ORIGINAL ARTICLE

The Development and Validation of a Dysphagia-Specific Quality-of-Life Questionnaire for Patients With Head and Neck Cancer

The M. D. Anderson Dysphagia Inventory

Amy Y. Chen, MD, MPH; Ralph Frankowski, PhD; Julie Bishop-Leone, MA, CCC-SLP; Tiffany Hebert, MCD, CCC-SLP; Stacy Leyk, MA, CCC-SLP; Jan Lewin, PhD; Helmuth Goepfert, MD

Objective: To design a reliable and validated self-administered questionnaire whose purpose is to assess dysphagia's effects on the quality of life (QOL) of patients with head and neck cancer.

Design: Cross-sectional survey study.

Methods: Focus groups were convened for questionnaire development and design. The M. D. Anderson Dysphagia Inventory (MDADI) included global, emotional, functional, and physical subscales. One hundred consecutive adult patients with a neoplasm of the upper aerodigestive tract who underwent evaluation by our Speech Pathology team completed the MDADI and the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36). Speech pathologists completed the Performance Status Scale for each patient. Validity and reliability properties were calculated. Analysis of variance was used to assess how well the MDADI discriminated between groups of patients.

Results: The internal consistency reliability of the MDADI was calculated using the Cronbach α coefficient. The Cronbach α coefficients of the MDADI subscales ranged from 0.85 to 0.93. Test-retest reliability coefficients of the subscales ranged from 0.69 to 0.88. Spearman correlation coefficients between the MDADI subscales and the SF-36 subscales demonstrated construct validity. Patients with primary tumors of the oral cavity and oropharynx had significantly greater swallowing disability with an adverse impact on their QOL compared with patients with primary tumors of the larynx and hypopharynx ($P<.001$). Patients with a malignant lesion also had significantly greater disability than patients with a benign lesion ($P<.001$).

Conclusions: The MDADI is the first validated and reliable self-administered questionnaire designed specifically for evaluating the impact of dysphagia on the QOL of patients with head and neck cancer. Standardized questionnaires that measure patients' QOL offer a means for demonstrating treatment impact and improving medical care. The development and validation of the MDADI and its use in prospective clinical trials allow for better understanding of the impact of treatment of head and neck cancer on swallowing and of swallowing difficulty on patients' QOL.

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From the Department of Head and Neck Surgery, University of Texas M. D. Anderson Cancer Center (Drs Chen, Lewin, and Goepfert and Mss Bishop-Leone, Hebert, and Leyk), and the Department of Biometry, University of Texas School of Public Health (Dr Frankowski), Houston.

OROPHARYNGEAL dysphagia is defined as difficulty in swallowing because of structural or movement abnormalities involving the oral cavity, oropharynx, velopharynx, hypopharynx, larynx, and upper esophageal sphincter. Patients with cancer of the head and neck have signs and symptoms of swallowing problems because the primary neoplasm affects the organ of swallowing and/or because the treatment itself affects swallowing. Assessment of dysphagia by means of modified barium swallows or cinefluoroscopy is valuable in determining the extent of mechanical disability, but there are no such tools to address the impact of dysphagia on quality of life (QOL). In addition, although treated patients may be cancer free, 5-year survival rates or disease-free intervals do not measure the toll of treatment on their ability to swallow. This patient-based outcome may be measured by a valid and reliable questionnaire, such as the M. D. Anderson Dysphagia Inventory (MDADI).

The MDADI can be used to assess how patients view the outcome of their swallowing ability as a result of treatment and how this swallowing dysfunction affects their QOL. For this assessment to be valid and reliable, the scale used to assess the patients' views and perceptions must be developed in a psychometrically rigorous fashion. The aim of this project is to design a reliable and validated self-administered questionnaire that can be used to determine the effects of dysphagia (swallowing

PATIENTS AND METHODS

The use of focus groups facilitated questionnaire development and design. The initial focus group consisted of faculty (H.G.), fellows (A.Y.C.), and speech pathologists (J.B.-L., T.H., S.L., and J.L.) from the University of Texas M. D. Anderson Cancer Center (UTMDACC), Houston. This initial group formulated the basic content of the questions to be included in the MDADI and was indispensable in the development of the MDADI and the establishment of content or face validity.

