THE MEALTIME ASSESSMENT SCALE (MAS): II. PRELIMINARY PSYCHOMETRIC ANALYSIS

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Abstract

Aims: The Mealtime Assessment Scale (MAS) was developed to assess swallowing safety and efficacy during the meal. The study aims to undergo a preliminary validation of MAS by investigating internal consistency, inter-rater agreement, concurrent and known-group validity, and responsiveness.

Methods: MAS was tested on 100 persons without dysphagia (Group 1) and 100 persons with dysphagia (Group 2). Fifty subjects were simultaneously evaluated at mealtime using MAS by two independent clinicians to test inter-rater agreement. For concurrent validity, MAS was correlated with Mann Assessment of Swallowing Ability (MASA) and American Speech-Language-Hearing Association National Outcomes Measurement System (ASHA NOMS) swallowing scale. MAS scores of Groups 1 and 2 were compared for known-group validity. Responsiveness was tested re-assessing 36 patients from Group 2 after diet improvement.

Results: Internal consistency and responsiveness were established for efficacy but not for safety. For inter-rater agreement, an average deviation index<0.66 was found for all items. MAS showed strong correlations with MASA and ASHA NOMS. MAS scored significantly different for Groups 1 and 2.

Conclusion: Preliminary evidence of the validity and reliability of MAS was established, except for the internal consistency and the responsiveness of the safety subscale. Further studies need to complete the validation process.

Introduction

Complications of dysphagia comprise reduction of patients and caregivers' quality of life (QOL) [1-2], aspiration pneumonia, malnutrition, and dehydration [3]. Pulmonary complications are the result of the impaired safety of swallowing leading to tracheobronchial aspiration; malnutrition and dehydration are secondary to the impaired efficacy of swallowing reducing oral intake of nutrients and liquids [4-6]. Currently, dysphagia assessment mainly focuses on the quantification of the safety and efficacy of swallowing through the observation of a limited number of swallowing acts. However, when consuming a meal or drinking a beverage in everyday living, personal and environmental factors, such as food, appetite, fatigue, may impact swallowing safety and efficacy [7-9]. Hence, a specific assessment of swallowing safety and efficacy while consuming a meal should be conducted along with instrumental and clinical swallowing assessment in the management of individuals with dysphagia.

In a companion article, our working group developed a scale to assess swallowing safety and efficacy during the meal, named Mealtime Assessment Scale (MAS), to be applied to all the patients who consume a meal orally regardless of the diagnosis and the setting [10]. Potential applications of the scale in clinical practice and research, to be used in association with other swallowing measures, are: 1) appraising the risk of pulmonary and nutritional complications, 2) measuring changes in over time; 3) assessing swallowing treatments' efficacy in terms of impact on the activities of daily living; 4) comparing swallowing safety and efficacy during meal among different populations. The MAS was developed based on the International Classification of Functioning, Disability and Health (ICF) framework [11] and a pilot study for item selection and revision was conducted.

Consequently, this study aims to undergo ~~a~~ preliminary psychometric testing of the MAS including reliability and validity analysis. Our hypothesis are that: i) the item selection and revision conducted in the previous part of the study related to scale development have improved MAS reliability reaching adequate levels for both clinical and research application; ii) the MAS may represent a valid measure of meal safety and efficacy being able to discriminate individuals with different performances in meal consumption, to detect clinically relevant changes over time and to moderately correlate with other

swallowing outcome measures. The results of the study may point out the need for potential further revisions of the scale and represent the first step of the validation process of the MAS.

Methods

The present study was carried out according to the Declaration of Helsinki and approved by the Institutional Review Board of Luigi Sacco Hospital. Each patient included in the study gave written informed consent. The preliminary validity and reliability study of the MAS was conducted between July 2012 and January 2014. The study consisted of: i) reliability analysis; ii) validity analysis.

Mealtime assessment scale

The MAS is a scale for the assessment of the safety and the efficacy of swallowing during meal. It comprises an initial section to record demographic information and medical history of the patient. The scale is, then, divided into four subscales: 1) *structures, functions, and activities influencing the meal*, 2) *environmental factors influencing the meal*, 3) *swallowing safety during the meal*, 4) *swallowing efficacy during the meal*. Overall, 26 items are included in the MAS. The MAS ends with a section for the scoring and an optional section concerning eventual compensations and indications to give to the patient or to the caregiver during the post-assessment counseling. A 4-point Likert scale, ranging from 0 (normal) to 3 (severely deviant), was used to score each item. A safety score (0-12) and an efficacy score (0-18) can be computed by summing the items' scores of the subscales *swallowing safety during the meal* and *swallowing efficacy during the meal*, respectively. Moreover, in order to nullify the difference in the number of items, for both the safety and the efficacy sections a percentage can be calculated to quantify the level of impairment in each aspect. The higher the score or the percentage, the less safe or efficacious is the swallowing during the meal. The time the patient needed to end the meal must be recorded.

Patients

Patients were recruited in a rehabilitation center and an acute-care hospital of Northern Italy.

