DIGEST™

TRAINING MANUAL

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

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Dynamic Imaging GradE of Swallowing Toxicity

CONTENTS

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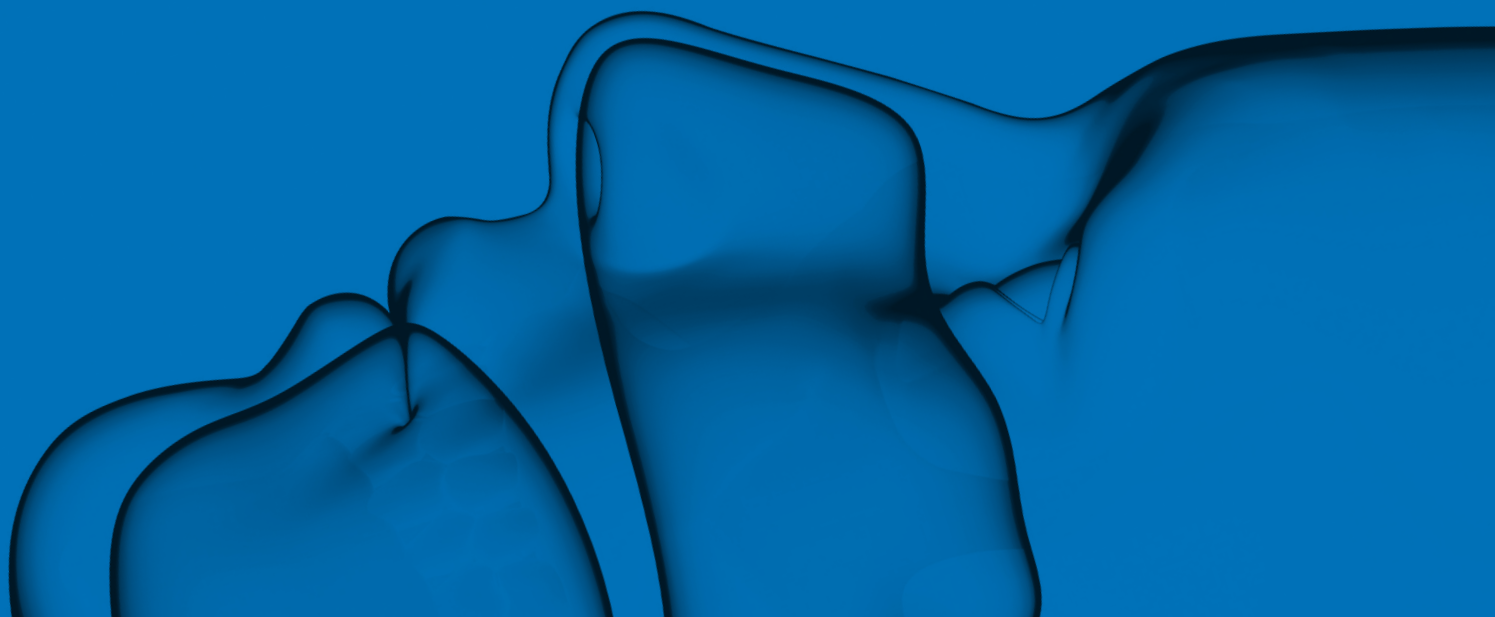


OPERATIONAL DEFINITIONS

Amount of PAS - Modifier applied to the Safety construct if max PAS is ≥5.

Amount of PAS is graded based on the amount of barium on or below the true vocal folds (TVF) on the worst PAS performance of any single bolus (trace, neither trace nor gross, or gross). The amount of PAS is the cumulative amount of bolus on/below the TVF for any given bolus trial.

Bolus break - Point where the bolus separates in the pharynx between the portion that is transferring into the upper esophagus and the portion that may remain as residue. The bolus break is typically close in time to the peak maximal squeeze of the swallow. The bolus break is a key point in the swallow that assists in making the estimate of pharyngeal residue.

Chronic - Selection option for the Frequency of PAS modifier in which either PAS 3-4 or PAS 5-6 or PAS 7-8 occurs on ≥50% of thin liquid trials OR on >1 consistency. More than one consistency could be thin AND nectar, or thin AND pudding, for example.

