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ORIGINAL ARTICLE

Development and validation of a cancer-specific swallowing assessment tool: MASA-C

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Abstract
Objective We present data from a sample of patients receiving radiotherapy for head/neck cancer to define and measure the validity of a new clinical assessment measure for swallowing.
Methods Fifty-eight patients undergoing radiotherapy (±chemotherapy) for head/neck cancer (HNC) supported the development of a physiology-based assessment tool of swallowing (Mann Assessment of Swallowing Ability—Cancer: MASA-C) administered at two time points (baseline and following radiotherapy treatment). The new exam was evaluated for internal consistency of items using Cronbach's alpha. Reliability of measurement was evaluated with intraclass correlation (ICC) and the Kappa statistic between two independent raters. Concurrent validity was established through comparison with the original MASA examination and against the referent standard videofluoroscopic swallowing examination (VFE). Sensitivity, specificity, and likelihood ratios along with 95 % confidence intervals (CIs) were derived for comparison of the two evaluation forms (MASA vs. MASA-C). Accuracy of diagnostic precision was displayed using receiver operator characteristic curves.
Results The new MASA-C tool demonstrated superior validity to the original MASA examination applied to a HNC population. In comparison to the VFE referent exam, the MASA-C revealed strong sensitivity and specificity (Se 83, Sp 96), predictive values (positive predictive value (PPV) 0.95, negative predictive value (NPV) 0.86), and likelihood ratios (21.6). In addition, it demonstrated good reliability (ICC=0.96) between speech–language pathology raters.
Conclusions The MASA-C is a reliable and valid scale that is sensitive to differences in swallowing performance in HNC patients with and without dysphagia. Future longitudinal evaluation of this tool in larger samples is suggested. The development and refinement of this swallowing assessment tool for use in multidisciplinary HNC teams will facilitate earlier identification of patients with swallowing difficulties and enable more efficient allocation of resources to the management of dysphagia in this population. The MASA-C may also prove useful in future clinical HNC rehabilitation trials with this population.

Keywords Dysphagia · Swallowing · Validation · Assessment

Introduction

Cancer is the second leading cause of death after heart disease in the USA [1]. In 2004, approximately 23.1 % of the US population died from some complication with cancer [2]. Squamous cell carcinoma (SCC) of the oral cavity and oropharynx is responsible for an estimated 37,000 new cancer cases in the USA per year. Although SCC of the head and neck accounts for only a small percentage of all malignant neoplasms, they are associated with profound functional deficits [3, 4]. One of the most common side effects is difficulty swallowing (dysphagia).

Both preventative and rehabilitative swallowing treatment studies have reported that head/neck cancer (HNC) patients can make significant swallowing improvement if intervention

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is offered early [5–9]. Early identification of dysphagia may enable patients to receive simple interventions to alleviate symptoms and avoid development of complications. Earlier intervention is founded upon the use of accurate assessment tools. Earlier identification of dysphagic individuals may promote improved access to preventative and rehabilitative services and dramatically impact outcomes in this population. Although numerous assessment tools are available for the measurement of dysphagia, few cancer-specific tools exist. Further, no clinical instruments have been developed to measure the specific physiological changes in swallowing that occur over the trajectory of HNC and its treatment.

Only one swallowing-specific assessment currently exists for the measurement of dysphagia following HNC, the MD Anderson Dysphagia Index (MDADI) [10]. This tool is a survey-based assessment of swallowing quality of life. Alternatively, clinicians utilize a range of symptom-specific self-administered tools (e.g., Functional Assessment of Cancer Therapy—Head and Neck (FACT H & N) [11], MDASI [12]) which ask patients to rate their own abilities in the areas of feeding or saliva management. These tools, however, do not focus explicitly on swallowing physiology. Other available swallowing tools (Mann Assessment of Swallowing Ability (MASA) [13], PEN-ASP [14], EAT-10 [15]), while encompassing general swallowing measures, have either been validated on noncancer groups or are not specifically adapted to the unique features of a HNC population. One example of this is the Mann Assessment of Swallowing Ability [13]. This clinical swallowing assessment was designed for and validated on stroke populations and includes items not expected to be impaired in a HNC group (e.g., language). Consequently, scores derived using this tool on HNC patients are often inflated or suffer ceiling effects reducing discrimination among HNC subjects.