Three groups of patients were included: group 1) 100 patients without dysphagia; group 2) 100 patients with dysphagia of different etiology and tolerating a complete or partial oral diet; group 3) 36 patients with dysphagia from the group 2 evolving from a more restricted diet to a less restricted diet during the

hospitalization period. The sample size of 100 subjects was determined as Hansen et al. set this number as the cut-off for an excellent sample size [12]. Inclusion criteria were: group 1) hospitalized or non-hospitalized, Mann Assessment of Swallowing Ability (MASA) score ≥178, aged over 18; group 2) hospitalized, dysphagia of any origin, MASA score <178, aged over 18; group 3) hospitalized, dysphagia of any origin, MASA score at the first assessment <178, diet restriction improvement during the hospitalization period. Patient's characteristics for the three groups are reported in Table 1. None of the patients were lost or had withdrawn.

Procedure

All patients from Groups 1 and 2 were evaluated with the MASA protocol [13] and scored with the American Speech-Language-Hearing Association National Outcome Measurement System (ASHA NOMS) swallowing scale [14] by a SLT. All the patients were then observed during mealtime by a different SLT blinded to the results of the previous evaluation within 7 days (in the rehabilitation center) or within 24 hours (in the acute-care hospital) from the assessment with MASA and ASHA NOMS, in order to use of the MAS protocol. For 50 patients from the Group 2, the meal observation was simultaneously conducted by two independent SLTs, blinded to the results of the clinical assessment, who observed the same meal and independently filled in the MAS protocol at the end of the meal. Overall, 5 SLTs with over five years of experience in dysphagia assessment and management were involved in patients' assessment. Each rater read MAS' instruction manual and could ask the working group of the MAS for explanations during a dedicated meeting.

The MASA is a standardized and validated clinical bedside assessment tool for the evaluation of oropharyngeal dysphagia, composed of 24 items scored on a 10-point scale. The total score ranging from 38 to 200 is obtained by summing up items scores; the lower the score, the higher the swallowing impairment. A MASA score of 178 is considered to be the cutoff for the absence of dysphagia, and a MASA score of 170 is considered to be the cutoff for the absence of aspiration risk. Inter-rater reliability for the MASA had been established with values of k=0.85 for dysphagia and k=0.74 for aspiration [15]. The ASHA NOMS swallowing scale is a 7-point outcome scale. It is used to rate the functional severity of dysphagia. The ASHA NOMS level, ranging between 7 (safe swallowing with all consistencies) and

1 (not able to swallow anything safely by mouth), is defined on the basis of the safety of swallowing, of the necessity of diet modifications and compensatory strategies, of the independence level and of the type of nutrition required.

The setting of the meal observation was not established to allow the observation of each patient in the most ecologic setting as possible. Out-patients were assessed in the therapy room, hospitalized patients were evaluated in their ~~own~~ room or in the ward's dining room. Patients in Group 1 were observed in the setting where they usually consume the meal (home, workplace canteen, ward dining room). In case the patients needed assistance during the meal, the usual helper gave it. During meal, the rater could talk with the patient, encourage him to complete the meal or ask for specific tasks required to complete the MAS (e.g., open the mouth to assess post-swallow residue in the oral cavity), but no additional request nor alimentary instruction could be given, unless necessary for patient's safety. Patients were not asked to assume any particular position. Each patient was allowed to choose the food to eat, respecting eventual consistencies restrictions indicated by previous swallowing evaluations. The whole meal was observed for all the patient, and the MAS was filled in only once meal consumption was ended.

In Group 3, a fiberoptic endoscopic evaluation of swallowing (FEES) was performed before diet modification by a phoniatrician who verified that patients could tolerate a less restricted oral diet; SLT's observation of the patients during mealtime and MAS' compilation was conducted twice: first during the more restricted diet, secondly after less restricted diet, before the patient's discharge.

Data analysis

Results are reported as median and range. Statistical analysis was performed using IBM Statistics SPSS® version 20.0 for Windows software (SPSS Inc, Chicago, IL). A Shapiro-Wilk test showed that the normality assumption was violated for all variables in all groups ($p<0.05$).

Reliability analysis. Reliability is the degree to which the measurement is free from measurement error [16]. Among the different types of reliability, internal consistency is the degree of the interrelatedness among the items, while inter-rater reliability represents the extent to which scores for patients who have not changed are the same when assessed by different persons on the same occasion [16]. Cronbach's

alpha was used to calculate internal consistency of both the *swallowing safety during the meal* and the *swallowing efficacy during the meal* subscales using Group 1 and Group 2 scores. A Cronbach's alpha >0.70 was regarded as "good" internal consistency [17]. The average deviation index (AD index) was used to test the inter-rater agreement. A good inter-rater agreement was considered for AD index below 0.66 [18].

Validity analysis. Validity is the degree to which a tool measures the construct it aims to measure [16]. It includes concurrent validity, namely the degree a test correlates with a known indicator of the behavior being measured [19]. As a gold standard for meal assessment does not exist and no other validated tools assessing meal consumption are available in Italian, the MAS scores were correlated with MASA and ASHA NOMS scores. Non-parametric Spearman correlation test was used to analyze the correlations between MAS total and subscale's scores and the score obtained on the MASA protocol and ~~on~~ the ASHA-NOMS scale in Group 1 and 2. The correlations between MASA, ASHA-NOMS, and MAS were considered strong for values >0.6, moderate for values ranging between 0.4 and 0.6, and weak for values <0.4 [20].

