ORIGINAL ARTICLE

MEASURING HEAD AND NECK CANCER SYMPTOM BURDEN: THE DEVELOPMENT AND VALIDATION OF THE M. D. ANDERSON SYMPTOM INVENTORY, HEAD AND NECK MODULE

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Abstract: *Background.* The aim of this study was to develop and validate a symptom inventory for patients with head and neck cancer and to assess the occurrence and severity of symptoms, the overall symptom burden, and the interference the symptoms cause in daily life.

Methods. Items were generated from a comprehensive literature review, our prior work, and focus groups with head and neck cancer patients, symptom researchers, and a multidisciplinary group of head and neck cancer health care workers. We selected 11 provisional head and neck cancer-specific items for addition to the core M. D. Anderson Symptom Inventory (MDASI), and conducted a cross-sectional validation study among patients with head and neck cancer.

Results. Construct validity was established using principal axis factoring with direct oblimin rotation, and tests of concurrent and known-groups validity were conducted. Two items were dropped because of low severity scores and low frequency of complaint, leaving 9 final head and neck cancer-specific items. The coefficient α reliabilities were 0.88, 0.83, and 0.92 for the 13 core MDASI items, the 9 head and neck cancer-specific items, and the 6 interference items, respectively. The most prevalent severe symptoms were problems with mucus, mouth/throat sores, tasting food, difficulty with chewing or swallowing, dry mouth, pain, and fatigue.

Conclusions. The M. D. Anderson Symptom Inventory-Head and Neck (MDASI-HN) is a reliable and valid instrument to measure head and neck cancer symptom burden, and the interference symptoms cause in the major aspects of a patient's daily life. A subset of specifically distressing symptoms was identified, many of which are not included in commonly used head and neck cancer quality of life instruments. *Head Neck* **29:** 923–931, 2007

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Head and neck cancer often arises in cosmetically or functionally important areas. Thus, these cancers frequently affect a patient's appearance, as well as the hitherto taken-for-granted ability to eat, speak, and breathe easily, as well as the patient's overall sense of comfort. In addition to these disease-specific symptoms, patients with head and neck cancer may also experience symptoms related to surgery (eg, disfigurement) or to radiation therapy (eg, dysphagia, xerostomia, and mucositis). These may lead to a feeling of general overall sickness and can potentially result in social isolation.

An instrument sensitive to short-term head and neck cancer symptoms could lead to their accurate identification and quantification, allow earlier interventions for individual patients, and serve as a research tool to compare the symptom burdens associated with various treatment options. The detection and treatment of cancer and cancer treatment–related symptoms may make it more likely that patients will continue treatment without unplanned interruptions, thereby improving long-term outcomes.

Symptoms in patients with head and neck cancer have been assessed using a variety of instruments designed to measure functionality, health-related quality of life (HRQOL), or both.[1,2] However, these instruments are often lacking in important symptoms and features. For example, instruments that measure changes in functionality do not necessarily address the patients' perceptions of, or feelings about, these outcomes or the symptom distress that patients suffer.[1] In addition, although it is frequently assumed that reduced functionality leads to reduced HRQOL, this relationship has not been consistent in past studies, either because the relationship does not always exist or because the instruments used for assessment are not sensitive to the endpoint being evaluated. HRQOL measures are limited too, because they frequently overlook specific symptoms and the distress they cause. These shortcomings have prompted the recent development of instruments specifically designed to measure symptom distress (that is, the severity of symptoms and the extent to which they interfere with aspects of daily functioning) and thereby permit appropriate interventions.

