THE MEALTIME ASSESSMENT SCALE (MAS): I. DEVELOPMENT OF A SCALE FOR MEAL ASSESSMENT

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Abstract

Aims. Safety and efficacy of swallowing in instrumental assessment may not overlap safety and efficacy of swallowing during meal, as personal and environmental factors can influence the performance. The study aims to develop a scale to assess safety and efficacy of swallowing during meal.

Methods. A working group discussed the latent construct, target population and purposes of the scale. Items were generated based on the International Classification of Functioning framework. Thirty-nine items were created and divided into 4 subscales. A pilot test was conducted on 40 patients, assessed by a speech and language therapist (SLT) while consuming a meal. In 10 patients, meal observation was simultaneously conducted by 2 SLTs to assess inter-rater agreement. Criteria for identification of items candidate for exclusion or revision were defined.

Results. Twelve items were "not assessable" in at least 10% of the patients. An inter-item correlation $r>0.7$ was found in 2 cases and a discrimination index equal to 0 in 7/22 items. Inter-rater agreement was satisfactory. After items revision, the Mealtime Assessment Scale (MAS) was created, including 26 items divided into 4 subscales.

Conclusion. The MAS was developed to assess the safety and efficacy of swallowing during meal. A validation process should be conducted.

Introduction

Swallowing disorder is defined as an alteration in the bolus transit from mouth to stomach [1] and represents a common clinical condition in both acute and long-term care settings [2-3]. Several conditions can interfere with the swallowing process, such as neurological disorders and damages, oncological diseases and the aging process [4]. Swallowing disorders may reduce patients and caregivers' quality of life (QOL) [5]; moreover, swallowing disorders may lead to severe complications, such as aspiration pneumonia, malnutrition, and dehydration [6]. Therefore, the identification and the accurate assessment of patients at risk for swallowing disorders are of primary importance, to reduce the complications and to improve QOL.

Several bedside screening tools have been validated to identify patients at risk for aspiration or unsafe swallowing [7-8]. Standard protocols for clinical assessment have been introduced in daily practice [9]. Videofluoroscopy (VFS) and fiberoptic endoscopic evaluation of swallowing (FEES) are considered the two gold standard methods of instrumental assessment: bolus flow measures have been developed [10-11], and both methods demonstrated to have a good and comparable validity and reliability [12-13]. Finally, the growing attention to the impact of a specific impairment on patient's daily living has led to the introduction of self-evaluation and swallowing-related QOL questionnaires, such as the SWAL-QOL and the EAT-10 [5, 14]. In summary over the last decades, several tools for both clinical and instrumental assessment of swallowing disorders have been developed. Quantification of swallowing impairment relies on two major components: safety and efficiency [15-17]. Safety refers to a bolus transfer without penetration or aspiration into the airway, and its impairment health effect is aspiration pneumonia; efficiency refers to a bolus transfer without residue, and its impairment health effect is the nutritional compromise.

In the management of patients with swallowing disorders, the goal of treatment is not only improving swallowing function but also enhancing eating as an activity of daily living. With

the introduction of the International Classification of Functioning, Disability and Health (ICF), the World Health Organization (WHO) has stressed the importance of considering, and therefore assessing, not only the body structures and functions, but also the activity, the participation and environmental and personal factors of a person [18]. Currently used clinical and instrumental assessment tools aim to investigate only the swallow physiology and pathophysiology; little attention has been paid to the related activities: eating and drinking and, in particular, eating and drinking during a meal. There are several differences between a swallow and a meal assessment; swallowing assessment is usually shorter than meals, it is carried out in standard conditions, and it allows testing only a few boluses for a limited number of consistencies [19]. Besides, during VFS and FEES, patients may be asked to assume an unnatural position and are controlled to maintain the requested position during the assessment; patients are also asked to eat foods with unfamiliar taste and texture [20]. Moreover, the safety and efficacy of a single swallowing act do not overlap with the safety and efficacy of swallowing during the meal, like other personal and environmental factors (e.g., setting, food variability, fatigue, eating desire, eating autonomy) can influence these aspects during mealtime. Previous studies showed that factors not strictly related to swallowing disorder impact on the management and outcome of patients with dysphagia. Steele et al. examined eating-related difficulties in a multicare level facility for elderly persons; they reported that 87% of residents experienced mealtime difficulties, but only 68% presented signs of swallowing impairment [21]. In two studies, Langmore et al. investigated the factors that contribute to the development of aspiration pneumonia in elderly patients [22-23]. The role of swallowing disorders was controversial: indeed, the presence of dysphagia was found to be a significant risk factor for pneumonia only in the study of 2002, but not in the study of 1998. The difference in findings may be attributed to the different populations (patients from 3 different settings in the study of 1998 vs. only patients in nursing home in the study of 2002)

and the different modality used to identify the presence of a swallowing impairment (instrumental assessment vs. observation of the patient eating, respectively). Conversely, both studies highlighted that dependence on eating is a significant predictor. Finally, factors other than swallowing disorders per se impact on treatment prescription; one of these is compliance with clinician prescriptions, as diet recommendation and swallowing compensation strategies. Patients with swallowing disorders with a modified oral diet were demonstrated to show a high level of non-compliance with speech and language pathologist's (SLP) recommendations [24-25]. Therefore, all these data stress the need to develop valid and reliable tools to assess swallowing during meals.

In 2011, Hansen et al. conducted a review of assessment tools measuring elderly dysphagic patient's performance in eating [26]. They identified only two assessment tools demonstrating adequate psychometric properties, the McGill Ingestive Skills Assessment (MISA) [20, 27-28] and the Minimal-Eating Observation Form-version II (MEOF-II) [29]. The MISA is a bedside assessment tool for the evaluation of the functional ingestive skills of elderly persons with neurologic impairment. It was initially developed for occupational therapists (OTs) in Canada and afterwards translated, adapted and validated in Danish [30-32]. The MEOF-II is a screening tool typically carried out by nurses that aim to identify meal-time problems among elderly (>65 years) inpatients. The MEOF-II was further developed by combining items describing meal-time problems with items detecting classic signs of undernutrition. The results of these subsequent studies lead to the development of the Minimal Eating Observation and Nutrition Form-version II (MEONF-II) [33-34]. To the best of our knowledge, no other tools for the assessment of meals have been validated. However, although the MISA and the MEOF-II show a good validity and reliability, some limitations can be identified when aiming to assess both the safety and the efficacy of swallowing during the meal. Indeed, being a screening tool, the MEOF-II is made up of only 9 yes-no items, which meet the rapidity criteria but make it

little value for a complete assessment of patients' performance during the meal. Concerning the MISA, it mainly focuses on safety and independence, while the efficacy of swallowing during the meal is investigated only by few items, limiting the ability of the tool to appraise the risk of nutritional and respiratory complications.

Therefore, the aims of this study were to (i) develop a scale to assess swallowing safety and efficacy during a meal; (ii) carry out a pilot study to test the scale; (iii) revise the scale. The development of a valid and reliable scale would allow the assessment of swallowing during the activities of eating and drinking, which should be considered one of the goals of a successful management of patients with swallowing disorders. Swallowing performance during meal could be used as an outcome measure for any swallowing treatment, including surgery, diet modification, postures and maneuvers, sensori-motor training or neuromodulation. Finally, swallowing assessment during meal might more strongly correlate with patients and caregivers' QOL and better predict dysphagia complications than swallowing assessment during instrumental evaluation. Indeed, the ability of instrumental assessment in predicting the risk of aspiration pneumonia has been demonstrated in both neurological [35] and oncological patients [36], while no predictive study has been conducted concerning nutritional complication. Meal observation, assessing a higher number of swallowing acts [37] and including information on factors such as feeding dependency (predicting the risk of aspiration pneumonia) [22-23] and meal duration (correlating with food intake) [38], may be a stronger predictor of swallowing complications.