Given the physiologic burden of swallowing impairment in HNC, it is imperative that simple, innovative clinical swallowing tools, directly translatable to HNC characteristics, be developed. This study details the development of a swallowing-specific assessment tool for the identification and quantification of oropharyngeal dysphagia in patients with HNC. The objective of this study was to examine the diagnostic accuracy, reliability, and concurrent and predictive validity of the Mann Assessment of Swallowing Ability—Cancer version (MASA-C).

Methods

Setting and participants

Fifty-eight patients with confirmed HNC undergoing radiation therapy (±chemotherapy) at a university hospital cancer clinic provided data for the current study. Patients were included if they had (1) HNC of oropharyngeal or adjacent regions, confirmed by clinical history and exam, with positive cross-sectional imaging studies and histopathological biopsy excluding other pathologies; (2) planned external beam radiation therapy; and (3) no previous history of nonoral feeding for cancer-related illness.

Baseline measures

All appropriate patients were identified by physicians within the radiation oncology department and referred for baseline evaluation by speech–language pathologists. Subjects were recruited from those patients referred for baseline swallowing evaluation prior to commencement of radiation/chemotherapy. The local Institutional Review Board approved the study, and all enrolled patients signed an approved consent form.

Prior to initiation of medical treatment, each patient completed a baseline evaluation to ensure inclusion criteria and to obtain a pretreatment measure on outcome assessments. Baseline measures included clinical and videofluoroscopic swallowing evaluation, documentation of weight, and patients' self-perception of swallowing ability. Clinical assessment of swallowing ability was completed using two methods, (1) the MASA and (2) a new cancer version of the Mann Assessment of Swallowing Ability (MASA-C). In addition, patients were assessed using the Functional Oral Intake Scale (FOIS) [16] to document the level of oral intake and the FACT H & N, a HNC-specific quality-of-life scale [11]. Assessments were repeated at baseline and following conclusion of medical treatments.

Clinical evaluations of dysphagia

Mann Assessment of Swallowing Ability Two forms of clinical swallowing evaluation were utilized for concurrent validity comparison. Initially, all subjects were given the MASA. The MASA is a clinical examination designed for the assessment of oropharyngeal dysphagia following stroke [9]. The examination consists of 24 items comprising three main components. The MASA includes a quantifiable measure in each item of the scale, reflecting the severity of impairment on that item. The maximum possible score is 200. It has been validated by comparison to videofluoroscopic evaluation (VFE) in stroke patients and demonstrates strong inter- and intrarater reliability [17].

Mann Assessment of Swallowing Ability—Cancer version A new cancer version of the MASA was administered to the same population of patients by a separate clinician within a 2-h window. The development and evaluation of this cancer version is presented below.

Videofluoroscopic assessment Instrumental swallowing evaluation was completed via a standard VFE [18]. The VFE is an accepted standard for the evaluation of swallowing. Every

subject received a VFE examination at pretreatment and following completion of treatment. Materials utilized in these examinations included thin liquid, nectar thick liquid, and pudding (Varibar; E-Z-Em, Inc. Westbury, NY) in 5- and 10-ml amounts. Testing was conducted in the lateral view using a standard protocol [14]. Swallows were recorded digitally for subsequent analysis. VFE results were used to provide an accepted referent for the presence and severity of dysphagia. Dysphagia and aspiration (presence, absence, and severity) on VFE were identified by two speech pathologists (SLP) blinded to patient information. Identification and scoring were conducted using a previously published scoring protocol [17].

Development of the tool

Face validity: item identification and selection

To develop the MASA-C, the original MASA items were reviewed theoretically, via previous literature, to identify items relating to a HNC population. Items were also considered in reference to the utility of each potential item within currently administered swallowing assessments. To reduce the item pool and increase the probability of including discriminate items, five expert reviewers were asked to rate each potential new item. Subsequently, a field test of all the items (new and original) was performed on the first ten subjects in the study. Item analysis techniques were completed on the results of the field test to determine the value of each new individual item included in the revised test. Revised items were selected on the basis of correlation, with item to total correlations of >0.4, and each item's individual Cronbach ά >0.85 denoting inclusion. Finally, performance of the MASA-C was compared to the separately administered MASA and VFE results for all study patients. Comparisons were modeled using receiver operator curves (Figs. 1, 2, and 3).