Another type of validity is the known-group validity. It addresses the ability of a tool to reflect in its score a difference between two or more groups that are known to have or that logically should have different levels of the construct to be measured [21]. For the known-group validity analysis, MAS scores in Group 1 and Group 2 were compared. Subjects were divided into four age groups: young (18-39 years), adult (40-64), old (65-74), very old (over 75). Based on this age division, Group 1 and Group 2 patients were distributed as follows: 24/100 (24%) and 1/100 (1%) young, 35/100 (35%) and 9/100 (9%) adults, 14/100 (14%) and 17/100 (17%) old, 27/100 (27%) and 73/100 (73%) very old respectively. Non-parametric Mann-Whitney U test was used to compare MAS scores of Group 1 and Group 2 for the age groups of adults, old and very old. Kruskal-Wallis non-parametric test with Dunn post-hoc test and Bonferroni correction was used to compare MAS scores between different age groups within Group 1, as a slow deterioration of meal safety and efficacy may be observed with the aging process even in individuals without swallowing alterations. A p <0.05 was considered statistically significant.

An assessment tool should be able to detect variations in the construct to be measured over time, a property known as responsiveness [16]. The responsiveness of the scale was tested re-assessing patients with the MAS after the modification of diet recommendation. Non-parametric Wilcoxon test was used to compare the first and the second SLT's assessment in Group 3's patients. A $p < 0.05$ was considered statistically significant.

Results

Reliability analysis

Cronbach' alpha was α=-0.615 for the safety scale and α=0.858 for the efficacy scale. Results of the inter-rater agreement are reported in Table 2. An AD index<0.66 was found for all the items.

Validity analysis

Concurrent validity. Correlations between MAS scores and MASA and ASHA NOMS scores were used to analyze concurrent validity. Median MASA score was 188.5 (range 107-200), while median ASHA NOMS score was 6.5 (range 1-7), with 90/100 of the patients (90%) scoring 3 or 4. The correlation with MASA scores showed Spearman's coefficient of r=-0.75 (p<0.01) for safety score and of r=-0.81 (p<0.01) for the efficacy score, while a correlation of r=-0.66 (p<0.01) and of r=-0.80 (p<0.01), respectively, was found with the ASHA-NOMS swallowing scale.

Known-group validity. Comparison of the MAS scores obtained by Group 1 and Group 2 are reported in Table 3. A statistically significant difference, with Group 1 patients scoring higher than Group 2 patients, was found for both the safety score and the efficacy score for all age groups. The time needed to complete the meal was significantly lower in individuals without dysphagia (median 25 minutes, range 15-40) than in individuals with dysphagia (median 30 minutes, range 10-60) for the >75 years age group (p=0.024), while no statistically significant difference was found for the other age groups. In the 40-64 years age group, no statistically significant difference was found for 5/12 items of the scale *structures, functions and activities influencing meal*, for the item "Possibility to rely on caregiver" of the scale *environmental factors influencing meal*, for the item "Oral control of the bolus" of the safety scale and ~~for~~ 5/6 items of the efficacy scale. Concerning the 65-74 years age groups, no statistically significant difference was found for the items "Head-to-trunk control," "Control of drooling" and all except 1 item of the safety scale. Subjects without dysphagia scored significantly higher than subjects with dysphagia in all items in the >75 years age group.

Results of the Kruskal-Wallis test comparing different age groups within Group 1 are reported in Table 4. All subjects scored lower than or equal to 3 on both the safety and efficacy score. All subjects scored 0 in all the items of the *environmental factors influencing meal* scale. Time needed to end the meal was

shorter than or equal to 40 minutes in all age groups. A statistically significant difference between age groups was found for the safety score (p=0.041), for the efficacy scale (p<0.001) and for the following 4 items: “Teeth” (p=0.048), “Control of food leakage while chewing” (p=0.041), “Oral preparation” (p=0.014), “Amount of food” (p=0.041). In particular, 18-39 years old patients scored higher than >75 years old patients in the item “Oral preparation” (p=0.028), the safety score (p<0.001), the preliminary assessment scale (p=0.028), the signs of dysphagia scale (p=0.050), and the efficacy scale (p=0.001). Moreover, patients in the 40-64 age group scored higher than patients in the >75 years old age group in the efficacy scale (p=0.004).

Responsiveness. The MAS responsiveness was analyzed in Group 3; Table 5 shows the results. All patients evolved from a C1 diet, corresponding to homogenous puree consistency diet, to a C2 diet, corresponding to a soft food diet. A statistically significant improvement was found in the efficacy score but not in the safety score. The time needed to finish the meal did not change significantly (p=0.056). Five out of 12 items of the *structures, functions, and activities influencing the meal* subscale scored significantly higher at the second assessment; they were mostly related to patient’s independence and ~~to~~ postural and oral cavity control. A statistically significant difference was found for all the items of the *environmental factors influencing the meal* subscale, except for the item “Consistency modification of liquids” (p=0.088). Finally, a significant difference was recorded in only 3/6 items of the efficacy scale, in particular “Ability to continue the meal without solicitations” (p=0.003), “Percentage of meal eaten” (p=0.001) and “Amount of food eaten” (p=0.002), while none of the items of the safety scale.

Discussion

The preliminary psychometric analysis of the MAS, a scale for the assessment of swallowing safety and efficacy during the meal, has been conducted. The results suggest that preliminary evidence of MAS validity and reliability, except for the internal consistency of the safety subscale. An adequate inter-rater agreement was found for all the items. A strong correlation was found with swallowing clinical assessment and swallowing outcome scales. The MAS seems to distinguish among different levels of performance in consuming a meal as well as to register improvements over time.