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. This first part of the study was divided into three stages: i) scale development; ii) pilot study; iii) scale revision.

Conceptual framework

A working group composed of 2 phoniatricians and 4 SLTs working with individuals with dysphagia in an acute care hospital (inpatient and outpatient care) and a rehabilitation center in Northern Italy was created for the development of the scale.

During the first meeting, the latent construct of the scale was discussed. The latent construct is a variable of an individual that cannot be measured directly but can be assessed by measuring related behaviors, defined by sets of standardized item [39]. Moreover, the latent variable can be influenced by the characteristics of the individual and the environment. The safety and efficacy of swallowing during the meal was unanimously identified as the latent construct of the scale. The definition of the concepts of safety and efficacy established by the group of Clavé in the development of the Volume-Viscosity Swallow Test (V-VST) [15] was assumed. Safety is defined as "*the patient's ability to ingest all needed calories and water with no respiratory complications*," while efficacy as "*the patient's ability to ingest all the calories and water he or she needs to remain adequately nourished and hydrated*" [16]. In the original definition of swallowing safety the concept of both efficacy (i.e., the ability to produce the desired result) and efficiency (i.e., the ability to produce the result without wasting time or effort) are incorporated.

The working group individuated as target population all the patients who consume a meal orally regardless of the diagnosis and the setting.

The purposes of the scale were discussed as well, both for clinical practice and research. The primary purpose is the evaluation of swallowing during the meal; and the secondary purpose is the prediction of complications. Potential clinical applications of the scale are: 1) measuring changes of swallowing safety and efficacy during meal over time; 2) assessing swallowing treatments' outcomes regarding the impact on the activities of daily living; 3) appraising the risk of pulmonary and nutritional complications. Concerning research, the potential applications of the scale are: 1) comparing swallowing safety and efficacy during meal among different populations or within the same population at different moments; 2) assessing treatments' efficacy regarding impact on the activities of daily living.

Scale development

Literature review. A review of the literature was conducted between December 2010 and February 2011 to identify already developed scales for the assessment of meals. A PubMed and PsycINFO search was conducted, and national sector-based journals were consulted. In the free-text search the following terms were used and combined through the boolean operator AND: safety OR safe, efficacy OR efficiency OR efficient, meal OR mealtime, swallowing OR deglutition OR ingestion OR eating, dysphagia OR "deglutition disorder" OR "deglutition disorders," assessment OR evaluation. In PubMed the MeSH headings *eating*, *deglutition* and *deglutition disorders* were searched, while in PsycINFO the subject heading thesaurus *ingestion*, *swallowing* and *dysphagia* were used. The records were firstly selected based on the title, then on the abstract and lastly on the full-text. Moreover, the reference lists of included studies were screened for the presence of any novel citations, which were not identified during the initial search. Four tools for the assessment of the patients during mealtime were identified: the Swallowing Assessment Checklist [40], the McGill Ingestive Skills Assessment (MISA) [20], the *Griglia di Osservazione del comportamento durante il pasto del paziente disfagico*

[41] and the Minimal-Eating Observation Form-version II (MEOF-II) [29]. The Swallowing Assessment Checklist is an instrument of the "Swallowing…on a Plate" (SOAP) training program, developed to teach nurses how to manage patients with dysphagia in nursing homes properly. Filled in by a nurse during the patient's meal, the checklist assesses the oral phase, the pharyngeal phase, the posture, the level of independence in eating and cognitive behaviors influencing swallowing. No data on validity and reliability are available. The MISA is a valid and reliable bedside assessment tool for the evaluation of the functional ingestive skills of elderly persons with neurologic impairment. A 3-point ordinal scale is used to score 43 items, divided into 5 domains: positioning, self-feeding, solid ingestion, liquid ingestion, texture management. The *Griglia di Osservazione del comportamento durante il pasto del paziente disfagico* ("Mealtime observation checklist for dysphagic patients") is an observation chart for clinical assessment of dysphagia during the meal in Italian. This checklist is divided into two parts: in the first one, demographic information and medical history of the patient are recorded, while the second part includes a checklist of aspects to assess during mealtime. The checklist is made up of 41 yes-no or multiple choices items; moreover, the time needed by the patients to end the meal must be recorded. The MEOF-II is a nursing screening tool for the identification of patients with eating difficulties. It is made up of 9 items dichotomously rated from the ability of the patient to manage without problems different aspects related to three domains: ingestion, deglutition and energy and appetite.

Item generation. Item generation began in March 2011. Items have been developed and operationalized in the Italian language. A reflective model was used for scale development. In a reflective model, the latent construct causes its visible indicators or items [42-43]. Item generation was firstly based on the ICF. Two previous papers reporting ICF codes related to dysphagia were consulted [44-45]. Twenty ICF codes from the paper of Threats and 17 ICF codes from the study of Nund et al. were considered relevant for the assessment of meal

assumption by the working group, for a total of 24 ICF codes as some ICF codes were the same in the two papers. Moreover, the working group added 8 additional ICF codes which were not included in the studies mentioned above. Therefore, 32 ICF codes were ultimately identified for item generation (Table 1). In particular, 20 codes belonged to Body functions, 5 codes to Activities and Participation, 7 codes to Environmental Factors. No code in the Body structures domain was identified as the assessment of structures is part of the purposes of clinical assessment, but not of mealtime observation. Furthermore, the reason beyond the small number of codes related to Activities and Participation is that the scale does not claim to assess the social impact of dysphagia concerning participation restriction.

- *Table 1 approximately here* -

Based on the 32 ICF codes, 36 items were formulated. Afterwards, the working group assessed the comprehensiveness of the items and, based on the clinical experience, decided to add 3 items ('Patient's compliance with alimentary instructions,' 'Bolus size' and 'Time period between bites') and to record the total time needed to complete the meal.

The items were grouped into 4 subscales: functions and activities influencing the meal, environmental factors influencing the meal, swallowing safety during the meal, swallowing efficacy during the meal. The subscale *functions and activities influencing the meal* contained the items related to mental functions, voice functions, neuromusculoskeletal and movement-related functions and activities other than *eating* and *drinking* which are not strictly connected with swallowing but may impact on its safety and efficacy during the mealtime. Items related to environmental factors influencing swallowing performance during the meal (e.g., caregiver, food, and liquid characteristics) were allocated to the *environmental factors influencing the meal* subscale and distinguished according to the fact that the factor analyzed by the item could be a facilitator or a barrier to the safety and efficacy of swallowing during the meal. Items assessing safety and efficacy of swallowing during the meal were divided into the subscales

swallowing safety during the meal and *swallowing efficacy during the meal*, respectively. The working group unanimously accepted items allocation to the subscales. The 39 items divided into the 4 subscales are reported in Table 2. Items are reported both in Italian (original items) and in English to help the reader in understating the scale; no back-translation process was performed.