Jones et al[3] recently published a preliminary study validating the Head and Neck Distress Scale (HNDS), a modification of the Cancer Disease and Treatment Concern Scale (CDTCS) that included 15 additional items specific to head and neck cancer. Although the HNDS was shown to be a valid measure of acute symptom distress, it did not contain items designed to measure how symptoms might interfere with activities of daily life. In addition, in keeping with the original CDTCS, the HNDS asked for patient recall of symptom severity over the previous month, and used a 0 to 6 response scale, rather than the 0 to 10 response scale currently recommended by the FDA and by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT).[4,5]

The M. D. Anderson Symptom Index (MDASI) is a symptom distress instrument designed to measure general cancer symptom burden. In addition, the MDASI measures "symptom interference," the degree to which symptoms interfere with the major aspects of a patient's daily life: general activity, mood, work, relations with other people, walking, and enjoyment of life. In the MDASI, the combined effects of all symptoms related to the disease or therapy are assessed relative to a patient's ability to function as he or she did before the onset of the disease or therapy. The instrument thus reflects the magnitude of distress that patients suffer because of their individual or combined symptoms. The core MDASI was validated for use in all cancer populations, regardless of the specific diagnosis or type of therapy.[6] It asks patients to rate the severity of 13 general symptoms and 6 symptom interference items. All items are scored on the recommended 0 to 10 scale, and patients are asked to rate each symptom at its best or worst over the previous 24 hours. Because of the 0 to 10 scale, the MDASI is readily adapted to an interactive voice response (IVR) system. The MDASI-HN is currently being used in several clinical trials at the University of Texas M. D. Anderson Cancer Center to assess the symptoms of outpatients via the IVR system.

The MDASI was designed to be supplemented with questions related to specific disease diagnoses. Disease-specific modules have already been developed and validated for heart failure[7] and brain tumors.[8,9] The present study reports the development and validation of head and neck cancer-specific module (MDASI-HN) to complement the core symptoms assessed in the MDASI.

MATERIALS AND METHODS

Patient Recruitment. Consecutive patients were recruited during the study interval from the various head and neck cancer treatment clinics at The University of Texas M. D. Anderson Cancer Center. Eligible patients for this cross-sectional study had biopsy-proven head and neck cancer, tumor- and/or treatment-related symptoms. They may have been recruited before, during, or after surgery, chemotherapy, or radiation therapy. This study was reviewed and approved by the institutional review board. We abided by its rules and regulations in conducting this study, specifically including, but not limited to, maintaining patient confidentiality. All patients signed informed consent documents.

Multisymptom Assessment Tool—MDASI. The MDASI and its supplementary modules rank symptoms on a 0 to 10 scale to indicate the presence and severity of the symptom, with 0 being "not present" and 10 being "as bad as you can imagine." Patients are asked to rate each according to its worst severity during the previous 24 hours. The interference items are also measured on a 0 to 10 scale, with 0 being "did not interfere" and 10 being "interfered completely." The mean of all 6 symptom interference item scores is used to represent the degree of symptom interference.

Other Data Collection Instruments. Other data collection tools used in this study were a patient-completed demographic data sheet (including age, sex, ethnicity, education level, and employment status) and an investigator-completed clinical checklist (including diagnosis, treatment history, performance status, and presence/absence of a laryngectomy, tracheotomy, feeding tube, and common National Cancer Institute Common Terminology Criteria for Adverse Events [CTCAE] version 3.0[10] toxicities: mucositis, dysphagia, dermatitis, and xerostomia).

Development of the Head and Neck Module of MDASI. The first step in the development of the MDASI-Head and Neck (HN) module was to identify items to include and to establish the content validity of the items. Content validity measures how well each item in a newly developed tool measures its respective objective or content domain. The stages in addressing content validity include a developmental stage (including domain identification, item generation, and instrument formation) and a judgment-quantification stage.[11]

Domain Identification and Item Generation. Domain identification and item generation were completed using our previous work[3] and a comprehensive review of the literature. In addition, surveys were completed by patients with head and neck cancer and by focus groups, and interviews were conducted with health care professionals working with this patient population, including surgeons; radiation, medical, and dental oncologists; speech-language pathologists; and symptom researchers.