MASA-C items

Following item analysis, the MASA-C included 15 of the original 24 items from the MASA. Additional items selected to comprise the MASA-C were neck palpation, mouth opening, taste, smell, current diet, oral mucous membrane, and weight loss. In addition, items "saliva" and "tracheostomy tube" were retained, but scoring conventions were modified to reflect the cancer-specific nature of this assessment. Items deleted from original MASA included alertness, cooperation, respiratory rate for swallowing, dysphasia, dyspraxia, gag, and cough reflex. Within each category of the MASA-C, a severity score was formulated using the original weighted scoring formula applied to this sample population. In total, nine cancer-specific items were added to the original item cluster of the MASA. The total maximum score from the MASA-C was 200 points (see Appendix 1).

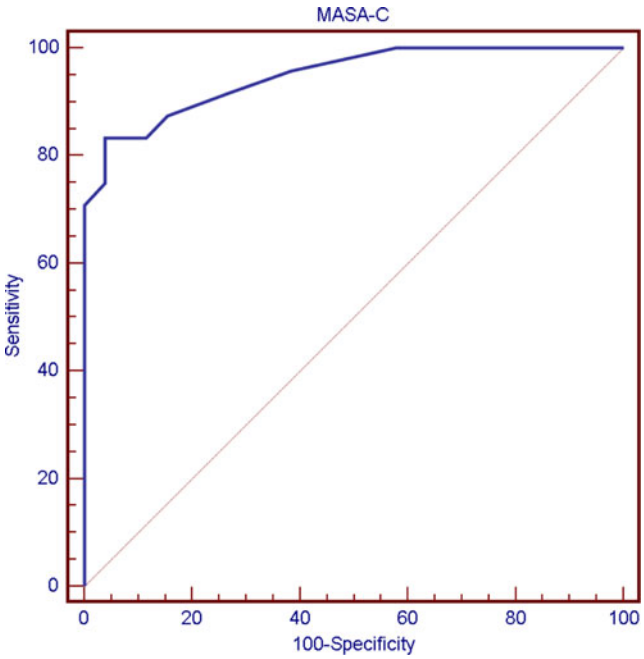

Fig. 1 Receiver operator characteristic curve for HNC dysphagia (MASA-C compared to VFE)

Timing of assessments

The study SLPs performed the MASA and MASA-C assessments within 2 h of each other. Each assessor was blind to the score derived by the other. The VFE was completed on the same day as the swallowing assessments and was conducted by a separate SLP and a radiologist who were blind to the

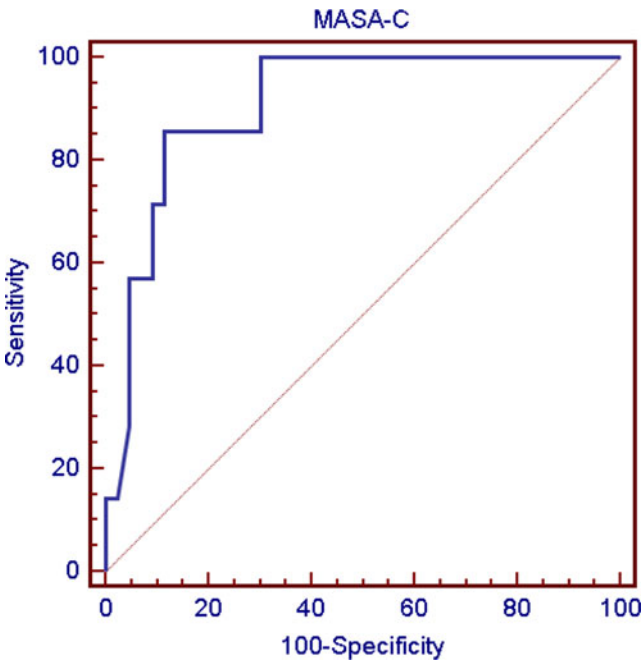

Fig. 2 Receiver operator characteristic curve for HNC aspiration (MASA-C compared to VFE)