- *Table 2 approximately here -*

Scoring development. The working group discussed the scoring of the items and decided to assign the same number of scoring categories to all the items. Moreover, group members agreed to use an even number of scoring categories so that no neutral category exists and the raters would be forced to choose between either side of a moderate level of functioning. Current evidence suggests that generally, people are unable to discriminate much beyond seven levels [46]. However, the use of only 2 scoring categories would lead to a loss of information being less than the rater's ability to discriminate, while using 6 scoring categories was challenging to give a label to each level. According to the ICF classification, it was decided that a higher score would be representative of a more critical problem in the observed variable. Therefore, a 4-point Likert scale, ranging from 0 (normal) to 3 (severely deviant), was used to score each item of the subscales *functions and activities influencing the meal*, *swallowing safety during the meal* and *swallowing efficacy during the meal*. Concerning the scale *environmental factors influencing meal*, the 4-point scoring system was maintained, but the sign + or – was associated to the number according to the fact that the factor analyzed in the item could be considered a facilitator or a barrier to swallowing performance during the meal. An operational definition was given for each score, to reduce the subjectivity of the scoring system (e.g. for the bolus size a score of 0 corresponded to a tablespoon, a score of 1 to a half tablespoon, a score of 2 to a teaspoon, a score of 3 to a half tablespoon). Moreover, the *Not assessable (N.A.)* box was added to be crossed in case that an item was not assessable. The working group decided not to

sum the scores of the items from the scales *body functions and activities influencing meal* and *environmental factors influencing meal* because of the clear multidimensionality of these two scales, but their items can be used to interpret the scores of the following two scales. Two scores (a safety score and an efficacy score) resulted from the sum of the scores of the items from the *swallowing safety during the meal* and *swallowing efficacy during the meal* scales; the higher the scores, the more reduced the safety or the efficacy of swallowing during meal. For both the scales, the score ranged from 0 to 33. A percentage score could also be calculated to nullify the impact of not assessable skills, using the following proportion: $Total\ score : [117 - (3 * number\ of\ N.A.items)] = x : 100$. The time the patient needed to end the meal had to be recorded.

Overall, scale development required seven meetings between March and April 2011. The scale was named "Mealtime assessment scale" (MAS). An instruction manual was developed to train the staff in the conduction of the assessment.

Pilot study

The developed protocol was tested on 40 patients between May and July 2011 in a rehabilitation center and a University Hospital of Northern Italy. Inclusion criteria were: age over 18, hospitalized, the presence of swallowing disorder in a previous instrumental or clinical assessment. The patients' sample is described in Table 3.

- *Table 3 approximately here* -

Each patient was assessed during lunchtime using the MAS by a SLT who was not part of the working group for item development and was instructed to use the scale by reading the developed manual. A specific setting of the evaluation was not established for each patient, and they were assessed where they usually ate meals. Patients were not asked to assume any particular position; some patients already used compensation postures or maneuvers. The

whole meal was observed. Ten out of 40 patients were assessed during the same meal by a second SLT who independently scored the MAS to test its inter-rater agreement.

Statistical analysis. Results are reported as median and range or absolute and relative frequencies. Statistical analysis was performed using IBM Statistics SPSS® version 20.0 for Windows software (SPSS Inc, Chicago, IL). The 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. Moreover, Cronbach's alpha without an item was computed to identify items to be removed to improve internal consistency. A Cronbach's alpha >0.70 was regarded as "good" internal consistency [47-49]. Corrected item-to-total correlation was calculated; ultimate item-to-total correlation was considered for values between 0.30 and 0.70 [50-51]. Non-parametric Spearman correlation test was used to assess inter-item correlation. An inter-item correlation above 0.70 suggests that item are redundant (Kline, 1979). Significance was set for $p<0.05$. 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 [52]. A discrimination index was calculated for each item of the subscales *swallowing safety during the meal* and *swallowing efficacy during the meal*. The discrimination index is the difference between the number of individuals with a total score above the median who scored positive (2 or 3) on the item and the number of individuals with a total score below the median who scored positive on the item divided by the number of individuals above the median. The discrimination index ranges from -1 to +1; values of 0.20 or above are considered desirable, and values of 0.40 or above are regarded as high [53]; a negative discrimination index suggests the need of item revision.

Scale revision

Based on the pilot study results, items were collegially revised by the working group. Criteria for identification of items candidate for exclusion or revision were: 1) percentage of N.A. higher than 10%; 2) increase of the Cronbach's alpha without the item; 3) item-to-total correlation lower than 0.30; 4) inter-item correlation $r>0.7$; 5) inter-rater agreement with an AD index >0.66; 6) negative discrimination index or equal to 0; 7) variance in the scores equal to 0.

Results

Pilot study

Cronbach' alpha was α=-0.088 for the safety scale and α=0.660 for the efficacy scale. The items *presence of cough or throat cleaning with dual* consistencies, *food loss through the* cannula, *liquid loss through the cannula* and *velopharyngeal competence* were not included in the analysis because of the absence of variance between scores or of the high number of not assessable items. Tables 4 and 5 report Cronbach's alpha without the item and item-to-total correlation for the safety and the efficacy scales, respectively. Table 6 shows median scores and range obtained on the MAS by the patients included in the pilot study; absolute frequency and percentage of not assessable items are also reported as well as AD index values for inter-rater agreement and the discrimination indexes. Twelve items were not assessable in at least 10% of the patients. The AD index was <0.66 for all the items, except for 4/39 items for which it was not computable because of the high frequency of not assessable items. Discrimination index was not computable in 3/11 items of the *swallowing safety during the meal* subscale because of the high prevalence of N.A. answers. No items showed a negative discrimination index and a value equal to 0 was found in 2/11 items of the *swallowing safety during the meal* subscale and 5/11 items of the *swallowing efficacy during the meal* subscale.

Table 4 approximately here -

An inter-item correlation r>0.7 was found in 2 cases. The item "Swallowing medicines" and the item "Alternative feeding methods" showed a correlation of r=0.77 (p=0.003). The item "Patient's desire to eat" strongly correlated with the item "Ability to continue the meal without solicitations" (r=0.92, p<0.001).

Scale revision

The working group discussed the items that were candidates for exclusion or revision based on the criteria previously defined.

Eleven items were removed:

- 6 items which were frequently not assessable (*liquids delivery method, oral medications delivery method, reflexive cough quality, time period between bites, food loss from the cannula, liquid loss from the cannula*); moreover the item *reflexive cough quality* was removed to improve the Cronbach's alpha of the *safety* scale
- the item *responsiveness* because of the impossibility to conduct a meal observation in case the item was assigned a high score
- the items *setting* and *alternative feeding methods* because they were judged to be improper to score and were maintained in a separate section without a scoring system as variables to be contemplated in the scores interpretation
- the item *velopharyngeal competence* because it scored 0 in all patients
- the item *shortness of breath while eating* because of the high item-item correlation with *fatigue* ($r=0.66$; $p<0.001$).

Other items were revised. Revisions mainly consisted of 1) rephrasing the items and the operational definitions of the scoring levels, using a more specific and univocal terminology and defining, when possible, exact numerical references, such as the frequency of occurrence of a specific behavior; 2) improving the definition of what each item assesses in the instruction manual; 3) unifying items.

Functions and activities influencing the meal. Five items (*linguistic comprehension, attention, memory, patient's compliance with alimentary instructions, head-to-trunk control*) were better defined in the instruction manual; indeed, it was specified that these aspects should be rated

based on the performance of the observed meal and not in relation to other information that the SLT may have previously acquired on the patient.

Two items were added to the *functions and activities influencing meal* subscale: the item *teeth* and *voluntary cough*. The item *teeth* belong to the ICF Body structures, which were not included in the scale as stated before. However, because of the variability of this structure in case of removal dental prosthesis, the working group considered essential to assess it during the observed meal. Consequently, the subscale was renamed *structures, functions, and activities influencing the meal*.