Eleven potential symptoms specific to the head and neck cancer population were identified and provisionally added to the core MDASI. This composite instrument—with the 13 core symptom items, 11 provisional head and neck cancer-specific symptom items, and 6 interference items—was referred to as the provisional MDASI-HN.

Judgment–Quantification of Provisional Module Components. The judgment-quantification stage involved administration of the provisional MDASI-HN to patients with head and neck cancer. In accordance with institutional guidelines and international conventions, the present study was approved by the Institutional Review Board of M. D. Anderson Cancer Center where patients were recruited. Patients were required to be at least 18 years of age, be able to read and understand English, have a histopathologic diagnosis of head and neck cancer, be able to understand the informed consent process, and be able to complete the questionnaire forms. A total of 205 patients with head and neck cancer who met these criteria were enrolled in the study.

Statistical Analyses of the MDASI-HN. Statistical methods and clinical judgment were used to reduce instrument length. Several tests of validity, including known-groups validity and concurrent validity, were conducted. Statistical analyses were carried out using SPSS 12.0.

Reducing the Length of the MDASI-HN. The mean severity of individual head and neck cancer-specific symptoms was evaluated and used to determine item inclusion in the final instrument. Based on our previous work in developing instruments for the assessment of pain and fatigue,[12,13] we provisionally categorized symptoms on the MDASI-HN that had ratings of 5 or 6 as "moderate" and symptoms with ratings of 7 or greater as "severe." We used several methods to reduce the number of symptoms in the MDASI-HN module, including (1) examination of descriptive statistics for the

severity and prevalence of symptoms, (2) use of regression models to determine the greatest source of variability in predicting symptom interference, and (3) review by clinicians.

Validation of the MDASI-HN. We validated the revised HN module using principal axis factoring with direct oblimin rotation to determine the constructs being represented by the additional items in the MDASI-HN module.

Reliability of the MDASI-HN. Reliability tests were done to determine the proportion of the observed variance in the measurements that could be attributed to real score differences among subjects and the proportion attributable to internal variability in the instrument itself. In this analysis, we calculated coefficient αs (using the Kronbach α reliability estimate) to determine the reliability of the sets of items comprising the core MDASI, the 2 factors in the HN module defined by principal axis factoring, and the mean interference score.

Known Groups Validity of the MDASI-HN. Scores on the MDASI-HN should be highly correlated with independent measures of disease severity for it to be a clinically useful instrument. To examine the sensitivity of the MDASI-HN to disease severity, patients were divided into 2 groups based on their Eastern Cooperative Oncology Group (ECOG) performance status.[14] ECOG status grade is assigned on a 0 to 5 scale: 0 = fully active; 1 = restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature; 2 = ambulatory and capable of all self-care but unable to carry out any work activities; up and about >50% of waking hours; 3 = capable of only limited self-care; confined to bed or chair >50% of waking hours; 4 = completely disabled; and 5 = dead. Those patients with an ECOG grade of 0 or 1 were categorized as having a "good" performance status, and those patients with an ECOG grade of 2 or higher were categorized as having a "poor" performance status. These groups were then compared to groups defined by the mean symptom severity reported in the HN module.

Concurrent Validity of the MDASI-HN. The 12-item Short Form Health Survey (SF12v2) is a widely used generic survey of health-related QOL.[15] It consists of 7 items assessing functional status, 4 items assessing well-being, and 1 item assessing overall health. In addition to responding to the MDASI-HN, patients were also asked to complete the SF12v2. Mental and physical component scores were calculated from the SF12. We calculated 3 subscale scores from the MDASI-HN. These were the 13-item core MDASI, the 9-item HN, and the 6-item interference. Correlations were then computed between the 2 scores from the SF12 and the 3 scores from the MDASI-HN.