However, few, if any, of the individuals in this first focus group have experienced dysphagia themselves, except in short duration. The expected value (or utility) of a given health state may be considered quite differently by healthy subjects and subjects with disease, or by patients before and after a disease is diagnosed. Thus, additional focus groups consisting of head and neck cancer patients with dysphagia were formed. In these groups, patients with dysphagia were asked to complete the initial version of the MDADI and to share their life experiences regarding dysphagia. Aspects of their life that were particularly difficult or troublesome to them were discussed and elaborated. Four such focus groups of 4 to 8 patients each were convened. Specific comments regarding wording of the questionnaire items were considered and incorporated into the final version of the MDADI (**Figure**).

Patients eligible for the study were English-speaking adults with a neoplasm of the upper aerodigestive tract who were undergoing evaluation by UTMDACC Speech Pathology team. One hundred consecutive patients were included in this study. Each patient completed the MDADI and the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36), a generic health status measure.[1] Twenty-nine patients completed the MDADI 2 weeks after initial enrollment for test-retest reliability (reproducibility). Speech pathologists (J.B.-L., T.H., S.L., and J.L.) completed the Performance Status Scale (PSS) by List et al.[2]

Chart abstraction was performed to identify the age and sex of the patient, site and stage of the initial primary tumor of the head and neck, time elapsed since completion of the last treatment, type of treatment, and pathological findings.

The data were then entered into a worksheet (Excel 97; Microsoft Corp, Redmond, Wash). Analysis was performed using commercially available statistical software packages (SAS, Version 6.12; SAS Institute, Cary, NC; and Minitab, Version 12.2; Minitab Inc, State College, Pa).

RELIABILITY

Test-retest and internal consistency reliability were measured in this study. Test-retest reliability was evaluated by administering the questionnaire at the time of enrollment and 2 weeks thereafter. Aday[3] suggests a minimum acceptable test-retest correlation of 0.7 for group-level comparison and 0.9 for individual comparison. Internal consistency reliability is useful in the construction of new scales or questionnaires and measures the inconsistency or nonequivalence of different questions intended to measure the same concept. Three main procedures for assessing the intercorrelation among items are the corrected item-total, split-half, and α reliability coefficients. The internal consistency reliability measure calculated in this study was the Cronbach α coefficient. In most applied studies, the lowest acceptable level of internal consistency reliability is 0.7 for group level and 0.9 or higher for individual analysis.[4] Values lower than 0.7 suggest that some items in the scale do not capture the patient's attitude in the same manner as other items. Items contained within a scale that have high correlations with the total contribute to the scale's overall reliability and are more representative of scale content than items with low item-total correlations. Individual-level analysis is used for case-by-case assessment.

VALIDITY

The types of validity analyzed in this study were content, criterion, and construct. Content validity was ensured by using a focus group of experts and focus groups of patients and their family members. Criterion or concurrent validity examines the strength of association of the new survey measure with what is deemed to be an accurate measure of the same concept. The PSS is a clinician-rated instrument consisting of 3 questions regarding normalcy of diet, understandability of speech, and eating in public. Thus, it served as the gold standard. We established construct validity by correlating item and subscale scores with related constructs from other health status instruments administered simultaneously with the MDADI. The SF-36[5] was used to test convergent and discriminative validity of the MDADI. A strong correlation was defined to be 0.60 or greater; moderate to substantial, 0.40 to 0.60; and weak, less than 0.40.[6]

As a further demonstration of construct validity, the MDADI score was expected to discriminate between groups of subjects, ie, scores on the MDADI should differ when patients are grouped by severity (such as the site of the tumor, pathological findings, and time elapsed since last treatment). These between-group differences in MDADI scores were analyzed by analysis of variance. Recurrent cancers were not included in the analysis.