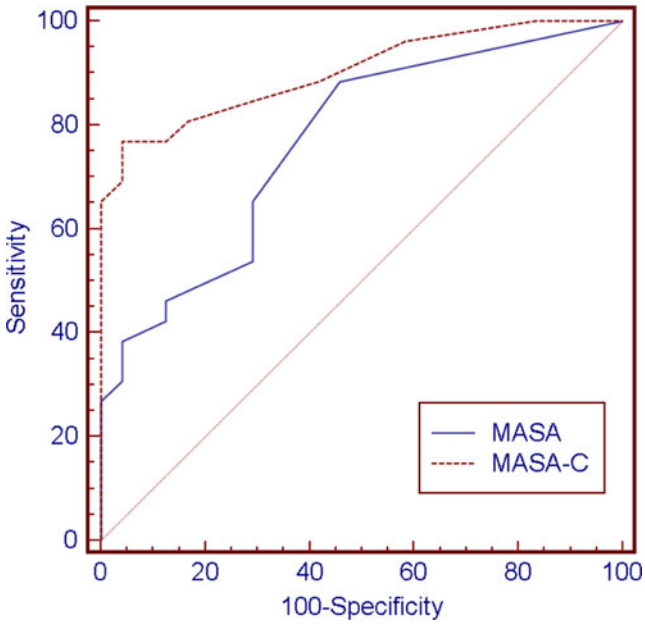

Fig. 3 Comparison of receiver operator characteristic curves for MASA and MASA-C by HNC dysphagia

clinical assessments. This procedure was repeated at the 6-week (posttreatment) time point.

Data analysis

The sample was evaluated both descriptively and analytically. Internal consistency of items from the MASA-C was evaluated using Cronbach's alpha. The correlation between each item and the total score was calculated. Due to the lack of a true "gold standard" for swallowing diagnosis, concurrent validity was established through comparison with the MASA-C and four different referents. The referent VFE was utilized for the development of MASA-C cut points. The value of the MASA-C was evaluated using the following epidemiologic criteria: sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), likelihood ratios, and classification accuracy. The 95 % confidence intervals (CIs) of these measures were calculated using standard methods [19]. The accuracy of diagnostic precision was determined and displayed using receiver operator characteristic curves (ROC). The optimal score on the MASA-C that discriminated between patients with and without dysphagia as identified on VFE was determined. The area under the ROC curve (AUC) was calculated according to the method of Hanley and McNeil [20]. Yield was determined by the number of true positives correctly identified (i.e., true positives divided by the total number of patients assessed) and reported as percentages. Reliability of measurement between raters for the MASA-C was evaluated with intraclass correlation (ICC) (two-way random effects model) statistic [17]. Test–retest reliability was assessed with the ICC coefficient for repeated administrations of the MASA-C across time points (baseline vs. 6 weeks). To examine construct validity, exploratory factor analysis of the MASA-C was completed using principal component analysis with oblique ("varimax") rotation. The predictive validity of the scale was assessed through associations with functional feeding levels (FOIS) at the posttreatment time point. Multivariate logistic regression analysis was used to evaluate risk factors associated with a favorable feeding outcome posttreatment. Variables significantly related to the dependent variable in univariate analyses were entered into the regression model using the backward elimination method. The final model was constructed by iteratively retaining significant variables.

Results

Baseline characteristics

The mean time from cancer diagnosis to recruitment was 35.1 days (SD 28.6). Swallow assessment was completed an average of 2.8 (SD 8.2)days after radiation oncology assessment. Thirty-six patients received radiation therapy, and 22 received concurrent chemotherapy. During the treatment period, three patients died from complications associated with their primary medical diagnosis or treatment (Table 1). Five subjects were excluded due to loss to follow-up or incomplete assessment. Data for the analysis of the MASA-C were complete on 50 subjects at both time points (Table 1).

Prevalence of dysphagia

The original MASA scoring cutoff (≤178) revealed evidence of dysphagia in only one patient posttreatment. Conversely, VFE assessment revealed evidence of dysphagia in 28 patients

Table 1 Demographic characteristics

Characteristics	
Age (mean; SD)	57.6 (11.35)
Gender (male/female)	44:14
Time postdiagnosis (mean days)	35
Time to randomization (mean days)	2.85
Tumor size (T grade), median (range)	2 (0–4)
Tumor site (mode)	
Base of tongue	11
Tonsil	16
Tumor side (left/right/bilateral)	22/16/20
+ Chemotherapy (count)	22
Radiotherapy dose (mean, SD)	69.7 (8.12)
Neck dissection (count)	22
Side of dissection (left/right)	8/14
BMI (baseline) (mean, SD)	28.8 (1.0)

(56 %; 95 % CI 41–70). The mean MASA-C score for dysphagic patients identified by VFE was 177 (14.01). Mean MASA-C scores for dysphagia severity identified by VFE were as follows: mild 183 (9.8), moderate 172.6 (12), and severe 163.4 (8). Overall, the prevalence of dysphagia estimated by VFE at posttreatment was 56 %.