One hundred patients with dysphagia were involved in the validation process of the MAS. Swallowing disorders had different etiologies in the patients' group. It allowed testing the MAS on patients showing different type and different severity of swallowing impairment. Moreover, patients were recruited in two different clinical settings, a University acute-care hospital and a rehabilitation center. The heterogeneity of the population and the setting is of primary importance for the application of the MAS in several clinical settings and in patients with different pathologies [12, 22].

A Cronbach's alpha >0.70 was regarded as "good" internal consistency, at least in the early stage of research and for scales with fewer than 7 items [17, 23-24]. The Cronbach's alpha of the efficacy scale reached the recommended limit, with a value of α=0.858, while it was slightly below it for the safety scale, with an α=0.615. Therefore, subsequent revision of the MAS should focus on improvement of the safety scale's internal consistency. Cronbach's alpha is a measure of the correlation among the items of a scale. However, Cronbach's alpha is not only dependent on the magnitude of the items' correlation, but also on the number of items that are included in the scale [25]. The safety subscale includes only 4 items, compared to the 6 items of the efficacy subscale. Hence, a revision of the safety scale should focus on increasing the number of items. It may be achieved by 1) investigating comprehensiveness of the scale by a working group of experts; 2) performing a Rasch analysis to identify the level of difficulties that newly developed items should cover. Finally, as the value of Cronbach's alpha also depends on the sample size, the MAS should be tested on a higher number of patients.

A good inter-rater agreement is necessary for the clinical use of the assessment tool as it allows to compare the results obtained by different clinicians and for the research use in order to compare results

of different studies [25]. All items showed a desirable inter-rater agreement, suggesting that the MAS may be applied to both clinical and research practice.

Since no "gold standard" evaluation for assessing meal exists, criterion validity could not be investigated. Other scales aiming to assess patients while consuming a meal exist and were considered during the development study of the MAS [10], even though exhibit some limits when aiming to assess both safety and efficacy of meals. However, the only validated assessment tool for the meal, the McGill Ingestive Skills Assessment [22, 26] has not been translated and validated in Italian and, therefore, could not be used in the present study. Therefore, the relationship between the MAS and constructs with a known relationship to eating and drinking was investigated for testing concurrent validity. In particular, the MASA protocol and the ASHA NOMS swallowing scale were used, being currently adopted and validated tools for clinical evaluation of swallowing. The statistical analysis showed a strong correlation between MAS scales and both tools, slightly higher for the efficacy scale than for the safety scale. Indeed, in the ASHA NOMS scale, each level of the scale contains information on both safety and efficacy of swallowing (e.g., Level 5 corresponds to "Swallowing is safe with minimal diet restrictions […] All nutrition and hydration needs are met by mouth at mealtime). In the MASA, the efficacy of swallowing is not directly assessed, as a limited number of trial for each consistency is performed, while ~~a~~ great attention is given to the prerequisites of swallowing, such as alertness, cooperation, respiration, lip seal, tongue strength, and coordination. It can be speculated that these aspects play an important role on the ability of a person in completing a whole meal and can account for the strong correlation among the efficacy scale of the MAS and the MASA. For example, Namasivayam and colleagues have shown a statistically significant correlation between tongue strength, meal duration and food intake, with lower tongue strength associated with longer meal duration and lower food intake [27]. Moreover, although not directly assessing efficacy, it is intuitive that some of the items assessed in the MASA (e.g., "lip seal" or "oral preparation/transit") have an influence on those of the efficacy scale of the MAS (e.g., respectively "control of food leakage while chewing" and "oral preparation").

An essential property of an assessment tool is the ability to distinguish between different health states. A significant difference between subjects with dysphagia and subjects without dysphagia was found for

the safety and the efficacy scales in all age groups; therefore, the MAS seems to differentiate between individuals with and without dysphagia adequately. Differences between age groups were found for single items. The number of items showing significant differences between patients with and without dysphagia increased with the increasing of age. Moreover, a significant difference concerning the time the patient needed to end the meal was found only for the >75 years old group. Concerning signs of dysphagia, control of drooling, voice, fatigue and time needed to end the meal, we can suppose that the pathological mechanisms leading to dysphagia may have a higher impact on swallowing function in older patients than in younger patients, involving muscles already reduced in strength, stability and endurance because of the aging process. Indeed, the aging process contributes to a shift in muscle composition from faster to slower contracting muscle fibers' type [28]. As a result, swallowing speed decreases [28]. Pathological mechanisms associated with the onset of a disease (e.g., stroke) may further contribute to muscle wasting, impacting on strength and endurance. For instance, muscle atrophy and disuse generally affects slow contracting muscle fibers [29]. Longer meal duration is associated with a deterioration of swallowing safety and an increase in the sense of effort in older adults [30]. However, in the interpretation of the present data, it should be taken into account that the sample size of patients and control groups differ in each age group, which is a limit of the study. Significant differences were found for the items "Percentage of the meal eaten," "Amount of food eaten," "Patients desire to eat" in the 65-74 years old group and in the >75 years old group, but not in the 40-64 years old group. This is in accordance with the study of Serra-Prat et al., who investigated the risk of malnutrition in a cohort of persons aged 70 years and over; they reported a significantly higher incidence of malnutrition because of poor oral intake in elderly with oropharyngeal dysphagia than in elderly without dysphagia [31]. Moreover, the reduction in patient's appetite and oral intake may be correlated with the results of the item "Teeth." Indeed, as for the items mentioned above, a significant difference between patients and control groups were found for the item "Teeth" in the 65-74 years old group and in the >75 years old group, but not in the 40-64 years old group. Ortega et al. studied oral health in subjects aged over 70 and found that subjects with dysphagia showed a significantly higher prevalence of edentulism than subjects without dysphagia [32]. Concerns on the inclusion criteria used to recruit subjects without dysphagia may be raised. Indeed, as both hospitalized or non-hospitalized subjects were included in