Cluster Analysis. We used hierarchical cluster analysis to examine the tendency for symptoms to occur either together or independently. Unlike factor analysis, which only shows which items belong to which factor, cluster analysis gives an overall view of the branched structure (called a dendrogram) of patient responses to the total set of items.[16] Distances between symptoms were calculated using squared Euclidian distances, and clusters were formed using Ward's method.[17] Symptoms are separate items on the left of the dendrogram, but moving from left to right in the figure, items join together according to the similarity in their patient-assigned ratings. The items that join with others earlier (further to the left side of the dendrogram) are rated more similarly by patients than items that join together later. Items in the questionnaire that joined together quickly give very similar information and may be redundant.

RESULTS

Patients. Table 1 presents demographic and disease-related characteristics of the 205 patients in the study population. The mean patient age was 56.9 years, two thirds of patients were men, and almost two thirds were educated beyond the 12th grade level. The overwhelming majority of patients (80%) were white non-Hispanic. Less than half were currently employed outside the home. The most common disease sites were pharynx, oral tongue, larynx, and other oral cavity sites. The most common severe toxicity was dysphagia, with a CTCAEv3 grade of 2 or 3 occurring in 41% of patients.

Severity and Prevalence of the 24 Symptom Items. Table 2 shows the 13 core and 11 proposed HN symptom items rank-ordered from highest to lowest in terms of mean severity for the sample, and also indicates the percentages of patients reporting each symptom as moderate or severe, based on the provisional classification. Several of the head and neck cancer-specific symptoms were reported as moderate or severe by at least one third of the patients, including difficulty

Table 1. Patient characteristics.

Characteristic	Patients ($n = 205$) Number	%	Characteristic	Patients ($n = 205$) Number	%
Age			Skin	8	4
<60 years	118	58	Not reported	14	7
≥60 years	87	42	CTCAE grade		
Sex			Dermatitis		
Female	63	31	Grade 0	115	56
Male	142	69	Grade 1	49	24
Educational level			Grade 2	34	17
12th grade and below	81	40	Grade 3	5	2
Beyond 12th grade	121	59	Not reported	2	1
Not reported	3	1	Mucositis		
Ethnicity			Grade 0	117	57
White non-Hispanic	164	80	Grade 1	29	14
Black non-Hispanic	20	10	Grade 2	43	21
Hispanic	12	6	Grade 3	15	7
Other	9	4	Not reported	1	1
Employment status			Xerostomia		
Employed	85	41	Grade 0	53	26
Homemaker	17	8	Grade 1	90	44
Retired	57	28	Grade 2	48	23
Medical leave of absence	16	8	Grade 3	13	6
			Not reported	1	1
Disabled due to illness	22	11	Dysphagia		
Unemployed	6	3	Grade 0	54	26
Not reported	2	1	Grade 1	66	32
Disease site			Grade 2	51	25
Tongue (oral)	30	15	Grade 3	32	16
Oral cavity, excluding tongue	26	13	Not reported	2	1
			Patients with feeding tubes	37	18
Pharynx	54	26			
Larynx	30	15	Feeding tube used for >1.2 of intake	31	15
Thyroid	13	6			
Salivary	17	8	Tracheotomy/laryngectomy stoma	21	10
Paranasal sinus	13	6			

Abbreviations: CTCAE, Common Terminology Criteria for Adverse Events, v. 3.[10]

swallowing, problems with mucus, and problems tasting food. Hair loss and diarrhea were dropped from the list, because their mean severity was less than 1.5 and very few patients (13.3% and 4.4%, respectively) reported these symptoms as moderate to severe (ie, score ≥ 5). Although constipation and skin pain had reported severity and prevalence similar to those for hair loss and diarrhea, these items were retained in the list because treating clinicians consider them to be critical in assessing patients with head and neck cancer receiving treatment.

Final MDASI-HN Module Items. Because it was important to retain the symptom items associated with symptom interference, we used regression analysis to determine how much variability in symptom interference was explained by the retained HN module items. The results of this analysis indicated that the final 9-item HN module explained 60% of the variability in total symptom interference.