Prevalence of aspiration

VFE assessment revealed evidence of aspiration in seven patients (14 %; 95 % CI 5.8–27.7). The mean MASA-C score for the patients demonstrating aspiration was 167 (12.09). Aspiration severity was not categorized due to the limited cases.

Internal consistency

Items included in the MASA-C were initially reviewed to examine their relationship as a scale. Means and standard deviations for each item were reviewed for central tendency and variability. Items were then entered into a correlation matrix to explore interrelationships. From this analysis, the items auditory comprehension, lip seal, and tracheostomy tube were significantly skewed. Inspection revealed a limited number of exemplars from the sample; however, due to the theoretical relationship with the swallowing process, they were retained in the analysis. After adjustment for skewed variables, the alpha coefficient obtained was high, $\alpha = 0.94$, indicating individual items in the MASA-C were sufficiently homogeneous and reliable for the discrimination of dysphagia between individuals and groups suffering HNC. The MASA-C also showed high item consistency (relationship of individual exam items to the overall exam score) for each of the 24 items (i.e., corrected item to total correlation $= r > 0.5$). A value greater than 0.4 indicated that the corresponding item correlates well with the scale and should be retained [21]

Interobserver agreement (reproducibility)

Interjudge agreement in the clinical diagnosis of a swallowing disorder between SLPs was calculated. Interjudge agreement on MASA-C was excellent (ICC=0.96, 95 % CI 0.94–0.98).

Intrajudge agreement: High consistency of measurement by judges against themselves on repeated measures was demonstrated as ICC=0.94 (95 % CI 0.91–0.97).

Accuracy of MASA-C identification of dysphagia (validity)

Accuracy of the MASA-C to identify degrees of dysphagia severity was analyzed in comparison to VFE scores using ROC curves (Fig. 1). The optimal cut point (identified by the largest separation from the diagonal line on the curve) from the MASA-C to identify any dysphagia was ≤185. Area under the ROC curve was 0.95 (0.84–0.99); $P < 0.0001$. Sensitivity and specificity of this cut point for the detection of dysphagia were high (83 and 96 %, respectively). Likewise, predictive values were strong (PPV 95 %, NPV 86 %). Likelihood ratios (+LR 21.6, −LR 0.17) also conveyed strong diagnostic probability.

The optimal cut point on the MASA-C to identify presence of any aspiration was ≤176 out of 200 possible points. The area under the ROC curve was 0.90 (0.793–0.971); $P < 0.0001$ (Fig. 2).

Yield

The highest yield for dysphagia using the MASA-C (patients correctly identified as dysphagic) was 72 % (36/50; true-positive subjects identified by the MASA-C) at the 6-week time point.

Test–retest reliability

Test–retest reliability was assessed by ICC coefficients on repeated measurements of the MASA-C. The ICC was 0.96 (baseline) and 0.92 (posttreatment) demonstrating good test–retest reliability

Concurrent validity

To evaluate the ability of the MASA-C to reflect the breadth of swallowing deficits in a HNC population, its performance was compared to the FACT H & N, FOIS, MASA, and VFE at posttreatment (Table 2). A significant strong correlation was found between the FOIS and MASA-C ($r = 0.83$). Correlation between MASA-C and original MASA demonstrated a moderately strong correlation ($r = 0.66$). Correlation to the FACT H & N revealed a moderate relationship ($r = 0.49$). A modest correlation was noted between the MASA-C and VFE score ($r = -0.39$).