Confirmatory Evidence - Term used by our raters to describe visible evidence of delayed bolus entry into the airway. Evidence of delayed airway entry/migration of the bolus may be detected when fluoroscopy turns back on for next bolus trial and change the preceding PAS score. That is, confirmatory evidence can be used to adjust PAS on the preceding bolus and most often results in a worsening of PAS score (e.g., PAS of 3, now with barium outlining the TFV and changed to a PAS 5).

CTCAE - Common Toxicity Criteria for Adverse Events, the National Cancer Institute's (NCI's) CTCAE is the method used to grade toxicities of cancer. DIGEST was developed to grade results of the MBS using the CTCAE framework for mild (grade 1), moderate (grade 2), severe (grade 3), and life threatening (grade 4).

DIGEST - Dynamic Imaging GradE of Swallowing Toxicity (DIGEST); clinician-rated method to grade the severity of pharyngeal phase dysphagia using reproducible criteria based on patterns of penetration/aspiration and pharyngeal residue on MBS. DIGEST grades are compatible with NCI's CTCAE toxicity grading system.

DIGEST Grade [D] - Clinician-rated severity of pharyngeal phase dysphagia based on MBS results. DIGEST grade is identified by the interaction of the DIGEST Safety Grade and Efficiency Grade. Rated on uncompensated swallows of liquid, pureed/pudding, and cracker/cookie bolus trials on MBS; graded per 5-point ordinal scale.

Efficiency Grade [E] - Clinician-rated severity of pharyngeal inefficiency based on MBS results. Based on the pattern of maximum Percent Residue on the first or primary swallow. Rated on uncompensated swallows of liquid, pureed/pudding, and cracker/cookie bolus trials on MBS; graded per 5-point ordinal scale.

First swallow - Initial or primary pharyngeal swallow of a bolus after oral transfer; implies bolus entered the pharynx.

Flow chart - DIGEST criteria are organized in a flow diagram or decision tree depicting the sequence of decision making used to determine Safety Grade and Efficiency Grade and DIGEST.

FOV - Field of view; pertains to MBS acquisition parameters.

FPS - Frames per second; pertains to MBS acquisition parameters.

Frequency/pattern of PAS - Modifier applied to the Safety construct if max PAS is ≥3. This modifier defines the pattern with which PAS 3-4 or PAS 5-6 or PAS 7-8 occurred over the course of the MBS (single event, single+, intermittent, or chronic) to assist in determining Safety Grade.

Gross - Selection option for Amount of PAS modifier relevant to PAS 5 or higher only; amount of bolus on or below the vocal folds is defined as >25% total bolus volume. The total bolus volume is the bolus that entered the pharynx.

Intermittent - Selection option for Frequency of PAS modifier in which the PAS 3-4 or PAS 5-6 or PAS 7-8 ratings occur on multiple but less than 50% of bolus trials on a single consistency. For example, 2 of 6 thin liquid trials with PAS 7 or 8 ratings is rated as Intermittent PAS 7-8.

Maximum Percent of Pharyngeal Residue - Maximum estimated amount of pharyngeal residue remaining in the pharynx after the first or primary swallow on unmodified swallows across all bolus trials in the standard bolus protocol. Based on what enters the pharynx and what exits the pharynx; often estimated at the bolus-break point.

Modified barium swallow (MBS) - Also referred to as videofluoroscopic swallow (VFS) evaluation; dynamic x-ray procedure designed to assess anatomy and physiology of the oropharyngeal swallow and bolus clearance during swallows of contrast material. DIGEST ratings taken in the lateral or mid-sagittal plane.

Neither trace nor gross - Selection option for Amount of PAS modifier relevant to PAS 5 or higher; only can be characterized as greater than trace but less than 25% of total bolus volume.

Penetration-Aspiration Scale (PAS) - by Rosenbek et al, is used as the primary measure of swallowing safety in DIGEST criteria. PAS is applied at the bolus level, meaning each bolus trial receives a single PAS grade based on all attempts to swallow that bolus up to the point that a strategy is applied.

PAS Modifiers - Criteria applied to describe the frequency and amount of higher grade penetration-aspiration events during the MBS. Required for DIGEST grade when maximum PAS is ≥3.