Environmental factors influencing the meal. As the *liquids delivery method* was removed, information on the utensils used to take liquids were incorporated in the item *liquids consistency*.

Swallowing safety during meal. The item *amount of food in the mouth* and the operational definitions of the item *residue in the oral cavity after swallowing* were rephrased because of the weak item-to-total correlation but were considered essential to be maintained by the working group. The 5 items related to the presence of cough or throat cleaning were frequently not assessable because mealtime observation often did not allow to observe patient consuming all the food consistencies; therefore, they were unified in a single item *presence of cough or throat cleaning.*

Swallowing efficacy during the meal. The operational definitions of the items *oral preparation, ability to end the whole meal* and *amount of food eaten* were rephrased and improved because of the weak item-to-total correlation, but the working group decided to maintain them. Analogously, relative frequencies of occurrence were added to the operational definitions of

the item *control of food leakage while chewing*. The items *patient's desire to eat* and *ability to complete the meal without exhortations* that showed a high inter-item correlation were both maintained and redefined in the instruction manual; indeed, although the two items include some overlapping aspects, the latter address a broader concept than solely appetite and palatability of the food. Moreover, the items *control of drooling* and *patient's desire to eat* were moved to the *structures, functions, and activities influencing the meal* subscale.

Mealtime Assessment Scale. The revised version of the MAS is shown in Appendix 1. It consists of:

- a first section to record demographic information and medical history of the patient, which may be useful to interpret the scoring of the items.
- the *Structures, functions and activities influencing meal* subscale: it includes 12 items related to mental functions, voice functions, neuromusculoskeletal and movement-related functions and activities other than eating and drinking which are not strictly connected with swallowing but may impact on its safety and efficacy during mealtime.
- the *Environmental factors influencing meal* subscale: it includes 4 items related to environmental factors influencing swallowing performance during the meal. The items are divided into facilitators and barriers based on to the fact that a more deviant score may ease or worsen the safety and efficacy of swallowing during the meal.
- the *Swallowing safety during meal* subscale: it includes 4 items assessing signs of swallowing safety, defined as "the […] ability to ingest all needed calories and water with no respiratory complications". A *safety* score (0-12) can be computed by summing the items' scores.
- the *Swallowing efficacy during meal* subscale: it includes 6 items assessing signs of swallowing efficacy, defined as "the […] ability to ingest all the calories and water he

or she needs to remain adequately nourished and hydrated". An *efficacy* score (0-18) can be computed by summing the items' scores.

- a section for the scoring the protocol: in this section the *safety* and *efficacy* scores are computer and the time the patient needed to end the meal is recorded. To nullify the difference in the number of items of the safety and efficacy subscales, 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.
- an optional section concerning eventual compensations and indications to give to the patient or to the caregiver during the post-assessment counseling.

The instruction manual of the MAS can be requested by contacting the corresponding author.

Discussion

The MAS has been developed to assess the safety and efficacy of meal. Twenty-six items divided into 4 subscales were selected from the original 39 items divided into 4 subscales. The item revision aimed to improve scale reliability, to reduce items' redundancy, to increase the discrimination ability of the tool and its internal consistency, and to remove items that may be not assessable or modify these to guarantee the possibility to score all the items in all situations. The psychometric characteristics of the revised tool need to be tested to verify if the scale revision reached the above-mentioned aims.

This study represents only the first step in the development and validation of the MAS. The importance of having shared assessment tools stands in the possibility to improve communication among clinicians and to compare results from different studies, contributing building evidence for swallowing treatment. This study laid the groundwork for further development and validation of the MAS, which may support the use of a common language among swallowing expert when assessing swallowing during meals.

The ICF framework was the reference for the item generation process. Other authors have previously recommended the application of the ICF in swallowing assessment to expand the evaluation to aspects other than solely body structures and functions and to better estimate the psychological and social burden derived from dysphagia onset [44-45]. In the ICF classification, eating and drinking are classified as activities and participation, involving different body structures and functions and being influenced by environmental and personal factors [18]. Items selected in the MAS cover several ICF components, including body structures involved in swallowing (e.g., teeth), body functions that directly describe swallowing process (e.g., oral control of the bolus), other body functions that may significantly influence the success in eating and drinking (e.g., attention), activities (e.g., ability to bring food to mouth), environmental factors (e.g., food consistency) and personal factors (e.g.,

patient's desire to eat). However, participation, defined as 'involvement in a life situation' or as "the lived experience" of people in the actual context in which they live' [18], was not included in the MAS. Indeed, assessing patients in their everyday context is frequently not possible in clinical practice, while the MAS aims to be a tool that can be extensively applied in a wide range of settings. Thus, participation is not directly assessed. Nevertheless, swallowing performance during mealtime may better predict the psychosocial impact of swallowing disorders than safety and efficacy of a limited number of swallowing acts tested during the clinical and instrumental assessment.

The items of the subscales *structures, functions and activities influencing meal* and *environmental factors influencing meal* are not summed together because of their clear multidimensionality. Moreover, a sum-score for these subscales would be a little informative. Indeed, the MAS was developed with the aim to assess swallowing safety and efficacy during the meal and therefore the items included in the above-mentioned subscales do not assess these aspects directly. However, the analysis of their scores can be helpful to the clinician in order to understand in which condition the patient can or cannot consume the meal safely and efficiently and subsequently identify those aspects, other than solely swallowing ability, to focus on during swallowing therapy (e.g., environmental modifications, bolus modifications, counseling to the patient and/or caregivers). Therefore, practical information can be gained from the MAS for the management of the patient with dysphagia. However, no Rasch analysis has been currently performed for testing whether or not items from the subscales *swallowing safety during the meal* and *swallowing efficacy during the meal* measure an unidimensional construct, which is necessary for summation of ordinal scores [54]. Moreover, Rasch analysis may be useful to investigate whether the reliability of the tool could be increased by modifying the number of scoring categories, to achieve the greatest homogeneity within the same category and the most significant distance among different categories. Therefore, it should be conducted

in a further study. Moreover, a factor analysis should be performed as well to confirm the assignation of items into subscales.

A strong point of the MAS is its feasibility. Firstly, after meal observation, it can be quickly filled in, taking around 5-10 minutes. Secondly, its administration is not intrusive and, except for the presence of an observer, it preserves the ecologicity of the situation. Moreover, the need of patient's collaboration is limited to the consumption of at least part of a meal (minimum a quarter of a course), and it can be therefore applied to all individuals who consume a meal orally, despite of cognitive impairment, aphasia or behavioral issues. Furthermore, no specific equipment is required. The working group was made up of professionals daily involved in the evaluation and treatment of individuals with swallowing impairments. Thanks to the different background and working facilities of the group members, high regard to the applicability of the scale to different settings and populations was held during item generation and revision.

The variability of each meal situation represents a limit of meal assessment. Indeed, as stated in the introduction, several personal and environmental factors may interfere with swallowing safety and efficacy during a meal, and they changes every lunch and dinner. Being aware of this intrinsic limit, it is, therefore, essential to conduct the meal observation using typical food and amounts (e.g., consistencies, number of courses, quantity of food for each course) usually consumed during meals in daily living and, if possible, to observe the patient in its typical meal setting (e.g., posture, utensils, dining companion, eventual source of distraction).

