stage (3.46 vs. 2.04, $P = 0.002$), N2–N3 (3.62 vs. 2.56, $P = 0.01$) stage, tracheostomy (3.97 vs. 2.55, $P < 0.001$), and gastrostomy (4.40 vs. 2.63, $P < 0.001$) also exhibited higher symptoms scores.

Table 4
Reliability of the Spanish MDASI-HN

MDASI-HN	Specific Item	α
All core symptoms α = 0.87	Pain	0.867
	Fatigue	0.862
	Nausea	0.869
	Disturbed sleep	0.864
	Distress	0.869
	Shortness of breath	0.860
	Difficulty remembering	0.868
	Lack of appetite	0.867
	Drowsiness	0.865
	Dry mouth	0.868
	Sadness	0.865
	Vomiting	0.871
	Numbness	0.877
All head and neck symptoms α = 0.81	Mucus in mouth/throat	0.775
	Difficulty swallowing/chewing	0.760
	Choking	0.774
	Difficulty with voice/speech	0.778
	Skin pain/burning/rash	0.778
	Constipation	0.787
	Problem tasting food	0.777
	Mouth/throat sores	0.790
	Problems with teeth/gums	0.802
All interference items α = 0.91	Activity	0.881
	Mood	0.881
	Work	0.882
	Relations with others	0.893
	Walking	0.915
	Enjoyment of life	0.894

MDASI-HN = M. D. Anderson Symptom Inventory–Head and Neck Module.

Test–Retest Reliability

The test-retest reliability between the pretest and the posttest HN subscale ratings in a sample of 18 patients was 0.62.

Table 5
Factor Analysis of the Head and Neck Cancer–Specific Items Included in the Spanish MDASI-HN

Scale Items	Factor 1	Factor 2
Core item		
Difficulty remembering	0.673	−0.0503
Vomiting	0.6517	−0.0048
Nausea	0.6581	0.0175
Lack of appetite	0.6332	0.0582
Fatigue	0.7222	0.0833
Dry mouth	0.6143	0.0901
Shortness of breath	0.7155	0.1867
Drowsiness	0.6002	0.1876
Numbness	0.3132	0.2211
Pain	0.5038	0.3234
Disturbed sleep	0.5232	0.405
Sadness	0.3998	0.7221
Distress	0.3504	0.723
Head and neck item		
Difficulty with voice/speech	0.6335	−0.2391
Mucus in mouth/throat	0.6354	−0.1954
Choking	0.6313	−0.0282
Constipation	0.5105	−0.0233
Difficulty swallowing/chewing	0.6807	0.1494
Skin pain/burning/rash	0.5566	0.1634
Mouth/throat sores	0.4483	0.2632
Problem tasting food	0.5377	0.2878
Problem with teeth/gums	0.3416	0.4321

MDASI-HN = M. D. Anderson Symptom Inventory–Head and Neck Module.

Discussion

The evaluation of the presence of symptoms, their severity, and their effects on daily life is an important factor during the treatment and follow-up of patients with head and neck tumors. In this study, we assessed the psychometric validity of the Spanish version of the MDASI-HN module and found that this instrument can evaluate symptom burden with good reliability and validity. Validations of this instrument in other languages have previously been performed.[23]

We recruited 130 patients with head and neck tumors from several centers, with wide distributions of location, stage, and age, who were representative of the socioeconomic conditions of Latin American countries; this makes the results easy to extrapolate to other countries that speak the Spanish language.

The mean scores obtained for the core symptoms exhibited distributions that differed from those reported by Rosenthal et al.[22] In their original study, these authors described dry mouth, fatigue, pain, and disturbed sleep as the symptoms with the highest ratings. However, in our group, sadness, dry mouth, distress, and pain were the most important symptoms, which suggests that the effects of the psychological symptoms were greater burdens in our population. However, regarding the head and neck symptoms, the ratings of the symptoms were similar to those reported by Rosenthal et al.[22] Our reliability scores were very similar to those that have been reported previously; all of the scores were above 0.7 and were thus good scores according to the recommendations of Nunnaly and Bernstein.[27]

Regarding the factor analysis, the core symptom structure resembles that reported by Cleeland et al.[13] but with a different distribution of items, which is indicative of the different populations and weights given to symptoms by those populations. In the original study, Cleeland et al.[13] found two factors (general symptoms factor with pain, fatigue, disturbed sleep, emotional distress, shortness of breath, drowsiness, dry mouth, sadness, remembering, and numbness and a gastrointestinal factor with nausea and emesis), whereas we found two factors, but one of them included items originally included in the gastrointestinal factor (nausea and emesis) while the other included factors originally grouped in the general symptom factor (distress, sadness, disturbed sleep, and pain). In the present study, only head and neck cancer patients were included. Similar validation results have been published in other countries.[16,18,28] However, for the head and neck symptoms, we obtained a one-factor solution, which differed from the solution reported by Rosenthal et al.[22] Nonetheless, both models explained more than 94% of the variability, which supports the confidence in the ability of the instrument to measure specific symptoms.

When compared with the UW-QOL, we observed good correlations, particularly with the physical subscore, which supports the utility of this instrument for measuring specific domains related to symptoms. Previous studies have suggested that measurements of symptoms are more informative than measurements of QOL because specific instruments are more sensitive to change.[29] Additionally, comparisons between the higher and lower ECOG scores, tumor stages, nodal stages, and presence of tracheostomies and gastrostomies revealed significantly different values, which demonstrates the good discrimination ability of the instrument. The test-retest evaluation also revealed stable results and the potential of the use of this instrument to assess sensitivity to change.

Gunn et al.[2] collected the symptoms of patients before radiotherapy using the MDASI-HN in a prospective study and found that 32% of the patients experienced severe symptoms and that the symptom burdens were different for the different tumor stages and functional statuses. Rosenthal et al.[30] followed head and neck cancer patients during treatment with radiotherapy and chemotherapy and observed differential patterns of symptom behavior. Pain, fatigue, loss of appetite, dry mouth, mucus, chewing, tasting, and mouth sores were the symptoms that exhibited the higher burdens, whereas others such as shortness of breath, remembering, sadness, and teeth and gum problems only exhibited mild increases. Symptom severity changed in relation to the type of treatment received and the time of measurement. Hanna et al.[1] confirmed those findings in a cohort of naïve head and neck cancer patients.

The Spanish language validation of the MDASI-HN instrument provides a tool that ameliorates some difficulties for patients during the treatment phase. Although other instruments are too long, the MDASI-HN is short and easy to answer because of the numeric rating scale that is used to rate the symptoms; this scale is a familiar method for patients.

This study has some limitations. Because of the design, these results only revealed the symptoms at a single point in the lives of the patients. Longitudinal studies are necessary to assess the ability of the instrument to respond to the changes related to each tumor, different treatments, and different times in the evolution of the disease.

The validation of this instrument has several clinical and research uses. First, it offers an objective method to evaluate symptoms in Spanish-speaking patients. Almost 400 million people who speak Spanish live in Latin America and another 40 million live in the U.S., but the knowledge of symptom burden in this population 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 as a monitor of deterioration 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.

In conclusion, our study demonstrated that the Spanish version of the MDASI-HN is valid, reliable, and cross-culturally sensitive for use with head and neck cancer patients in countries that speak Spanish. The use of this instrument could contribute to the measurement of symptoms in a more objective manner and the use of those measurements to adjust the treatment and management of sequelae during follow-up.

Disclosures and Acknowledgments

This research received no specific funding/grant from any funding agency in the public, commercial, or not-for-profit sectors. The authors declare no conflicts of interest.

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