Pattern of Residue - Criteria applied as a modifier to the maximum pharyngeal residue score to derive the DIGEST efficiency grade. Required for DIGEST grade maximum residue of ≥50%.

Pharynx - Membrane lined cavity behind the nose and mouth connecting to the upper esophageal sphincter; encompasses the nasopharynx, oropharynx, and hypopharynx. For DIGEST, the bolus is considered to have entered the pharynx when it crosses the ramus of the mandible. The bolus is considered to have exited the pharynx when it enters into the esophagus.

Primary swallow - First pharyngeal swallow triggered after oral transit of the bolus into the pharynx; implies one or more swallows occurred prior to oral transit of the bolus to the pharynx.

Ramus of the Mandible - Angle of the mandible; defines the point at which the head of the bolus is considered to have entered the pharynx, for purposes of DIGEST.

Safety Grade [S] - Clinician-rated severity of swallowing safety impairment based on MBS results. Based on the worst Penetration-Aspiration Scale score(s) coupled with modifiers of frequency and amount of penetration/aspiration pattern across a standard bolus protocol. Rated on uncompensated swallows of liquid, pureed/pudding, and cracker/cookie bolus trials on MBS; graded per 5-point ordinal scale.

Single Event - Selection option for Frequency of PAS modifier in which either a PAS 3-4 or PAS 5-6 or PAS 7-8 occurs on only one bolus trial.

Single+: Selection option for Frequency of PAS modifier that denotes special scenario when a single PAS 7-8 is accompanied by additional PAS 5-6 that will upgrade from S1 to S2.

Trace - Selection option for Amount of PAS modifier in which penetration and/or aspiration resembles faint coating, droplets or trickle of barium on or below the TVF.

PURPOSE

This manual is intended to provide training on use and interpretation of the Dynamic Imaging Grade of Swallowing Toxicity (DIGEST)[1]. DIGEST is an analysis method used to grade the severity of pharyngeal dysphagia based on results of a modified barium swallow (MBS) study. DIGEST uses a basic flowsheet and rubric to summarize the **patterns of penetration/aspiration and pharyngeal residue** observed on the MBS as markers of swallowing **safety** and **efficiency**. This process, therefore, provides a reproducible way to achieve a summary grading of dysphagia from the MBS observations (i.e., none, mild, moderate, severe, or profound/life threatening pharyngeal dysphagia). Reliable and valid application of DIGEST assumes competency with MBS administration, adherence to a standard MBS acquisition protocol, familiarity with anatomy and physiology of the oropharyngeal swallow, and reliable application of Rosenbek's Penetration-Aspiration Scale (PAS)[2].

DIGEST™ OVERVIEW

DIGEST is a swallowing analysis method that summarizes the results of an MBS into an overall severity grade of pharyngeal dysphagia **(DIGEST)** on a 5-point scale by first grading levels of safety impairment **(DIGEST-S)** and efficiency impairment **(DIGEST-E)**. DIGEST grades are as outlined below:

- Grade 0 = none
- Grade 1 = mild
- Grade 2 = moderate
- Grade 3 = severe
- Grade 4 = life threatening/profound

To obtain a DIGEST grade, the rater assigns both a penetration/aspiration scale (PAS) score and estimates the percentage of pharyngeal residue (PR) on each bolus trial over the entire MBS. PAS and PR are rated on uncompensated bolus trials only, specifically prior to any clinician cuing or compensation technique, such as a chin tuck or cued throat clear or cough. Thus, the DIGEST grade describes the severity of dysphagia without application of strategies or therapies.

The MBS must be conducted using a standard bolus protocol for valid DIGEST scoring. Skipped bolus trials should be avoided when clinically feasible and compensation techniques should be applied after standard bolus trials have been given.

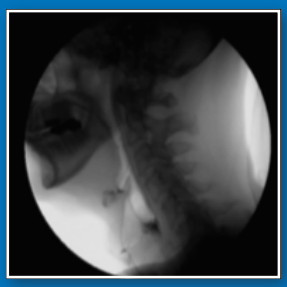
The DIGEST **Safety Grade** is determined by identifying the maximum PAS score observed across the entire study, then applying PAS modifiers to account for the frequency, pattern, and amount of higher grade PAS events (PAS≥3). The DIGEST **Efficiency Grade** is based on the maximum estimated percentage of residue remaining in the pharynx after the initial or primary swallow for each bolus, with modifiers accounting for the pattern of higher grade residue (≥50% of the bolus) over various bolus types (liquid, pudding, cookie/cracker).