SCORING OF THE MDADI

The complete MDADI is depicted in the Figure. The global assessment consisted of a single question that asked how the individual's swallowing difficulty affected overall daily routine. This question is a general, overall assessment of QOL that has been affected by swallowing difficulty. The emotional subscale of the MDADI consisted of statements representing the individual's affective responses to the swallowing disorder. The functional subscale attempted to capture the impact of the individual's swallowing problem on daily activities. Items of the physical subscale represented self-perceptions of swallowing difficulty. Five possible responses to the items on the MDADI were printed for each item (strongly agree, agree, no opinion, disagree, and strongly disagree) and scored on a scale of 1 to 5. One item on the emotional subscale (I do not feel self-conscious when I eat) and another on the functional subscale (I feel free to go out to eat with my friends, neighbors, and relatives) were scored as 5 points for strongly agree and 1 point for strongly disagree. All other items were scored as 1 point for strongly agree and 5 points for strongly disagree. The first question (global subscale) was scored individually. All other questions regarding each aspect (emotional, functional, and physical) of dysphagia were summed, and a mean score was then calculated. This mean score was multiplied by 20 to obtain a score, with a range of 0 (extremely low functioning) to 100 (high functioning). Thus, a higher MDADI score represented better day-to-day functioning and better QOL.

The M. D. Anderson Dysphagia Inventory

This questionnaire asks for your views about your swallowing ability. This information will help us understand how you feel about swallowing.

The following statements have been made by people who have problems with their swallowing. Some of the statements may apply to you.

Please read each statement and circle the response which best reflects your experience in the past week.

My swallowing ability limits my day-to-day activities.

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

E2. I am embarrassed by my eating habits.

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

F1. People have difficulty cooking for me.

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

P2. Swallowing is more difficult at the end of the day.

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

E7. I do not feel self-conscious when I eat.

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

E4. I am upset by my swallowing problem.

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

P6. Swallowing takes great effort.

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

E5. I do not go out because of my swallowing problem.

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

F5. My swallowing difficulty has caused me to lose income.

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

P7. It takes me longer to eat because of my swallowing problem.

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

P3. People ask me, "Why can't you eat that?"

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

E3. Other people are irritated by my eating problem.

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

P8. I cough when I try to drink liquids.

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

F3. My swallowing problems limit my social and personal life.

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

F2. I feel free to go out to eat with my friends, neighbors, and relatives.

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

P5. I limit my food intake because of my swallowing difficulty.

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

P1. I cannot maintain my weight because of my swallowing problem.

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

E6. I have low self-esteem because of my swallowing problem.

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

P4. I feel that I am swallowing a huge amount of food.

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

F4. I feel excluded because of my eating habits.

Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree

Thank you for completing this questionnaire!

disability) on the QOL of patients with head and neck cancer.

RESULTS

PATIENT CHARACTERISTICS

The final sample consisted of 100 patients with characteristics as outlined in **Table 1**. Mean (SD) age was 58 (10) years, with a range of 21 to 80 years. Most patients (70%) had advanced-stage or recurrent cancer. For the 75 patients who received treatment, the mean (SD) time since last treatment was 22 (47) months, with a range of 0.3 to 324 months. The distributions of the subscale scores are depicted in **Table 2**.

RELIABILITY

The overall Cronbach α coefficient for the questionnaire was 0.96. The MDADI Cronbach α of 0.96 exceeds the minimum acceptable value and suggests that each item of the MDADI addresses the same concept. The subscales also had acceptable internal consistency, as seen in **Table 3**. The test-retest reliability correlations of MDADI and the subscales also exceeded the minimum acceptable correlation (global, 0.69; emotional, 0.88; functional, 0.88; and physical, 0.86).

CRITERION VALIDITY

Criterion or concurrent validity establishes that the new survey instrument accurately reflects the attitudes of a previously used gold standard. In the development of the MDADI, the PSS was used as the gold standard. Spearman correlation coefficients were calculated. The global MDADI question had moderate correlation with the questions on the PSS related to diet and eating in public (0.53 and 0.47, respectively), as did the emotional (0.55 and 0.54, respectively) and physical (0.59 and 0.53, respectively) subscales. The functional subscale had moderately high correlation with the PSS (0.61 and 0.60 subscales). These results demonstrate an acceptable level of correlation, thus establishing that the MDADI and the PSS (eating in public subscale) measure psychosocial aspects of swallowing (criterion validity).