In the present study comprehensiveness of the scale was judged by the working group which generated items. However, it would be more appropriate that a group of experts, not involved in item development and, preferably, made up of members from different professions, assess comprehensiveness and, in general, face validity of the MAS. It may be therefore addressed for the purposes of a future study aiming to further contribute to MAS development. Another limit of the study is the small sample size included, notably, concerning inter-rater agreement.

The present study did not aim to validate the scale but only to undergo a pilot testing to highlight items that should be revised or removed. Certainly, a bigger sample size should be included in further steps of MAS development and validation. Lastly, in case the MAS would be demonstrated to be a valid and reliable tool, its ability to predict dysphagia's complications on QOL, pulmonary function and nutritional status, which was addressed among potential clinical applications, should be investigated.

Conclusion

The MAS was developed to assess the safety and efficacy of swallowing during the meal. Further development steps, including Rasch analysis, factor analysis, content validity analysis by an external group of experts, and expanding sample size, as well as a validation process should be conducted. In case its validity and reliability would be demonstrated, it may represent a valuable tool to be used both in clinical practice and research.

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Appendix 1: MAS protocol

Surname _____ Name _____
Age _____ Sex _____ Assessment date_____
Diagnosis_____
_____ Disease onset date_____
Previous medical diagnosis_____
Current medications_____

- Previous respiratory tract infections with suspect of aspiration? □ Yes □ No
- Presence of tracheal cannula □ Yes □ No
  (□ cuffed, □ fenestrated, □ mini trach)?
- Concomitant alternative feeding methods □ Yes □ No
  (□ PEG, □ NGT, □ parenteral nutrition)?
- Setting characteristics □ calm □ with occasional sources of distraction
  □ with continuous sources of distraction □ chaotic

1. STRUCTURES, FUNCTIONS, AND ACTIVITIES INFLUENCING THE MEAL

	0	1	2	3
Teeth *Dentatura*	Complete *Completa*	Partial *Parziale*	Completely edentulous on one arch *Totale edentulia di un'arcata*	Completely edentulous *Totale edentulia*
Linguistic comprehension *Comprensione linguistica*	Normal *Nella norma*	Able to understand a usual conversation with few difficulties *Segue una conversazione ordinaria con poche difficoltà*	Mild comprehension difficulties *Lievi difficoltà di comprensione di una conversazione*	Severe comprehension difficulties *Gravi difficoltà di comprensione di una conversazione*
Attention *Attenzione*	Adequate *Adeguata*	Occasionally distracted *Si distrae occasionalmente*	Needs frequent recall *Necessita di richiami frequenti*	Unable to maintain the attention on the activity *Non riesce a mantenere l'attenzione sull'attività*
Short-term memory *Memoria a breve termine*	Adequate *Adeguata*	Needs occasional repetitions *Necessita di saltuarie ripetizioni*	Needs frequent repetitions *Necessita di frequenti ripetizioni*	Unable to remember any *Non ricorda alcuna indicazione*
Control of drooling *Contenimento orale basale*	Normal *Nella norma*	One episode of drooling *Un episodio di perdita di saliva*	Frequent drooling the patient is able to clean *Perdita di saliva frequente ma detersa*	Frequent drooling the patient is unable to clean *Perdita di saliva frequente e incapacità a detergersi*
Voluntary cough *Tosse volontaria*	Effective *Efficace*	Weak *Debole*	Only throat clearing *Solo raclage*	Absent *Assente*
Voice quality *Qualità fonatoria*	Normal *Nella norma*	Slightly breathy *Lievemente soffiata*	Severe hypophonia *Marcata ipofonia*	Aphonia *Afonia*
Patient's compliance with alimentary instructions *Complianza del paziente alle istruzioni alimentari*	Adequate *Adeguata*	Often adequate *Quasi sempre adeguata*	Occasionally adequate *Segue saltuariamente le indicazioni*	Non-adherence to any indication *Non segue alcuna indicazione*

Patient's desire to eat *Desiderio di alimentarsi per os*	Takes pleasure in eating *Mangia volentieri*	Indifferent towards food *È indifferente verso il cibo proposto*	Eat only when encouraged *Mangia solo se continuamente stimolato*	Rejects the food *Rifiuta il cibo*
Head-to-trunk control *Controllo del capo e del tronco*	Adequate *Adeguato*	Needs aids to maintain the posture *Necessita di ausili per mantenere la postura*	Aids allow to maintain the posture but only for few minutes *Mantenuto grazie agli ausili ma solo per pochi minuti*	Impossible to maintain despite the use of aids *Impossibile da mantenere con qualsiasi ausilio*
Independence in eating *Autonomia nell'alimentazione*	Completely indipendent *Totale autonomia*	Needs minimum assistance by the caregiver *Minimo intervento del caregiver*	Needs moderate assistance by the caregiver *Moderato intervento del caregiver*	Completely dependent *Completa dipendenza*
Ability to bring food to mouth *Capacità di portare il cibo alla bocca*	Adequate *Adeguata*	Occasional loss of food from the cutlery *Saltuari episodi di perdita di cibo dalla posata*	Frequent loss of food from the cutlery *Frequenti episodi di perdita di cibo dalla posata*	Unable to bring food to mouth *Incapace di portare il cibo alla bocca*

2. ENVIRONMENTAL FACTORS INFLUENCING THE MEAL

FACILITATORS	**0**	**+1**	**+2**	**+3**
Food consistency *Consistenza del cibo*	Normal diet *Dieta libera*	Normal diet with restrictions *Dieta libera con limitazioni*	Soft food diet *Dieta solida morbida*	Homogenous pureed consistency diet *Dieta semisolida*
Bolus size *Dimensione del bolo*	Tablespoon *Cucchiaio*	½ tablespoon *½ cucchiaio*	Teaspoon *Cucchiaino*	½ teaspoon *½ cucchiaino*
Liquid consistency *Caratteristiche reologiche del liquido*	Thin from the glass or using a straw *Normale (bicchiere o cannuccia)*	Thin with a spoon *Normale con cucchiaio*	Thin with multiple swallows between sips *Normale dopo deglutizioni a vuoto*	Thickened *Addensato*
BARRIERS	**0**	**-1**	**-2**	**-3**
Possibility to rely on caregiver *Possibilità di far affidamento sul caregiver*	Compliant caregiver or not necessary *Caregiver compliante o non necessario*	Caregiver is inconstant in adherence to indications *Caregiver incostante nel seguire le indicazioni*	Caregiver pays little attention to therapist's indications *Caregiver poco attento alle indicazioni del terapista*	Caregiver is absent or not reliable during mealtime *Caregiver assente al momento del pasto o non affidabile*

3. SAFETY AND EFFICACY OF SWALLOWING DURING THE MEAL

		0	**1**	**2**	**3**
SAFETY	Oral control of the bolus *Gestione endorale del bolo*	Adequate *Adeguata*	Slightly excessive food amount *Quantità di cibo leggermente eccessiva*	Excessive food amount *Quantità di cibo eccessiva*	Impossible *Impossibile*
	Residue in the oral cavity after swallowing (specify the eventual site _____)	Adequate *Adeguata*	Small residue amount *Pochi ristagni*	Copious residue amount in half oral cavity	Copious residue amount in the whole oral cavity