Validation of the MDASI-HN. Table 3 shows the pattern of factor loadings determined by principal axis factoring. The 9 retained items in the HN module measured 2 underlying constructs: (1) a factor comprising mouth sores, tasting food, constipation, teeth or gum problems, and skin pain, and (2) a factor comprising problems with the voice, choking/coughing, swallowing/chewing, and mucus. To demonstrate model fit, we examined the differences between the reproduced correlations based on the 2-factor solution and the observed correlations in the sample. According to Harman,[18] a solution is considered adequate if the SD of the residuals is less than or equal to the SE of a correlation coefficient. In this case, the 2-fac-

Table 2. Descriptive statistics for scores on 13 core and 11 proposed head and neck cancer-specific items on the MDASI-HN ($n = 205$).

Item	Mean score	SD	95% CI	Median score	Range	% ≥5*	% ≥7†
Core							
Having a dry mouth	4.11	3.35	3.65–4.57	4	0–10	45.1	27.5
Fatigue	3.52	2.76	3.14–3.91	4	0–10	40.2	15.2
Pain	2.91	2.98	2.50–3.32	2	0–10	30.9	17.6
Disturbed sleep	2.90	2.94	2.49–3.30	2	0–10	31.7	13.7
Feeling drowsy	2.65	2.75	2.26–3.03	2	0–9	25.4	13.9
Feelings of being distressed	2.38	2.75	2.00–2.76	1	0–10	23.2	11.3
Lack of appetite	2.25	2.95	1.85–2.66	1	0–10	22.9	14.1
Feeling sad	1.89	2.65	1.52–2.26	0	0–10	15.8	8.4
Numbness or tingling	1.53	2.44	1.19–1.87	0	0–10	12.3	6.9
Shortness of breath	1.35	2.27	1.04–1.67	0	0–10	11.3	5.4
Difficulty remembering	1.35	1.98	1.07–1.62	0	0–10	9.3	2.9
Nausea	1.24	2.29	0.92–1.56	0	0–10	11.0	5.5
Vomiting	0.53	1.57	0.32–0.75	0	0–10	5.0	1.5
Head and neck cancer							
Difficulty swallowing or chewing	4.16	3.62	3.66–4.66	3	0–10	43.9	31.7
Problem with mucus	3.41	3.28	2.96–3.87	3	0–10	32.7	22.0
Problem with tasting food	3.25	3.58	2.76–3.75	2	0–10	33.7	22.9
Difficulty with voice or speech	2.73	3.19	2.29–3.17	1	0–10	27.6	17.2
Mouth/throat sores	2.31	3.28	1.86–2.77	0	0–10	24.0	16.2
Problem with teeth or gum	1.98	2.95	1.57–2.39	0	0–10	18.6	12.3
Choking or coughing	1.91	2.83	1.52–2.30	0.5	0–10	17.2	10.8
Constipation	1.55	2.65	1.18–1.91	0	0–10	12.7	8.3
Hair loss	1.53	2.94	1.13–1.94	0	0–10	13.3	9.9
Skin pain, burning, or rash	1.47	2.25	1.15–1.78	0	0–10	10.4	5.0
Diarrhea	0.70	1.64	0.47–0.92	0	0–10	4.4	1.5

Abbreviations: SD, standard deviation; CI, confidence interval.
**≥5, moderate to severe.*
†≥7, severe.

tor solution was appropriate because the SD of the residual was 0.03, less than the SE of a correlation coefficient (0.07).

Reliability of the MDASI-HN. In reliability testing, α values for the core MDASI score, first and second factors of the HN symptom items, and the interference score were 0.88, 0.72, 0.83, and 0.92, respectively, indicating high levels of reliability for each set of items. Nunnaly and Berstein[19] have recommended a level of at least 0.7 as an acceptable reliability coefficient.