CONSTRUCT VALIDITY

Correlations between the subscales of the MDADI and the subscales of the SF-36 were calculated by using the Spearman correlation coefficient. The 8 domains of the SF-36 are physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. The results are summarized in **Table 4**. Correlation between the physical subscale of the MDADI and the physical functioning subscale of the SF-36 was expected and demonstrated (0.40). Divergent validity with the emotional (0.36)

The M. D. Anderson Dysphagia Inventory. E indicates emotional subscale; F, functional subscale; and P, physical subscale. The first item constitutes the global subscale. Scoring is explained in the "Scoring of the MDADI" subsection of the "Patients and Methods" section.

Table 1. Characteristics of 100 Patients With Head and Neck Cancer

Variable	No. of Patients
Sex	
Male	76
Female	24
Site	
Oral cavity	12
Oropharynx	8
Hypopharynx	6
Larynx	64
Other	10
Treatment	
None	25
Surgical	14
Nonsurgical	11
Combined	50
Pathological findings	
Benign	15
Malignant (squamous cell carcinoma)	82
Nonsquamous cell malignancy	3
Stage (of 82 squamous cell carcinomas)	
I and II	12
III	15
IV	19
Recurrent	36

Table 2. Distribution of MDADI Subscale Scores*

Subscales	Minimum	25%	50%	75%	Maximum
Global	20	40	80	90	100
Emotional	20	63	77	87	100
Functional	10	64	80	84	100
Physical	20	53	68	81.5	100

*MDADI indicates M. D. Anderson Dysphagia Inventory. N = 100.

and functional (0.31) subscales was also expected. Items of the role-physical domain of the SF-36 attempt to delineate the extent of problems with work or other daily activities as a result of physical health. The correlation with the MDADI physical subscale (0.39) was slightly less than 0.40, but suggests some correlation. Divergent validity with MDADI emotional (0.33) and functional (0.37) subscales was expected. Bodily pain was not measured in the MDADI emotional, functional, and physical subscales; thus, all correlation coefficients (0.23, 0.24, and 0.26, respectively) reflected divergence. General health also was not measured in any of these MDADI subscales, and divergence was evident in the correlation results (0.33, 0.28, and 0.32).

Because eating is one of the most common ways social beings interact, significant correlations between vitality and the 3 MDADI subscales mentioned (emotional, functional, and physical) were expected and observed (0.50, 0.45, and 0.52). The vitality domain measures individual pep and energy. The social functioning domain of the SF-36 measures the interference to social activities as a result of physical or emotional problems. Correlations between social functioning and these 3 MDADI subscales were also significant (0.50, 0.45, and 0.51). The role-emotional domain of the SF-36 measures the extent to which emotional problems interfere with work or other daily activities. Correlations between the role-emotional domain and the MDADI emotional, functional, and physical subscales were significant (0.40, 0.42, and 0.43, respectively). Mental health was not measured in any of these MDADI subscales; thus, divergence was evident in the correlation results (0.38, 0.32, and 0.37).

Table 3. Test-Retest and Internal Consistency Reliability for MDADI Subscales*

Subscale	Mean (SD)	1	2	3	4
Global	69.2 (26.89)	(0.93)			
Emotional	73.7 (18.90)	0.69	(0.85)		
Functional	74.4 (19.70)	0.58	0.82	(0.89)	
Physical	68.6 (20.63)	0.71	0.87	0.76	(0.85)

*MDADI indicates M. D. Anderson Dysphagia Inventory. N = 100. Reliability estimates appear on the diagonal.

Table 4. Construct Validity of MDADI and SF-36 Subscales*

	MDADI Subscales			
SF-36 Subscales	Global	Emotional	Functional	Physical
Physical functioning	0.29	0.36	0.31	0.40
Role-physical	0.31	0.33	0.37	0.39
Bodily pain	0.21	0.23	0.24	0.26
General health	0.21	0.33	0.28	0.32
Vitality	0.34	0.50	0.45	0.52
Social functioning	0.44	0.50	0.45	0.51
Role-emotional	0.34	0.40	0.42	0.43
Mental health	0.27	0.38	0.32	0.37
Physical Components Score†	0.25	0.30	0.29	0.34
Mental Components Score†	0.44	0.54	0.51	0.54

*Data are given as Spearman correlation coefficients. MDADI indicates M. D. Anderson Dysphagia Inventory; SF-36, Medical Outcomes Study 36-Item Short Form Health Survey. N = 100.
†Described in the "Construct Validity" subsection of the "Results" section.