DIGEST criteria are outlined in a basic flow chart to assist the rater in assigning the appropriate Safety Grade [S] and Efficiency Grade [E]. S and E grades are then cross-referenced in the DIGEST rubric to assign the final DIGEST Grade [D].

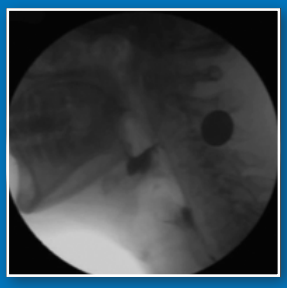
DIGEST results are documented in the clinical record the following way: [D: S, E]. This enables succinct communication of all key components and a mental snapshot of the individual's swallow function.

FIGURE 1. SUMMARY OF DIGEST™ METHODOLOGY

Step 1:
SLP rates pharyngeal bolus clearance on all bolus trials in a standardized MBS protocol

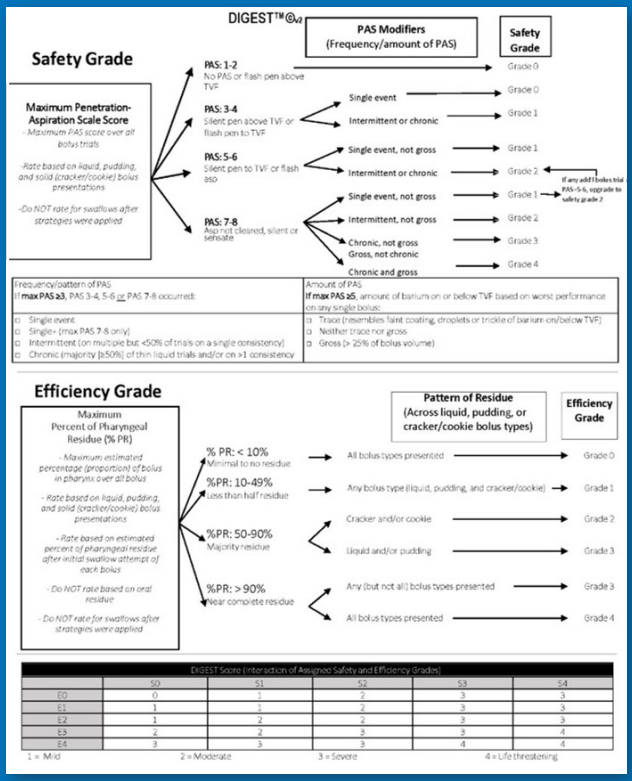


Swallow Safety
Per patterns of penetration-aspiration events (rated by Penetration-Aspiration Scale)



Swallow Efficiency
Per patterns of post-swallow pharyngeal residue

Step 2:
SLP applies DIGEST criteria per flowsheet below to derive DIGEST grade (Hutcheson K et al, Cancer, 2017)



1= *mild*, 2- = *moderate*, 3 = *severe*, 4 = *life threatening/profound*

BACKGROUND

DIGEST was developed as both a clinical and research tool. When created, the goals of DIGEST were:

1. Provide global measure of pharyngeal swallowing function combining both safety and efficiency
2. Provide a single score to summarize the severity of pharyngeal dysphagia based on the results of the full MBS, not merely a score based on performance for a single bolus
3. Focus on the 2 main functional domains of swallowing – swallowing safety and efficiency of bolus clearance
4. Complement and incorporate existing measures rather than replace or duplicate measurement efforts
5. Avoid the need for special analysis equipment thus enabling swallow grading in "real-time"
6. Remain simple enough for interdisciplinary medical teams to easily communicate and comprehend MBS findings
7. Provide common language across SLPs (my "mild dysphagia" is your "mild dysphagia")

CLINICAL ROLE

As a clinical tool, DIGEST was designed with "real-time" rating in mind. That is, the goal was to provide a measure that could be taken from bedside to bench. For this reason, DIGEST ratings do not require any particular software, timing, or distance measures from the imaging file.