Table 3. Factor analysis of 9 head and neck cancer-specific items included in the final MDASI-HN.*†

Head and neck cancer-specific item	Underlying constructs of the MDASI-HN defined by principal axis factoring	
	Factor 1	Factor 2
Mouth sores	**0.899**	0.149
Tasting food	**0.647**	−0.034
Constipation	**0.485**	−0.042
Teeth-gum	**0.397**	−0.183
Skin pain	**0.338**	−0.099
Voice-speech	−0.088	**−0.916**
Choking-coughing	0.012	**−0.654**
Chewing-swallowing	0.258	**−0.600**
Mucus	0.281	**−0.499**

**Extraction method: principal axis factoring; rotation method: Oblimin with Kaiser normalization.*
†Numbers in boldface indicate the loadings for the indicated factor.

Known Groups Validity of the MDASI-HN. In known groups validity testing, 152 patients (74%) had an ECOG performance status of 0 or 1 (good),

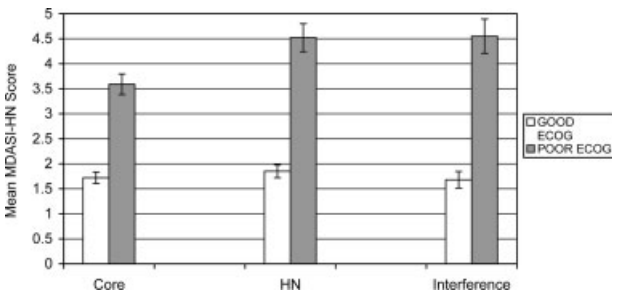

FIGURE 1. Mean MDASI-HN score as a function of ECOG performance status ($n = 205$). Patients with good (0,1) and poor (≥2) ECOG scores had highly significant differences in their MDASI-HN scores ($p < .001$).

Table 4. Correlations between the MDASI-HN and the 12-item Short Form Health Survey (SF12v2).

	Correlation coefficients*	
Subscales	SF12v2 physical component score	SF12v2 mental component score
MDASI core items	−0.526	−0.573
MDASI head and neck cancer-specific items	−0.504	−0.386
MDASI interference items	−0.567	−0.549

**All correlations are significant at the $\alpha = 0.01$ level (in 2-tailed analysis).*

and 53 (26%) had an ECOG performance status of 2 or higher (poor). As predicted, patients with good performance status and those with poor performance status differed significantly in terms of mean core symptom severity (1.72 vs 3.59, respectively; $p < .001$), mean HN symptom severity (1.85 vs 4.52, respectively; $p < .001$), and mean symptom interference (1.68 and 4.55, respectively; $p < .001$) (Figure 1).

Concurrent Validity of the MDASI-HN. There was a significant correlation between the subscales of the MDASI-HN and the 2 component scores of the SF12v2 (Table 4). These correlations indicate overlap between the 2 measures, suggesting concurrent validity of the MDASI-HN with another measure that is widely used for assessing cancer symptoms.

Identifying Symptom Clusters. The results of symptom cluster analysis are presented in Figure 2. The dendrogram shows, as an example, that the items "choking" and "voice" join together very quickly, indicating similar ratings from patients, in which "mouth sores" and "mucus" join together very late, indicating dissimilar ratings.

DISCUSSION

This article describes the development and validation of a new tool specifically designed to assess the burden of symptoms in patients with head and neck cancer. The MDASI-HN measures multiple symptom distress. We believe that the introduction and use of the MDASI-HN is an improvement over previous, especially HRQOL, assessment tools for several reasons. QOL measures frequently do not relate to symptom severity in a straightforward way, and may not include or be sensitive to the detection of a relatively comprehensive set of the relevant symptoms that patients with head and neck cancer experience. For example, in a study of survivors of head and neck cancer, Vokes et al[20] demonstrated that one of the most common residual side effect of concurrent chemoradiotherapy, the inability to eat solid food, was not related to measures of HRQOL. Other studies in patients with laryngectomy have shown that HRQOL is not associated with loss of the larynx, presence of a stoma, or use of alaryngeal speech.[21,22] Measuring treatment-related increases in symptom burden are, therefore, more informative to patients and their physicians than measuring HRQOL, as those instruments would not be expected to detect changes in symptoms not included, and would not be expected to be as sensi-