The global subscale of the MDADI consisted of only 1 question. This question had convergent validity only when correlated with the social functioning domain of the SF-36 (0.44), thus reflecting the wording of the question (Figure).

The Physical Components Score of the SF-36 is a compilation of the first 3 domains of the SF-36 (physical functioning, role-physical, and bodily pain). The Mental Components Score is a summary score of the social functioning, role-emotional, and mental health domains of the SF-36. The primary aim of the MDADI is to measure psychosocial aspects of dysphagia, thus the significant correlations of the Mental Components Score with all subscales of the MDADI (0.44, 0.54, 0.51, and 0.54) were expected and observed.

KNOWN-GROUPS VALIDITY ANALYSIS

As the final measure of validity, the MDADI was able to detect differences in groups of patients with head and neck

Table 5. Site and MDADI Subscale Scores*

Group	Mean (SD) Scores	P
	Global	
1	47.0 (27.0)	<.001
2	74.6 (24.3)	
	Emotional	
1	58.1 (30.6)	<.001
2	78.1 (16.8)	
	Functional	
1	57.9 (20.5)	<.001
2	78.8 (17.9)	
	Physical	
1	52.2 (16.4)	<.001
2	73.8 (19.7)	

*MDADI indicates M. D. Anderson Dysphagia Inventory; group 1, patients with tumor in the oral cavity or oropharynx (n = 20); and group 2, patients with tumor in the hypopharynx or larynx (n = 70). Between-group differences were compared using analysis of variance.

Table 6. Pathological Findings and MDADI Subscale Scores*

Pathological Findings	Mean (SD) Scores	P
	Global	
0	86.7 (12.3)	.005
1	65.6 (27.5)	
	Emotional	
0	88.5 (9.2)	.001
1	70.7 (19.0)	
	Functional	
0	89.6 (9.7)	.001
1	72.2 (18.7)	
	Physical	
0	87.7 (10.0)	<.001
1	64.5 (20.1)	

*MDADI indicates M. D. Anderson Dysphagia Inventory; 0, benign (n = 15); and 1, malignant (n = 82). Between-group differences were compared using analysis of variance. Pathological findings were not available for 3 patients.

cancer who were expected to be functioning at different levels. The significant differences were detected when the patients were grouped according to site and pathological features of the primary head and neck tumor and the time elapsed since the last treatment of the primary head and neck tumor (**Tables 5**, **6**, and **7**).

The site of initial primary head and neck tumor was significantly associated with the global assessment of swallowing-related QOL ($P<.001$) and with the remaining 3 subscales ($P<.001$ for all). Patients with primary tumors of the oral cavity and oropharynx had significantly greater swallowing disability that caused an adverse impact on their QOL. Patients with a malignant neoplasm also had significantly greater swallowing disability as measured by the global assessment ($P=.005$) and emotional ($P=.001$), functional ($P=.001$), and physical ($P<.001$) subscales. The time elapsed since completion of treatment significantly affected swallowing-related QOL as measured by the global assessment

Table 7. Time Elapsed Since Completion of Treatment and MDADI Subscale Scores*

Group	Mean (SD) Score	P
	Global	
1	58.8 (28.1)	.01
2	78.8 (20.0)	
	Emotional	
1	67.3 (20.2)	.31
2	72.88 (13.8)	
	Functional	
1	69.4 (19.8)	.13
2	77.3 (9.7)	
	Physical	
1	61.2 (20.4)	.19
2	68.3 (11.9)	

*MDADI indicates M. D. Anderson Dysphagia Inventory; group 1, 0.3-24 months since completion of treatment; and group 2, >24 months since completion of treatment (n = 16). Between-group differences were compared using analysis of variance.

($P=.01$). With longer time elapsed since completion of treatment, the individual reported better swallowing function and overall QOL.