Table 2 Correlation between MASA-C and other scales

Variable	Correlation (r)	Significance	95 % CI
MASA (original)	0.699	$P = 0.0001$	0.5232 to 0.8186
Fact H & N	0.488	$P = 0.0010$	0.2169 to 0.6901
FOIS	0.8295	$P = 0.0001$	0.7166 to 0.9000
VFE score[a]	−0.3901	$P = 0.0051$	−0.6030 to −0.1254

[a] VFE scoring is inverse (lower scores indicate positive scores)

Construct validity—factor analysis

To identify the structure underlying the MASA-C, responses on MASA-C administrations were submitted to an exploratory factor analysis. Exploratory factor analysis using principal component analysis was used to identify the minimum number of underlying dimensions required to explain intercorrelations among data. Further, clusters of interrelated factors were rotated to allow meaningful interpretation of their structure. For the purposes of this study, an oblique rotation was utilized as the intercorrelation among swallowing components was assumed. To identify the number of factors to be retained in the final solution, both the scree plot and the number of items loading significantly on each factor were reviewed. Results revealed a final model that explained 69.4 % of the variance–covariance matrix. Four factors containing >4 items were retained producing a 23-item measure. The four factors were judged to represent acute toxicity effects, pharyngeal function, oral function, and cognitive–motor functioning. Results showed that all items loaded significantly on their respective factors. Specifically, item loadings ranged from 0.7 to 0.90 for acute effects, 0.54 to 0.73 for pharyngeal function, 0.65 to 0.8 for oral function, and 0.47 to 0.85 for cognitive–motor function (Table 3).

Table 3 Rotated factor structure of MASA-C

Variable	Acute effects	Pharyngeal	Oral	Cognitive
Neck palpation	0.90			
Oral mucous membrane	0.72			
Saliva	0.88			
Weight loss	0.85			
Taste	0.87			
Smell	0.69			
Current diet	0.80			
Chest status		0.56		
Bolus clearance		0.54		
Oral transit		0.70		
cough voluntary		0.67		
Voice		0.61		
Pharyngeal phase		0.73		
Pharyngeal response		0.54		
Dysarthria			0.69	
Tongue movement			0.65	
Tongue strength			0.58	
Tongue coordination			0.80	
Oral preparation			0.85	
Auditory comprehension				0.85
Palate				0.90
Lip seal				0.75
Mouth opening				0.33

Predictive validity

Univariate associations identified that patients consuming more advanced oral diets with limited modification (FOIS >4) demonstrated higher MASA-C swallowing scores ($P<0.0001$). Patients receiving radiation alone were also more likely to have higher swallowing scores ($P<0.010$). Alternatively, patients who received chemo-radiotherapy and reported lower health status demonstrated significantly lower MASA-C scores. A multivariate logistic regression model (adjusted for the univariate significant variables age, tumor size (T stage), amount of radiation received, therapy regimen, weight loss, and presence of aspiration) was evaluated with respect to favorable outcome posttreatment. When all variables were included, the final model identified MASA-C score as the only independent predictor following the backward elimination procedure (adjusted OR, 1.32; 95 % CI 1.09–1.5, $P<0.003$). The final model explaining 56 % (Cox and Snell R^2) and 72 % (Nagelkerke R^2) of the variance in feeding outcome correctly classified 89 % of the cases. Interpretation of the final model (log odds) revealed that for every 10-point rise in MASA-C score, the odds of achieving a favorable outcome posttreatment rose by 15.49 times compared to patients not improving their MASA-C score.

Discussion

Few validated HNC-specific dysphagia assessments are available. Most tools currently utilized include only descriptions of patient-reported symptom clusters (swallowing performance scale [22]) or target quality-of-life concerns related to swallowing (MDADI [10]), but do not identify physiologic alterations in swallowing resultant from HNC and its treatments. Similarly, correlations between health-related quality-of-life instruments and functional feeding status in HNC patients from past research have proved modest, e.g., $r \leq 0.3$ [23, 24]. The purpose of this study was to develop and psychometrically evaluate a physiologic tool to identify dysphagia in HNC patients. To accomplish this, we revised an existing clinical dysphagia examination (MASA) previously validated on a neurological population and modified its items to address specific needs of the HNC population. This study provides preliminary evidence that the new MASA-C demonstrates a good tradeoff between sensitivity and specificity (Se 83, Sp 96) in the identification of dysphagia in HNC patients. Further, the MASA-C displays adequate yield (72 %), predictive values (PPV 0.95, NPV 0.86), and likelihood ratios (21.6, 0.17). In addition, MASA-C demonstrates adequate test–retest and reliability across SLP raters over time (ICC=0.96, 0.94) and

incorporates components of specific relevance to a HNC population.