	Detersione orale dopo la deglutizione (se rimangono residue specificare la sede _____)			*Abbondanti ristagni in metà del cavo orale*	*Abbondanti ristagni in ogni parte del cavo orale*
	Presence of cough or throat cleaning *Presenza di tosse o raclage*	Never *Mai*	Occasionally (2-5 times) *Raramente (2-5 volte)*	Sometimes (about 1/3 of the time) *Frequentemente (circa 1/3 delle volte)*	Often (≥½ of the time) *Quasi sempre (più di ½ delle volte)*
	Reflexive cough □ strong □ weak *Tosse riflessa □ forte □ debole*				
	Voice quality post-swallow (specify with which consistency/ies _____) Qualità della voce postdeglutitoria (specificare con quale/i consistenza/e _____)	Normal *Nella norma*	Occasionally wet/gurgly voice (2-5 times) *Voce raramente umida/ gorgogliante (2-5 volte)*	Sometimes wet/gurgly voice (about 1/3 of the time) *Voce frequentemente umida/ gorgogliante (circa 1/3 delle volte)*	Often wet/gurgly voice or not assessable (≥½ of the time) *Voce quasi sempre umida/ gorgogliante o non valutabile (più di ½ delle volte)*
EFFICACY	Control of food leakage while chewing *Contenimento orale in masticazione*	Normal *Nella norma*	Occasional food loss from the labial commissure (less than 1/3 of the time) *Fuoriesce saltuariamente del cibo dalla commessura labiale (meno di 1/3 delle volte)*	Frequent food loss from the labial commissure (about ½ of the time) *Fuoriesce frequentemente del cibo dalla commessura labiale (circa ½ delle volte)*	Complete labial incompetence (more than 2/3 of the time) *Assoluta incontinenza dello sfintere labiale (più di 2/3 delle volte)*
	Oral preparation *Preparazione orale*	Normal *Nella norma*	Slightly prolonged *Leggermente prolungata*	Prolonged *Prolungata*	Bolus formation inability *Incapacità a formare il bolo*
	Ability to complete the meal without exhortations *Capacità di continuare il pasto senza sollecitazioni*	Adequate *Adeguata*	need occasional exhortations *Necessita di saltuarie sollecitazioni*	Need frequent exhortations *Necessita di frequenti sollecitazioni*	Exhortations are useless *Sollecitazioni non efficaci*
	Fatigue *Affaticabilità*	Never *Mai*	Occasionally (less than 1/3 of the time) *Raramente (meno di 1/3 delle volte)*	Frequently (about ½ of the time) *Frequentemente (circa ½ delle volte)*	Almost always (more than 2/3 of the time) Quasi sempre *(più di 2/3 delle volte)*
	Percentage of the meal eaten *Percentuale del pasto assunta*	About 75% or more *Circa il 75% o più*	About 50% *Circa il 50%*	About 25% *Circa il 25%*	Less than 25% *Meno del 25%*
	Amount of food eaten *Quantità di cibo assunta al pasto*	Adequate *Adeguata*	Modest *Scarsa*	Insufficient *Insufficiente*	Almost nothing *Quasi nulla*

4. MAS CORRECTION

1) **Safety score** _____/ 12 **Performance** _____ %
Punteggio di sicurezza _____*/ 12* ***Performance*** _____ *%*

2) **Efficacy score** _____/ 18 **Performance** _____ %
Punteggio di efficacia _____*/ 18* ***Performance*** _____ *%*

Meal duration _____ min
Tempo impiegato _____ *min*

Appendix 2: MAS items' scoring

Teeth
0: all teeth are on site in both arches or all missing teeth are replaced by dentures
1: the patient has teeth (natural or dentures) in both arches, but one or both arches shows missing teeth
2: the patient has teeth (natural or dentures) only in one arch
3: the patient is completely edentulous or has a maximum of 3 teeth

Linguistic comprehension
0: adequate linguistic comprehension for potential need of communication within the meal
1: occasional clarifications are needed for patient's comprehension of the message
2: to allow the comprehension of the message, sentences should be short and simplified and may be repeated several times
3: the patient does not understand the message despite a simplified language is used

Attention
0: the patient is spontaneously focused on the activity of eating and/or drinking for the entire meal, although he may talk to other people within the meal
1: the patient is distracted from the activity of eating and/or drinking in 1 to 3 occasions
2: the patient is distracted from the activity of eating and/or drinking in 4 to 10 occasions
3: the patient is not able to spontaneously focus the attention on the activity of eating and/or drinking for more than few seconds

Short-term memory
0: the patient autonomously remembers all the alimentary instructions or no alimentary instruction has been given to the patient
1: the patient remembers the alimentary instructions after 1 to 3 repetitions by the caregiver or the clinician
2: the patient remembers the alimentary instructions after 4 to 5 repetitions by the caregiver or the clinician
3: the patient does not remember any alimentary instruction despite the repetitions by the caregiver or the clinician

Control of drooling
0: the patient is able to manage the saliva and no episodes of drooling occurs
1: one episode of drooling occurs before or after the meal and the patient autonomously clean the leakage of saliva
2: more than one episode of drooling occurs before or after the meal and the patient autonomously clean the leakage of saliva
3: episodes of drooling occur before or after the meal but the patient does not autonomously clean the leakage of saliva

Voluntary cough
0: the patient is able to produce a strong voluntary cough
1: the patient is able to cough voluntary but the cough is weak
2: the patient is only able to produce a throat cleaning
3: the patient isn't able to produce a voluntary cough, neither a throat cleaning

Voice quality
0: normal voice quality or dysphonic voice quality but not involving the parameters B and A of the GIRBAS scale (B0 and A0)
1: slightly breathy or asthenic voice quality (B1 and/or A1)
2: moderately breathy or asthenic voice quality (B2 and/or A2)
3: aphonic or severe hypophonic voice (B3 e/o A3) or not assessable voice

Patient's compliance with alimentary instructions
0: all alimentary instructions are followed by the patient for the whole meal or no alimentary instruction provided to the patient
1: alimentary instructions are followed by the patient for more than half meal
2: alimentary instructions are followed by the patient for less than half meal
3: no alimentary instruction is followed by the patient during meal

Patient's desire to eat
0: the patient takes pleasure in eating (e.g., the patient verbalizes the pleasure of eat or show enthusiasm when he is offered the food)
1: the patient eats the food during meal but is indifferent towards it; eating is an unimportant activity
2: the patient eats the food during meal but exhibit the will of avoiding it
3: the patient rejects the food after maximum 10 bites.

Head-to-trunk control
0: the patient autonomously maintains an adequate posture for the whole meal
1: the patient needs aids to maintain an adequate posture for the whole meal
2: the patient needs aids to maintain an adequate posture but it is maintained only for few minutes
3: the patient in unable to reach and maintain an adequate posture for meal consumption despite the use of aids

Independence in eating:
0: the patient is completely independent for the whole meal
1: the patient need minimum assistance by the caregiver during meal; the assistance is required only in few moments of the meal
2: the patient need moderate assistance by the caregiver during meal; the assistance is required throughout the meal
3: the patient need to be spoon-fed by the caregiver.