COMMENT

Most studies have provided physiological assessment of oral and pharyngeal swallowing function.[7-10] Valid and reliable QOL measurements may help to fill many voids in dysphagia assessment. Such questionnaires can assess how variations in treatment affect swallowing and how swallowing difficulty affects QOL. These scales can also systematically document the effectiveness of a given treatment in terms of physiological and QOL outcomes. Once data are gained on how QOL varies by treatment as assessed by a dysphagia-specific tool and generic health measures, the information can then be used to facilitate decision making by patients and physicians. This information may also be used to monitor the longitudinal course of individual patients' outcomes.

Functional status refers to the ability to perform daily activities, and *disease-specific functional status* refers to the impact of a given disease on particular functional aspects that are affected by the disease. Although several validated instruments have been designed to assess functional status in patients with head and neck cancer,[2,11-15] at present, no disease-specific instrument exists for evaluating dysphagia in the population with head and neck cancer.

The PSS[2] is one of the few instruments with items that measure how dysphagia affects one's performance status. However, it is not self-administered, and it lacks detailed questions pertaining to the psychosocial and emotional impact of dysphagia on patients' QOL.

McHorney and Rosenbek[16] have begun development of the SWAL-QOL (swallowing–quality-of-life instrument), a comprehensive measure of QOL and quality of care that is specific to neurogenic oropharyngeal dysphagia. This instrument is designed to represent the

neurologic patient's perspective in measuring QOL attributable to dysphagia. At present, it is undergoing validity and reliability analysis.

The MDADI consists of the global, emotional, functional, and physical subscales. Four subscales were developed to tap the different effects of dysphagia on QOL. The global assessment question is a simple way of determining an overall assessment. The values obtained in the global, emotional, functional, and physical subscales of the MDADI exceed the minimum level for group-level comparison. This suggests that the questions within the scale are consistently assessing the same issues. The value for the emotional subscale may be slightly lower than that for the other subscales because of the difficulty of reporting and describing emotional issues. However, the Cronbach α coefficient for the emotional subscale is considered acceptable.

Test-retest reliability was also calculated in this project. In general, minimum test-retest reliabilities of 0.70 are acceptable for group-level comparison.[3] The values for the emotional, functional, and physical subscales are thus acceptable for use in group-level comparison. Generally, a higher level of test-retest reliability is necessary for individual-level comparison, especially if the questionnaire is to be used to make clinical judgments regarding treatment or outcomes on a case-by-case basis. The global assessment had the lowest test-retest reliability score, possibly because it consists of only 1 question. The other subscales had multiple questions relating to the same domain.

Criterion validity was established by correlation using the PSS. The correlations were sufficient to demonstrate that the MDADI measures similar attributes as does the PSS. The correlation of the emotional subscale of the MDADI with the PSS was lower than that of the other subscales of the MDADI. A possible explanation for this lower correlation coefficient is that the PSS is limited in its ability to assess emotional aspects of swallowing. The PSS, in its original form, has 2 questions regarding swallowing and 1 question regarding speech. The 2 swallowing questions concern normalcy of diet and eating in public.[2] The normalcy of diet subscale assesses the degree to which a patient is able to eat a normal diet. The eating in public subscale assesses the degree to which the patient eats in the presence of others. Both questions assess more of the functional than the emotional aspect of swallowing. This may explain the higher correlations with the physical and functional subscales of the MDADI, compared with the emotional subscale.

If a good criterion already exists to assess psychosocial aspects of swallowing, why develop a new one? The purpose of developing the MDADI is not to eliminate the previously developed scale but to supplement it. One way the MDADI supplements the PSS is by measuring how dysphagia affects one's psychosocial and emotional well-being. In addition, the information obtained with the MDADI is from the patients. The PSS is not self-administered but is completed by a health care provider. The PSS asks 2 questions regarding swallowing. The MDADI's 20 questions capture more completely and effectively opinions and perspectives on the impact of dysphagia on QOL.