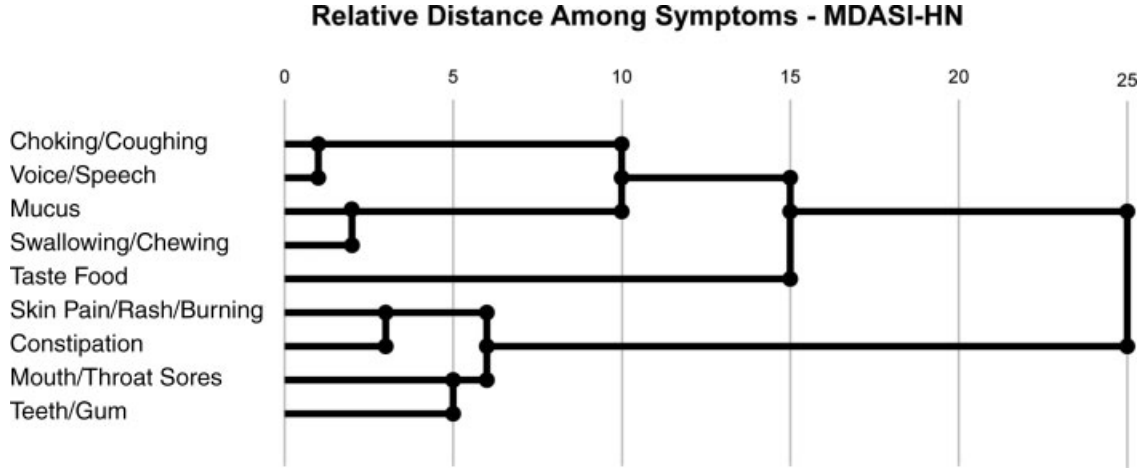

FIGURE 2. Relative distance among symptoms associated with head and neck (HN) cancer and HN cancer treatment. The dendrogram was created by hierarchical cluster analysis, using the Ward method,[17] from items in the HN subscale of the MDASI-HN ($n = 205$). Symptoms that cluster earlier in the analysis (toward the left side) are identified by patients as occurring together; items that do not cluster until late in the analysis (toward the right side) are identified by patients as being independent of each other.

tive to change. While QOL and symptom distress instruments have some questions that overlap, symptom distress instruments are more straightforward, focusing on symptoms related to the disease and treatment, and are more sensitive to short-term changes during these various treatments.[23]

The Functional Assessment of Cancer Therapy-Head and Neck (FACT-H&N) is a frequently used instrument that includes both functionality and HRQOL items, but similar to other head and neck cancer HRQOL instruments, it does not cover all relevant head and neck cancer-specific symptoms related to problems with, for example, mucus/secretions, aspiration, taste, skin rash and burning, and teeth and gums.[24] It was our clinical experience that many patients with head and neck cancer suffered these symptoms, however, and often with the highest relative intensity. We felt it imperative, therefore, to develop and validate the MDASI-HN. We are currently performing a prospective study in more homogenous, primarily oropharyngeal cancer, treatment populations in which both the MDASI-HN and the FACT-HN are given to patients before and during treatment with radiation therapy or chemoradiation, with the goal of evaluating the comparative sensitivity of the instruments to detecting changes in acute, treatment-related symptoms. This study will also include patients with primary tumors arising in a variety of head and neck sites, in order to determine differences in symptom burden according to primary site. Similar studies are planned for patients treated with chemotherapy or surgery alone.