Ability to bring food to mouth
0: the patient is able to bring the food to mouth without losing the food from the cutlery
1: the patient is able to bring the food to mouth but with occasional loss of the food from the cutlery (about 1/3 of the time)
2: the patient is able to bring the food to mouth but with occasional loss of the food from the cutlery (about 2/3 of the time)
3: the patient is unable to bring the food to mouth (loss of the food from the cutlery more than 2/3 of the time) or the item is not assessable

Food consistency
0: normal diet; the meal includes at least one dual consistencies or friable or filamentous foods
+1: normal diet with restrictions; the meal may include all type of foods except for dual consistencies and/or friable and/or filamentous foods
+2: soft food diet; the meal includes only soft solids and, potentially, pureed foods
+3: homogeneous pureed diet; the meal includes only pureed foods

Bolus size

0: each bite corresponds to the volume of a tablespoon
+1: each bite corresponds to the volume of half tablespoon
+2: each bite corresponds to the volume of a teaspoon
+3: each bite corresponds to the volume of half teaspoon

Liquid consistency

0: thin liquids from the glass or using a straw
+1: thin liquids from the spoon
+2: thin liquids with multiple swallows between sips
+3: thickened liquids

Possibility to rely on caregiver

0: the caregiver is present and follow potential alimentary instructions for the whole meal or a caregiver is not required during meal
-1: the caregiver is present and follow alimentary instructions for about half meal
-2: the caregiver is present but rarely follow alimentary instructions (less than half meal)
-3: the caregiver is absent although is necessary or the caregiver is present but do not follow any alimentary instruction

Oral control of the bolus

0: the patient easily manages the amount of food introduced in the oral cavity during the whole meal
1: the patient shows difficulties in managing the amount of food introduced in the oral cavity and tongue pumping is observed during meal
2: the patient shows difficulties in managing the amount of food introduced in the oral cavity and needs to introduce liquids (thin or thickened) to swallow the bolus
3: the patient is unable to manage the amount of food introduced in the oral cavity and needs to spit out part or all the food from the oral cavity

Residue in the oral cavity after swallowing

0: no oral residue are detected after swallow
1: a small amount of oral residue is detected after swallow (traces)
2: copious oral residues are detected after swallow but only in half of the oral cavity
3: copious oral residues are detected after swallow in different sites all over the oral cavity

Presence of cough or throat cleaning

0: no episodes of cough or throat cleaning detected during meal
1: occasional episodes of cough or throat cleaning detected during meal (2 to 5 episodes)
2: episodes of cough or throat cleaning detected for around 1/3 of the meal
3: episodes of cough or throat cleaning detected for more than half meal

Voice quality post-swallow

0: no alterations of voice quality are detected during meal
1: gurgly/wet voice is occasionally recorded during meal (2 to 5 times)
2: gurgly/wet voice is sometimes recorded during meal (about 1/3 of the time)
3: gurgly/wet voice is often recorded during meal (more than ½ of the time) or voice is not assessable

Control of food leakage while chewing

0: no episode of food or liquid leakage from the oral cavity during the meal
1: occasional episodes of food or liquid leakage from the oral cavity during the meal (< 1/3 of the time)
2: occasional episodes of food or liquid leakage from the oral cavity during the meal (about 1/2 of the time)
3: complete labial incompetence (food or liquid leakage from the oral cavity >2/3 of the time)

Oral preparation

0: the duration of oral preparation is adequate (approximately less than 30 seconds)
1: the duration of oral preparation is slightly prolonged (approximately between 30 seconds and 1 minute)
2: the duration of oral preparation is moderately prolonged (approximately more than 1 minute)
3: the duration of oral preparation is severely prolonged (several minutes) or the patient is unable to orally prepare the bolus.

Ability to complete the meal without exhortations

0: the patient spontaneously completes the meal; no exhortation is provided
1: the patient needs occasional exhortations to complete the meal (1 to 3 exhortations)
2: the patient needs occasional exhortations to complete the meal (> 3 exhortations)
3: the patient does not complete the meal despite frequent exhortations

Fatigue

0: no symptoms of fatigue are observed with the progression of meal consumption
1: occasional symptoms of fatigue are observed with the progression of meal consumption (approximately in the last 1/3 of the meal)
2: frequent symptoms of fatigue are observed with the progression of meal consumption (approximately in the last 1/2 of the meal)
3: symptoms of fatigue are observed during the whole meal (at least in the last 2/3 of the meal)

Percentage of the meal eaten

0: the patient eats about 75% of the meal or more
1: the patient eats about 50% of the meal
2: the patient eats about 25% of the meal
3: the patient eats less than 25% of the meal

Amount of food eaten

0: the amount of food eaten seems to be adequate for patient's nutritional needs
1: the amount of food eaten seems to be scarce for patient's nutritional needs
2: the amount of food eaten seems to be insufficient for patient's nutritional needs
3: the patient eats almost nothing and patient's nutritional needs aren't met

Table 1: ICF codes related to meal assumption identified by the working group for item generation

BODY FUNCTIONS		ACTIVITIES AND PARTICIPATION		ENVIRONMENTAL FACTORS	
ICF code	**Name of code**	**ICF code**	**Name of code**	**ICF code**	**Name of code**
b110	Consciousness functions[a]	d2302	Completing the daily routine[b]	e1100	Food[a,b]
b1301	Motivation[a,b]	d415	Maintaining a body position	e1101	Drugs[b]
b1302	Appetite[a,b]	d430	Lifting and carrying objects	e1151	Assistive products and technology for personal use in daily living[a,b]
b140	Attention functions[a]	d550	Eating[a,b]	e250	Sound[a]
b144	Memory functions[a]	d560	Drinking[a,b]	e310	Immediate family[a,b]
b147	Psychomotor functions[a]			e340	Personal care providers and personal assistants[a]
b1670	Reception of language[a]			e410	Individual attitudes of immediate family members[a,b]
b176	Mental function of sequencing complex movements				
b310	Voice functions				
b450	Additional respiratory functions[b]				
b455	Exercise tolerance functions				
b5102	Chewing[a,b]				
b5103	Manipulation of food in the mouth[a,b]				
b5104	Salivation[a,b]				
b51050	Oral swallowing[a,b]				
b51051	Pharyngeal swallowing[a,b]				
b530	Weight maintenance functions[b]				
b735	Muscle tone				
b740	Muscle endurance functions				
b760	Control of voluntary movement functions				

[a]ICF code from Threats (2007)

[b]ICF code from Nund et al (2014)

Table 2: Generated items

FUNCTIONS AND ACTIVITIES INFLUENCING THE MEAL (N=9) ***Funzioni e attività che impattano sul pasto***	**ENVIRONMENTAL FACTORS INFLUENCING THE MEAL (N=8)** ***Fattori ambientali che impattano sul pasto***	**SWALLOWING SAFETY DURING THE MEAL (N=11)** ***Sicurezza della deglutizione durante il pasto***	**SWALLOWING EFFICACY DURING THE MEAL (N=11)** ***Efficacia della deglutizione durante il pasto***
Responsiveness *Responsività*	Alternative feeding methods (F) *Metodi di alimentazione alternativi*	Residue in the oral cavity after swallowing *Detersione orale dopo la deglutizione*	Patient's desire to eat *Desiderio di alimentarsi per os*
Linguistic comprehension *Comprensione linguistica*	Food consistency (F) *Consistenza del cibo*	Presence of cough or throat cleaning with semisolids *Presenza di tosse o raclage con i semisolidi*	Ability to complete the meal without exhortations *Capacità di continuare il pasto senza sollecitazioni*
Attention *Attenzione*	Bolus size (F) *Dimensione del bolo*	Presence of cough or throat cleaning with solids *Presenza di tosse o raclage con i solidi*	Shortness of breath while eating *Presenza di affanno durante il pasto*
Memory *Memoria*	Liquid consistency (F) *Consistenza del liquido*	Presence of cough or throat cleaning with liquids *Presenza di tosse o raclage con i liquidi*	Time period between bites *Velocità nell'assunzione del boccone successivo*
Voice quality *Qualità vocale*	Liquids delivery method (F) *Modalità di assunzione del liquido*	Presence of cough or throat cleaning with dual consistencies *Presenza di tosse o raclage con le doppie consistenze*	Fatigue *Affaticabilità*
Patient's compliance with alimentary instructions *Complianza del paziente alle istruzioni alimentari*	Oral medications delivery method (F) *Modalità di assunzione dei farmaci*	Presence of cough or throat cleaning in the distance *Presenza di tosse o raclage a distanza*	Ability to end the whole meal *Capacità di terminare tutte le portate del pasto*
Head-to-trunk control	Setting (B)	Reflexive cough quality	Amount of food eaten