Group 1, it comprises both healthy individuals and patients with diseases not interfering with swallowing. Diagnosis of the patients, as well as physicians and nursing reports on mealtime, were accurately analyzed to avoid the risk of enrolling patients with possible swallowing impairment. The choice of including hospitalized patients without dysphagia in Group 1 lies in the need to assess whether the MAS should be able to reflect the presence of a swallowing impairment regardless to other medical conditions with a possible influence on other factors related to eating. Based on the results of known-group validity, showing a statistically significant difference in nearly all the items, as well as a ceiling effect in patients of Group 1 in most of the remaining items, we are confident in excluding any risk of bias introduced by having recruited hospitalized patients in Group 1.

Changes in MAS scores across different age groups within healthy subjects were investigated. It is currently accepted that aging process reduces swallowing efficacy [33-35]; therefore, a decrease of meal safety and efficacy can be supposed as age progression as well. A statistically significant difference was found between different age groups for the items "Control of food leakage while chewing" and "Oral preparation." Hiramatsu et al. compared the effort required for swallowing during the meal in healthy old and young adults [36]. They found that tongue pressure and motor function of the lips are reduced by aging, in particular after meal consumption because of fatigue. Decreased tongue pressure may impact on the ability to form a bolus, thus increasing the time needed for oral preparation; reduced lip closure may lead to anterior spillage. A significant difference was also found for the items "Teeth" and "Amount of food." Tooth loss and poor oral intake are common problems in the elderly [37-38]. Moreover, it has been demonstrated that poor oral status increases difficulties in eating and decreases eating pleasure, thus leading to an increased risk of malnutrition [37]. Therefore, our findings are in accordance with data reported in the literature.

An assessment tool should be able to measure clinically significant variations in patient's performance over time, a property known as responsiveness. In the present study, this property was tested re-assessing patients with the MAS after the modification of diet recommendation. All patients in Group 3 evolved from a pureed diet to a soft food diet. The MAS was found to be able to register patient's improvement as the efficacy score significantly increased. Improvements of the efficacy score may be directly related to the type of diet. Soft foods are usually more palatable than homogenous pureed foods.

Studies have shown that both the pleasure of eating and the amount of food intake significantly decrease also in healthy subjects when a meal is served pureed compared to standard texture [39-40]. Thus, changes in the scores of the items "Ability to complete the meal without exhortations," "Percentage of the meal eaten," and "Amount of food eaten" may reflect these findings. Moreover, a significant increase was also found for those items of the *structures, functions, and activities influencing the meal* scale related to patients' independence in eating. Hence, the improvement of swallowing efficacy may also reflect the improvement of patients general conditions, leading for instance to an improvement of upper limbs' movement which allows the patient to feed himself independently. A study by Lin et al. have found that moderate dependency triples the likelihood of low food intake compared to independence in feeding [41]. Furthermore, a significant improvement in the item "Teeth" was observed as more patients wore dentures at the time of the second meal observation. The use of dentures significantly affects the efficacy of the oral phase of swallowing [42]. As expected the safety score and the total time needed to complete the meal did not significantly change; this seems to be reasonable assuming, as it was done in the present study, that the diet recommendation was decided on the basis of an accurate swallowing instrumental evaluation. Indeed, although the patients' swallowing function and general conditions were improved, the management of a soft food diet requires a more efficient swallowing mechanism for its preparation and deglutition compared to a pureed diet. Thus, no differences were found in those items as diet evolution followed patient evolution. A possible interpretation is that patients maintained a safe oral feeding, even if they extended the range of consistencies taken orally. Finally, no significant variations were found for the consistency of liquids' scores. The majority of the patients continued to drink thickened liquids even after diet modification. It is not surprising as it is well known that the safety in the management and swallowing of solid foods do not overlap the safety in the management and swallowing of liquids.