A key concern in developing the head and neck cancer-specific module for the MDASI was ensuring that the overall instrument remained easy to understand and complete. To achieve this goal, the symptom list was kept as short as possible while still containing all the items needed to fully assess symptom distress. The MDASI-HN is intended to be a brief screen of the most relevant symptoms applicable to all patients with head and neck cancer, independent of disease subsite, histology, stage, and type of treatment. It is not intended to be an exhaustive list of symptoms, as specific scales exist for other problems, such as xerostomia,[25] dysphagia,[26] and postoperative neck–shoulder dysfunction.[27] It is estimated that the core MDASI takes less than 5 minutes to complete,[6] and the MDASI-HN, with 9 site-specific questions, requires at most about 2 additional minutes. The instrument's brevity and ease of use are important because many symptoms specific to head and neck cancer persist or change over time, even after the end of active treatment, and so repeated administration of the instrument may be useful. For example, Abendstein and colleagues[28] administered European Organization for Research and Treatment of Cancer QOL instruments 6 times to patients with head and neck cancer during the first year after diagnosis and then again 5 years later. That study showed that problems with teeth, opening of the mouth, and dryness in the mouth with sticky saliva persisted or worsened over the 5-year period. Longitudinal assessment of patients with head and neck cancer for extended periods after treatment can help to identify those in need of continuing support and symptom relief and can facilitate the early identification of recurrent or new second cancers, which may manifest by the development of symptoms.

The clustering of symptoms showed in Figure 2 means that the HN module could potentially be shortened further. For example, problems with choking/coughing or voice/speech could potentially be eliminated. It should be noted, however, that the health care workers involved in our study indicated that the 9 symptoms retained in the module are important clinically. Furthermore, the elimination of 2 or 3 questions would not significantly shorten the time required to administer the instrument. Perhaps, more importantly, the clustering might indicate a common etiologic factor for the symptoms involved, and thus help guide caregivers to interventions that address the root cause of a host of problems; this possibility could be examined by studies looking at longitudinal patterns of change among symptoms and symptom interferences.

The long-term assessment of symptom burden in patients with head and neck cancer could be facilitated by administration of the MDASI-HN through an IVR system, and we are currently using this in another longitudinal, long-term follow-up study. The MDASI and MDASI-HN subscales have been adapted for use in an IVR system, because the questions are unambiguous and easy to understand and the answers (scaled from 0 to 10) can be readily entered using a standard touch-tone telephone keypad. IVR systems can be programmed to call patients at predetermined times and to report directly back to the physician/health care professional via email, voice mail, or pager. The use of IVR systems to collect longitudinal data will contribute to continuity of care for individual patients, as well as being an important component of clinical symptom research. Even patients who are not familiar with computers should have little problem in

understanding and using the IVR system. For example, in a bone marrow transplantation symptom study, only 2 of 110 patients had difficulty understanding the use of the MDASI-IVR system.[29] Further, patients reported satisfaction with the IVR symptom assessment system; they were willing to use the system regularly and believed the symptom ratings were important information for their health care providers.

In summary, this report reviews the development and validation of the MDASI-HN. Although several screening instruments are available for use in patients with head and neck cancer, we believe this is the most comprehensive, covering both the relevant head and neck cancer symptoms and the interference they cause in activities of daily life. The MDASI-HN is easily understood, brief, and is readily used with an IVR system. Research comparing the MDASI-HN symptom burden instrument to head and neck cancer QOL instrument is ongoing, and the MDASI-HN is also being used longitudinally—throughout the course of diagnosis, treatment, and follow-up—in a group of patients with head and neck cancer being treated at our institution. Additionally, the MDASI-HN has been selected to compare the symptom burden suffered by patients in a phase III clinical trial evaluating an antimucositis drug, Radiation Therapy Oncology Group (RTOG) 0435,[30] which may yield additional insights into this module's power to discriminate differences in symptom burden between treatment arms of a prospective phase III symptom-control trial.

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