Controllo del capo e del tronco	*Setting*	*Qualità della tosse riflessa*	*Quantità di cibo assunta alla fine del pasto*
Independence in eating *Autonomia nell'alimentazione*	Possibility to rely on caregiver (B) *Possibilità di far affidamento sul caregiver*	Voice quality post-swallow *Qualità della voce post-deglutitoria*	Control of food leakage while chewing *Efficacia dello sfintere labiale durante la masticazione*
Ability to take food to mouth *Capacità di portare il cibo alla bocca*		Amount of food in the mouth *Quantità di cibo in bocca*	Control of drooling *Controllo orale della saliva*
		Food loss through the cannula *Fuoriuscita di cibo dalla cannula tracheale*	Oral preparation *Preparazione orale*
		Liquids loss through the cannula *Fuoriuscita di liquido dalla cannula tracheale*	Velopharyngeal competence *Continenza velare*

LEGEND: F = facilitator; B = barrier

NOTES: the original version of the items in Italian is reported in Italics

Table 3: Demographic and clinical characteristics of the pilot study's sample

		Median (range) or n/N (%)
Age		78 (28-92)
Sex	M	21/40 (52.5%)
	F	19/40 (47.5%)
Diet	C1	15/30 (37.5%)
	C2	14/40 (35%)
	C3	1/40 (2.5%)
	C4	10 /40 (25%)
Pathology	Ischemic stroke	13/40 (32.5%)
	Hemorrhagic stroke	5/40 (12.5%)
	PD	3/40 (7.5%)
	Vascular Parkinsonism	3/40 (7.5%)
	Encephalopathy	1/40 (2.5%)
	Cerebral hypoxia	1/40 (2.5%)
	MSA	2/40 (5%)
	MS	1/40 (2.5%)
	ALS	2/40 (5%)
	Thyroid cancer	1/40 (2.5%)
	Cranial nerve palsy	1/40 (2.5%)
	Psychogenic	1/40 (2.5%)
	Dysphagia of unspecified etiology	6/40 (15%)

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; MSA = Multiple system atrophy; MS = Multiple sclerosis; ALS = Amyotrophic lateral sclerosis

Table 4: *Swallowing safety during the meal* subscale - Cronbach's alpha and item-to-total correlation

Item	*Cronbach's alpha without the item*	*Item-to-total correlation*
Residue in the oral cavity after swallowing	-0.722	0.866
Presence of cough or throat cleaning with semisolids	-1.000	0.945
Presence of cough or throat cleaning with solids	0.219	-0.500
Presence of cough or throat cleaning with liquids	-0.667	0.327
Presence of cough or throat cleaning in the distance	-0.900	0.000
Reflexive cough quality	0.611	-0.655
Voice quality post-swallow	-0.900	0.000
Amount of food in the mouth	-0.970	0.000

Table 5: *Swallowing efficacy during the meal* subscale - Cronbach's alpha and item-to-total correlation

Item	*Cronbach's alpha without the item*	*Item-to-total correlation*
Control of food leakage while chewing	0.518	0.811
Control of drooling	0.580	0.600
Oral preparation	0.672	0.104
Patient's desire to eat	0.666	0.168
Ability to complete the meal without exhortations	0.658	0.187
Shortness of breath while eating	0.630	0.389
Time period between bites	0.643	0.310
Fatigue	0.678	-0.144
Ability to end the whole meal	0.579	0.583
Amount of food eaten	0.675	0.024

Table 6: Median (range) scores, frequency of not assessable items, inter-rater agreement and discrimination index of the items of the first version of the MAS

	Median	*range*	*N.A. (%)*	*AD index*	*Discrimination index*
Responsiveness	0	0-2	0/40 (0%)	0	-
Linguistic comprehension	0	0-2	1/40 (2.5%)	0.15	-
Attention	0	0-2	1/40 (2.5%)	0.35	-
Memory	0	0-3	3/40 (7.5%)	0.28	-
Voice quality	1	0-3	1/40 (2.5%)	0.15	-
Patient's compliance with alimentary instructions	0	0-2	2/40 (5%)	0.17	-
Head-to-trunk control	0	0-2	0/40 (0%)	0.3	-
Independence in eating	0	0-3	7/40 (17.5%)	0.06	-
Ability to take food to mouth	0	0-3	12/40 (30%)	0.25	-
Alternative feeding methods	0	0-3	0/40 (0%)	0	-
Food consistency	1	0-3	1/40 (2.5%)	0.05	-
Bolus size	0	0-3	2/40 (5%)	0.05	-
Liquids consistency	0	0-3	2/40 (5%)	0	-
Liquids delivery method	0	0-3	13/40 (32.5%)	0.17	-
Oral medications delivery method	2	0-3	28/40 (70%)	N.C.	-
Setting	1	0-2	0/40 (0%)	0.25	-
Possibility to rely on caregiver	0	0-3	0/40 (0%)	0.17	-
Oral cavity detersion after swallowing	1	0-3	2/40 (5%)	0.6	0.26
Presence of cough or throat cleaning with semisolids	0	0-2	10/40 (25%)	0.06	0.07
Presence of cough or throat cleaning with solids	0	0-2	16/40 (40%)	0	0.09
Presence of cough or throat cleaning with liquids	0	0-3	16/40 (40%)	0	0.19
Presence of cough or throat cleaning with dual consistencies	0	0-0	36/40 (90%)	0	N.C.
Presence of cough or throat cleaning in the distance	0	0-1	1/40 (2.5%)	0	0
Reflex cough quality	0	0-2	31/40 (77.5%)	N.C.	0.13

Voice quality post-swallow	0.5	0-2	2/40 (5%)	0.11	0.11
Amount of food in the mouth	0	0-1	1/40 (2.5%)	0.2	0
Food loss through the cannula	0.5	0-1	38/40 (95%)	N.C.	N.C.
Liquids loss through the cannula	0	0-0	39/40 (97.5%)	N.C.	N.C.
Control of food leakage while chewing	0	0-2	2/40 (5%)	0.22	0.17
Control of drooling	0	0-1	1/40 (2.5%)	0	0
Oral preparation	0	0-1	2/40 (5%)	0.14	0
Velopharyngeal competence	0	0-0	1/40 (2.5%)	0	0
Patient's desire to eat	0	0-3	1/40 (2.5%)	0.05	0.39
Ability to complete the meal without exhortations	0	0-2	2/40 (5%)	0.1	0.29
Shortness of breath while eating	0	0-2	2/40 (5%)	0.22	0
Time period between bites	1	0-2	12/40 (30%)	0.38	0
Fatigue	0	0-2	1/40 (2.5%)	0.11	0.17
Ability to end the whole meal	1	0-3	1/40 (2.5%)	0.2	0.72
Amount of food eaten	1	0-3	1/40 (2.5%)	0.18	0.56

Footnotes: N.C. = not computable