Limits of the present study are the lack of data on the intra-rater agreement and ~~of~~ a control of effect sizes, leading to a nonhomogeneous distribution of subjects with and without swallowing disorders in different age groups. Furthermore, data on the inter-rater agreement were gained only for the patients with dysphagia, but not for the healthy group. Moreover, even though swallowing disorders had different etiologies in the patients group, a large part of the participant sample was skewed towards

stroke, whereas other etiologies were only little represented. Therefore, MAS validation is still an ongoing process, and further studies should be conducted in order to overcome these limitations, as well as to describe MAS scores in different populations of patients (e.g. , frail elderly patients, head and neck cancer patients). The study on the MAS responsiveness may also be expanded to the study of the tool ability to measure modification of meal safety and efficacy in patients with dysphagia on free oral diet before and after swallowing assessment and diet restriction. Moreover, the correlation between MAS and nutritional status' indexes, and between MAS and general and swallowing-related QOL should be investigated. Instrumental assessment of swallowing through videofluoroscopy (VFS) or fiberoptic endoscopic evaluation of swallowing (FEES) represent the "gold standard" for the evaluation of swallowing safety and efficacy [43]. Hence, it would be interesting to study the correlation between MAS scores and findings from instrumental assessment during meal consumption. However, ethical issues related to x-ray exposition in VFS and discomfort due to the flexible endoscope in FEES make it not applicable. Lastly, the concurrent validity of the MAS against the McGill Ingestive Skills Assessment, another assessment tool for meal validated in English and Dutch, may be investigated after an adequate translation process and validation in Italian.

Conclusion

This study showed preliminary evidence of validity and reliability of the MAS for the assessment of swallowing safety and efficacy during the meal in patients with swallowing disorders of different etiology and severity. Its application in clinical and research practice may be beneficial to measure outcomes of swallowing treatments, to detect changes over time, to compare different populations, and to estimate the risk of swallowing complications. Further studies are necessary to 1) improve internal consistency of the MAS by assessing its comprehensiveness and conducting a Rasch analysis; 2) complete the validation process of the scale, according to COSMIN checklist [19], 3) investigate the predictive value of the MAS in appraising swallowing complications.

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Table 1: Demographic and clinical characteristics of the sample

		Group 1 (n = 100)	*Group 2 (n = 100)*	*Group 3 (n = 36)*
Age		58 (18-91)	81 (37-96)	78.5 (51-92)
Sex	**M**	30/100 (30%)	56/100 (56%)	23/36 (63.9%)
	F	70/100 (70%)	44/100 (44%)	13/36 (36.1%)
Diet	**C1**	0/100 (0%)	80/100 (80%)	36/36 (100%)
	C2	0/100 (0%)	16/100 (16%)	0/36 (0%)
	C3	0/100 (0%)	3/100 (3%)	0/36 (0%)
	C4	100/100 (100%)	1/100 (1%)	0/36 (0%)
Pathology	**Ischemic stroke**	-	50/100 (50%)	19/36 (52.8%)
	Hemorrhagic stroke	-	20/100 (20%)	10/36 (27.7%)
	PD	-	11/100 (11%)	4/36 (11.1%)
	Vasculopathy	-	5/100 (5%)	0/36 (0%)
	Encephalopathy	-	2/100 (2%)	0/36 (0%)
	Encephalitis	-	1/100 (1%)	0/36 (0%)
	Severe acquired injury	-	3/100 (3%)	1/36 (2.8%)
	NHL	-	1/100 (1%)	0/36 (0%)
	AD	-	1/100 (1%)	0/36 (0%)
	Lower motor neuron disease	-	1/100 (1%)	1/36 (2.8%)
	Glossectomy	-	1/100 (1%)	0/36 (0%)
	Cranial nerve palsy	-	1/100 (1%)	1/36 (2.8%)
	Dysphagia of unspecified etiology	-	3/100 (3%)	0/36 (0%)

Footnotes: C1 = homogenous puree consistency diet; C2 = soft food diet; C3 = normal diet except for dual consistencies, friable and filamentous foods; C4 = normal diet; PD = Parkinson's disease; NHL = Non-Hodgkin lymphoma; AD = Alzheimer's disease

Note: Values are median (range), n/N (%), or as otherwise indicated.

Table 2: MAS' inter-rater agreement

	AD index
STRUCTURES, FUNCTIONS, AND ACTIVITIES INFLUENCING THE MEAL	
Linguistic comprehension	0.04
Attention	0.07
Short-term memory	0.10
Patient's compliance with alimentary instructions	0.17
Patient's desire to eat	0.07
Head-to-trunk control	0.06
Independence in eating	0.02
Ability to take food to mouth	0.04
Control of drooling	0.02
Teeth	0.01
Voluntary cough	0.05
Voice quality	0.05
ENVIRONMENTAL FACTORS INFLUENCING THE MEAL	
Food consistency	0.03
Bolus size	0.02
Liquids consistency	0.02
Possibility to rely on caregiver	0.01
SWALLOWING SAFETY DURING THE MEAL	
Oral control of the bolus	0.09
Residue in the oral cavity after swallowing	0.06
Presence of cough or throat cleaning	0.01
Voice quality post-swallow	0.09
SWALLOWING EFFICACY DURING THE MEAL	
Control of food leakage while chewing	0.09
Oral preparation	0.08
Ability to complete the meal without exhortations	0.11
Fatigue	0.14
Percentage of the meal eaten	0.05
Amount of food eaten	0.07

Table 3: Comparison of the MAS scores between subjects without dysphagia (group 1) and subjects with dysphagia (group 2) in each age group