The SF-36 was used to establish validity in this study.[1,5] The SF-36 is a multi-item scale measuring the domains of physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health (psychological distress and well-being).[5]

The correlation between the physical functioning domain and the physical subscale of the MDADI was expected because both address physical functioning. Attempts were not made to measure bodily pain, general health, or mental health with the MDADI, and thus no correlation of these SF-36 domains with the MDADI subscales was expected. Eating is a social event for many humans, and thus one may surmise that an individual with a good energy level and social functioning would enjoy eating. On the contrary, one with a decreased energy level and lower social functioning may be ashamed, embarrassed, unmotivated, or unwilling to eat. Thus, the correlations with vitality, social functioning, and role-emotional domains of the SF-36 and the MDADI subscales are expected.

The Physical Components Score is a compilation of the physical functioning, role-physical, and bodily pain domains, and measures physical health status. The Mental Components Score is a summary score of the social functioning, role-emotional, and mental health domains, and measures emotional health status. Because the primary aim of the MDADI is to assess psychosocial aspects of dysphagia, it is not surprising that moderate correlations are evident with each of MDADI's subscales and the Mental Components Score, but that no correlation is evident with the Physical Components Score.

As a final measure of validity, the MDADI is able to detect differences in groups of patients with head and neck cancer who were expected to be functioning at different levels. The significant differences were detected when the patients were grouped according to site of, pathological findings of, and time elapsed since last treatment of the primary head and neck tumor. First, one would expect a lesion in the oral cavity or oropharynx to cause more swallowing difficulty. Indeed, when the head and neck cancer patients were grouped by tumor location (oral cavity or oropharynx and hypopharynx or larynx), significant decreases in global, emotional, functional, and physical aspects of dysphagia were evident as measured by the MDADI.

Second, diagnosis of a malignant neoplasm would certainly affect one's daily activities and health-related QOL. Indeed, global, emotional, functional, and physical subscale scores were significantly lower among patients with a malignant neoplasm compared with patients with a benign lesion in the head and neck.

Third, one assumes that the further one is from treatment, the more adept one is at adjusting to deficits caused by the tumor and/or treatment. In this patient population, the longer the interval between completion of treatment and assessment by the MDADI, the higher the global score, thus reflecting a higher QOL and functional status as related to swallowing. Survival bias may play a role in the association between time elapsed since last treatment and higher MDADI global scores.

The cross-sectional study design in this project lends itself to selection bias. The study population is selected from a tertiary care center; consequently, the patients may not be fully representative of the total population of patients with head and neck cancer. Furthermore, the study participants are selected from a particular clinic in the tertiary care center. The Speech Pathology clinic was selected because patients with swallowing difficulty are most likely referred to this clinic for assessment and evaluation. Thus, the largest number of patients with swallowing difficulty can be captured by targeting this clinic. However, other patients with swallowing difficulty may not present to the UTMDACC. Thus, those patients would not be offered an opportunity to participate in this study, thereby introducing noncoverage bias. Nonresponse bias did not play a major role in this project, because most patients (>95%) participated voluntarily. Because this instrument was developed in a study population consisting of head and neck cancer patients in a tertiary care center, caution is needed in its generalizability to other patient populations with dysphagia.

CONCLUSIONS

Head and neck cancer and its treatment can adversely affect a patient's QOL ability to eat. Disease-free survival, overall survival, and tumor response rates have been the traditional outcome measures of treatment efficacy. *Quality of life* describes nontraditional outcome measures of functional status and psychosocial well-being. Two general measures (general and disease-specific) are used in QOL analysis. Disease-specific instruments are designed to assess specific diagnostic groups or patient populations. These measures are more responsive to changes in patient status over time. The purpose of this project was to design a disease-specific instrument. The MDADI is designed to be a valid and reliable instrument for evaluating QOL issues associated with dysphagia.

To our knowledge, the MDADI is the first validated and reliable self-administered questionnaire designed specifically for evaluating the impact of dysphagia on the QOL of head and neck cancer patients. Standardized questionnaires measuring patients' QOL offer a means for demonstrating treatment impact and for improving medical care. Quality-of-life assessment is an important part of any clinical trial that compares different treatment modalities. The development of the MDADI and its use in prospective clinical trials will allow for better understanding of the impact of treatment of head and neck cancer on swallowing and of swallowing difficulty on patients' QOL.

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Corresponding author: Helmuth Goepfert, MD, University of Texas M. D. Anderson Cancer Center, 1515 Holcombe Blvd, Campus Box 441, Houston, TX 77030.

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