MASA-C demonstrates adequate face and content validity on pretesting and strong consistency following item analysis. Although three items were not prevalent in the study sample and needed transformation, the majority of the variables ($n=21$) remained homogenous and revealed good discrimination among groups and individuals with dysphagia from HNC. Similarly, the MASA-C demonstrated a strong correlation to functional feeding status (FOIS), in keeping with other dysphagic populations. Like other physiologic measures, MASA-C demonstrates modest correlation to the general index of cancer-specific health status (FACT H & N).

Tests with a high specificity denote a tool that accurately diagnoses a particular disease without giving false-positive results. The MASA-C provided a high specificity rate (0.96). A test with such high specificity has few false positives and can be used to confirm the results of sensitive, but less specific, screening procedures. Consequently, the high specificity of the MASA-C suggests this test can be used to "rule in" the diagnosis of dysphagia in this population. This characteristic is important for a test where the resultant treatment may be mentally and/or physically burdensome for a patient (e.g., a recommendation of tube feeding) [25].

Typically, assessment of diagnostic test accuracy includes three phases. First is an exploratory phase. It comprises the first clinical study performed to assess the efficacy of a new diagnostic test. Following this is a challenge phase, in which a test's sensitivity and specificity are evaluated as they vary with the extent and stage of the disease and presence of comorbidities. These studies include comparisons between diagnostic tests to compare their accuracies to the test under evaluation. The final phase is an advanced phase which involves randomized controlled trials from multiple centers to provide truly representative clinical populations [26]. The evaluation of the MASA-C as presented here is the first clinical study performed to assess the accuracy of this new test. Although preliminary, this study included subjects that were preclinical and did not present with dysphagia, as well as those who suffered more severe swallowing deficits. As such, it fulfills the first and partially fulfills the second phase of test examination, i.e., the challenge phase. Given the inclusion of patients with subtle dysphagia and with comorbidities that could interfere with the diagnostic precision, the observed psychometric strength of the MASA-C underscores the value of this new test.

Determining the appropriate reference standard for a study often is the most difficult part of designing a diagnostic accuracy study. In our study we chose to assess the accuracy of the MASA-C against a previously validated MASA and the VFE. The performance of the MASA-C against both standards was strong. The new exam is superior to the original MASA in reflecting the breakdown of swallowing in HNC. In comparison to the VFE, the MASA-C demonstrated added value in precision and diagnostic yield (low false-positive and negative rates).

The current evaluation of the MASA-C did not include HNC patients treated with surgical interventions or combined therapies (surgery +). Due to this, further evaluation of this tool in surgically treated HNC patients is warranted. Nonetheless, we feel that the items included on the MASA-C demonstrate the range of physiologic swallowing variables required to evaluate surgically treated patients. Furthermore, the sample included in our study was relatively small and derived from a single center which may have affected the prevalence of critical features in this group (e.g., aspiration). Although evaluation of the tool was compared with data from patient demographics, direct clinical evaluation, functional eating ability, videofluoroscopic assessment, saliometric assessment of saliva production, patient-reported outcome and tumor characteristics, dose and staging by the attending radiation oncologists, the low prevalence of items such as aspiration in the sample suggest results presented may require replication in larger samples. Finally, evidence is also needed to determine the longer-term prognostic ability of the MASA-C and its utility in facilitating better health outcomes for this group.

Summary

The MASA-C provides a cogent method of evaluating physiologic swallowing performance in HNC. Psychometric evaluation revealed strong sensitivity, specificity, likelihood, and yield values. Additional evidence for the validity of the MASA-C was provided via correlations with other relevant HNC and dysphagia instruments. The MASA-C score was an independent predictor of favorable swallowing outcome post-CRT treatment and performed favorably in comparison to an accepted HNC quality-of-life scale. Future research should aim to replicate these findings in a larger study sample and identify this tool's ability to predictively map outcomes for this population over longer time periods. In sum, the MASA-C offers a unique addition to the evaluation of swallowing morbidity in HNC populations.

Conflict of interest All authors are free of professional areas of conflict of interest such as financial remuneration as employee, consultant, or subcontractor with companies. We have full control of all primary data, and we agree to allow the journal to review our data if requested.

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