	40-64 years			*65-74 years*			*>75 years*		
	Group 1 (n = 35)	**Group 2 (n = 9)**	***p***	**Group 1 (n = 14)**	**Group 2 (n = 17)**	***p***	**Group 1 (n = 27)**	**Group 2 (n = 73)**	***p***
STRUCTURES, FUNCTIONS, AND ACTIVITIES INFLUENCING THE MEAL									
Linguistic comprehension	0 (0-0)	2 (0-3)	0.010*	0 (0-0)	1 (0-3)	<0.001*	0 (0-0)	2 (0-3)	<0.001*
Attention	0 (0-0)	1 (0-2)	0.010*	0 (0-0)	1 (0-3)	<0.001*	0 (0-1)	1 (0-3)	<0.001*
Short-term memory	0 (0-0)	1 (0-3)	0.010*	0 (0-1)	1 (0-3)	<0.001*	0 (0-1)	2 (0-3)	<0.001*
Patient's compliance with alimentary instructions	0 (0-1)	1 (0-3)	<0.001*	0 (0-0)	1 (0-3)	<0.001*	0 (0-0)	1 (0-3)	<0.001*
Patient's desire to eat	0 (0-0)	0 (0-2)	0.627	0 (0-1)	1 (0-3)	0.026*	0 (0-1)	1 (0-3)	<0.001*
Head-to-trunk control	0 (0-0)	0 (0-1)	0.627	0 (0-0)	0 (0-1)	0.053	0 (0-0)	1 (0-3)	<0.001*
Independence in eating	0 (0-0)	2 (0-3)	<0.001*	0 (0-0)	3 (0-3)	<0.001*	0 (0-0)	3 (0-3)	<0.001*
Ability to take food to mouth	0 (0-1)	1 (0-3)	0.010*	0 (0-1)	1 (0-3)	<0.001*	0 (0-1)	2 (0-3)	<0.001*
Control of drooling	0 (0-0)	0 (0-3)	0.314	0 (0-0)	0 (0-3)	0.597	0 (0-0)	0 (0-3)	0.005*
Teeth	0 (0-0)	0 (0-1)	0.132	0 (0-1)	1 (0-3)	0.023*	0 (0-1)	1 (0-3)	<0.001*
Voluntary cough	0 (0-0)	2 (0-3)	<0.001*	0 (0-0)	1 (0-3)	<0.001*	0 (0-0)	1 (0-3)	<0.001*
Voice quality	0 (0-1)	0 (0-3)	0.373	0 (0-1)	1 (0-3)	<0.001*	0 (0-1)	1 (0-3)	<0.001*
ENVIRONMENTAL FACTORS INFLUENCING THE MEAL									
Food consistency	0 (0-0)	3 (1-3)	<0.001*	0 (0-0)	3 (1-3)	<0.001*	0 (0-0)	3 (0-3)	<0.001*
Bolus size	0 (0-0)	1 (0-3)	0.010*	0 (0-0)	2 (0-3)	<0.001*	0 (0-0)	2 (0-3)	<0.001*
Liquids consistency	0 (0-0)	3 (0-3)	<0.001*	0 (0-0)	3 (0-3)	<0.001*	0 (0-0)	3 (0-3)	<0.001*
Possibility to rely on caregiver	0 (0-0)	0 (0-3)	0.132	0 (0-0)	3 (0-3)	<0.001*	0 (0-0)	3 (0-3)	<0.001*
SWALLOWING SAFETY DURING THE MEAL	0 (0-2)	3 (1-7)	<0.001*	0 (0-3)	1 (0-6)	<0.032*	0 (0-3)	3 (0-6)	<0.001*
Oral control of the bolus	0 (0-1)	0 (0-1)	0.165	0 (0-2)	0 (0-1)	0.860	0 (0-1)	0 (0-2)	0.013*
Residue in the oral cavity after swallowing	0 (0-2)	1 (0-1)	0.018*	0 (0-1)	0 (0-2)	0.215	0 (0-1)	1 (0-3)	<0.001*
Presence of cough or throat cleaning	0 (0-1)	1 (0-3)	0.005*	0 (0-1)	0 (0-2)	0.215	0 (0-1)	1 (0-3)	0.011*

Voice quality post-swallow	0 (0-1)	2 (0-3)	0.002*	0 (0-1)	0 (0-3)	0.173	0 (0-1)	1 (0-3)	<0.001*
SWALLOWING EFFICACY DURING THE MEAL	0 (0-1)	1.5 (0-6)	0.001*	0 (0-2)	6 (0-11)	<0.001*	0 (0-3)	7 (0-14)	<0.001*
Control of food leakage while chewing	0 (0-0)	0 (0-2)	0.314	0 (0-0)	0 (0-2)	0.100	0 (0-1)	1 (0-3)	<0.001*
Oral preparation	0 (0-1)	1 (0-1)	0.021*	0 (0-1)	1 (0-2)	0.006*	0 (0-1)	1 (0-3)	<0.001*
Ability to complete the meal without exhortations	0 (0-0)	0 (0-2)	0.314	0 (0-0)	0 (0-2)	0.026*	0 (0-0)	1 (0-3)	<0.001*
Fatigue	0 (0-0)	0 (0-1)	0.132	0 (0-0)	1 (0-3)	<0.001*	0 (0-1)	1 (0-3)	<0.001*
Percentage of the meal eaten	0 (0-1)	0 (0-1)	0.710	0 (0-1)	1 (0-3)	0.015*	0 (0-2)	2 (0-3)	<0.001*
Amount of food eaten	0 (0-0)	0 (0-0)	1	0 (0-0)	1 (0-3)	0.012*	0 (0-1)	1 (0-3)	<0.001*
TIME (minutes)	20 (15-30)	25 (15-40)	0.249	25 (15-40)	30 (15-60)	0.084	25 (15-40)	30 (10-60)	0.024*

* $p<.05$

Notes: Results are reported as median (range)

Table 4: Results of Kruskal-Wallis test across age groups within Groups 1

	18-39 (n= 24)	***40-64 (n= 35)***	***65-74 (n= 14)***	***>75 (n= 27)***	***p***
STRUCTURES, FUNCTIONS, AND ACTIVITIES INFLUENCING THE MEAL					
Linguistic comprehension	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	1
Attention	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-1)	0.440
Short-term memory	0 (0-0)	0 (0-0)	0 (0-1)	0 (0-1)	0.326
Patient's compliance with alimentary instructions	0 (0-0)	0 (0-1)	0 (0-0)	0 (0-0)	0.603
Patient's desire to eat	0 (0-0)	0 (0-0)	0 (0-1)	0 (0-1)	0.326
Head-to-trunk control	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	1
Independence in eating	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	1
Ability to take food to mouth	0 (0-0)	0 (0-0)	0 (0-1)	0 (0-1)	0.326
Control of drooling	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	1
Teeth	0 (0-0)	0 (0-0)	0 (0-1)	0 (0-1)	0.048*
Voluntary cough	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	1
Voice quality	0 (0-0)	0 (0-1)	0 (0-1)	0 (0-1)	0.659
ENVIRONMENTAL FACTORS INFLUENCING THE MEAL					
Food consistency	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	1
Bolus size	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	1
Liquids consistency	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	1
Possibility to rely on caregiver	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	1
SWALLOWING SAFETY DURING THE MEAL	0 (0-1)	0 (0-2)	0 (0-3)	0 (0-3)	0.041*
Oral control of the bolus	0 (0-0)	0 (0-1)	0 (0-2)	0 (0-1)	0.285
Residue in the oral cavity after swallowing	0 (0-0)	0 (0-2)	0 (0-1)	0 (0-1)	0.055
Presence of cough or throat cleaning	0 (0-1)	0 (0-1)	0 (0-1)	0 (0-1)	0.106
Voice quality post-swallow	0 (0-0)	0 (0-1)	0 (0-1)	0 (0-1)	0.518
SWALLOWING EFFICACY DURING THE MEAL	0 (0-0)	0 (0-1)	0 (0-2)	0 (0-3)	<0.001*
Control of food leakage while chewing	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-1)	0.041*
Oral preparation	0 (0-0)	0 (0-1)	0 (0-1)	0 (0-1)	0.014*
Ability to complete the meal without exhorations	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	1
Fatigue	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-1)	0.141
Percentage of the meal eaten	0 (0-0)	0 (0-1)	0 (0-1)	0 (0-2)	0.168
Amount of food eaten	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-1)	0.041*
TIME (minutes)	20 (15-30)	20 (15-30)	25 (15-40)	25 (15-40)	0.191

*$p<.05$

NOTE: Data are reported as median and range

Table 5: Comparison of the MAS scores obtained by group 3 (n = 36) at the first assessment and at the second assessment

	1st assessment		***2nd assessment***		***p***
	median	*range*	*median*	*range*	
STRUCTURES, FUNCTIONS, AND ACTIVITIES INFLUENCING THE MEAL					
Linguistic comprehension	1	0-3	1.5	0-3	0.822
Attention	1	0-2	1	0-3	0.334
Short-term memory	1	0-3	1	0-3	0.210
Patient's compliance with alimentary instructions	1	0-3	1	0-3	0.384
Patient's desire to eat	0	0-3	0	0-2	0.053
Head-to-trunk control	0	0-1	0	0-1	0.034*
Independence in eating	3	0-3	2	0-3	0.002*
Ability to take food to mouth	1.5	0-3	1	0-2	<0.001*
Control of drooling	0	0-3	0	0-2	0.031*
Teeth	1	0-3	0	0-3	0.005*
Voluntary cough	1	0-3	1	0-3	0.199
Voice quality	1	0-3	1	0-3	0.088
ENVIRONMENTAL FACTORS INFLUENCING THE MEAL					
Food consistency	3	2-3	2	2-2	<0.001*
Bolus size	3	0-3	0.5	0-3	<0.001*
Liquids consistency	3	3-3	3	0-3	0.083
Possibility to rely on caregiver	3	0-3	3	0-3	0.005*
SWALLOWING SAFETY DURING THE MEAL	3	0-6	3	0-7	0.916
Oral control of the bolus	0	0-2	1	0-2	0.149
Residue in the oral cavity after swallowing	1	0-3	1	0-3	0.503
Presence of cough or throat cleaning	1	0-3	0	0-2	0.056
Voice quality post-swallow	0	0-3	0	0-2	0.317
SWALLOWING EFFICACY DURING THE MEAL	5	0-11	3	0-7	0.001*
Control of food leakage while chewing	0	0-3	0.5	0-2	0.617
Oral preparation	1	0-2	1	0-2	0.373
Ability to complete the meal without exhortations	0.5	0-3	0	0-2	0.003*
Fatigue	1	0-2	1	0-2	0.059
Percentage of the meal eaten	1	0-3	0	0-2	0.001*
Amount of food eaten	1	0-3	0	0-2	0.002*
TIME (minutes)	35	10-60	40	20-50	0.056

**p<.05*