As a clinical measure, DIGEST has been used as a clinical practice standard on MBS studies conducted at MD Anderson Cancer Center since its release for use in 2016 – in that time period, as of January 2022, 29 clinicians have applied DIGEST on 12,137 MBS among 7,842 unique patients from a diverse oncology practice setting. Unpublished data from our institution support the reliability of "real-time" DIGEST grading by the trained SLP clinician conducting the MBS when compared to blinded laboratory ratings. Our experience has been that with basic training, DIGEST is easily implemented in a clinical setting.

Once implemented, DIGEST™ should:

- Provide common language across SLPs (my "mild dysphagia" is your "mild dysphagia")
- Encourage providers to look beyond aspiration (DIGEST considers both efficiency and safety)
- Provide a shared interdisciplinary language with other medical team members

RESEARCH ROLE

The research purpose of DIGEST was to provide a validated clinician-rated measure of dysphagia from results of the MBS. DIGEST was developed for the head and neck cancer population, specifically targeting populations treated with the organ preservation methods of therapy that most significantly impact the pharyngeal phase of swallowing. Given the oncology focus, DIGEST was designed to align to the standard method for grading toxicity in cancer – that is, the National Cancer Institute's (NCI's) Common Terminology Criteria for Adverse Events (CTCAE)[3]. CTCAE serves as the universal framework for toxicity reporting in oncology. CTCAE provides specific criteria for the clinician to grade severity of various toxicities of cancer using for over 700 toxicity items using general guidelines or universal descriptors shown in Table 1.

TABLE 1. FRAMEWORK FOR GRADING CANCER TOXICITIES PER NCI'S CTCAE[3]

Grade	Descriptions of severity for each AE based on general CTCAE guidelines	Description – CTCAE v. 5.0 Dysphagia Item
1	Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only, intervention not indicated	Symptomatic, able to eat a regular diet
2	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL*	Symptomatic and altered eating/ swallowing
3	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL**	Severely altered eating/swallowing; tube feeding, TPN, or hospitalization indicated
4	Life Threatening consequences; urgent intervention indicated	Life threatening consequences; urgent intervention indicated
5	Death related to adverse event	Death
A semi-colon indicates 'or' within the description of the grade;		
Abbreviations: AE, adverse events; ADL, activities of daily living; NCI, National Cancer Institute; CTCAE, Common Terminology Criteria for Adverse Events * Instrumental ADL refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc. ** Self care ADL refer to bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden.		

The current CTCAE dysphagia item, as shown in Table 1, is a clinical grading of dysphagia made by any member of the healthcare team. Clinical CTCAE dysphagia grading does not include results of instrumental testing (e.g., MBS or FEES) to grade dysphagia, rather it is based on reports of dietary restrictions, dysphagia symptoms, and enteral/parental nutrition requirements. Clinicians conducting MBS studies will appreciate that while these criteria certainly represent distinct functional conditions, they are neither sensitive nor specific to pharyngeal function. For instance, it is well documented in the head and neck cancer population that patients often elect to eat and refuse gastrostomy in the setting of clinically significant dysphagia and aspiration on MBS. Therefore, the goal of DIGEST was to use the same framework for grading dysphagia as a toxicity in head and neck cancer but rely on standard criteria achieved from MBS observations to do so.

DIGEST was and is not intended to be a stand-alone measure of swallowing. In both research and clinical practice, outcome measures should include both patient reported outcomes (PRO) and clinician-reported metrics of swallowing function. DIGEST is one of many measures representing the clinician-graded aspect of dysphagia. PRO measurement of dysphagia is beyond the scope of this manual, but it is important to note that at every MBS study conducted in our institution, patients are asked to self-report perceived swallowing-related quality of life as per the MD Anderson Dysphagia Inventory (MDADI)[4]. The MDADI is given at the time of check in, and results of the PRO are used in conjunction with the MBS to fully evaluate both the clinician and patient assessment. In our practice, DIGEST is also paired with a standardized diet rating (PSS-HN and IDDSI-FDS) as well as a physiologic rating (MBSImP).

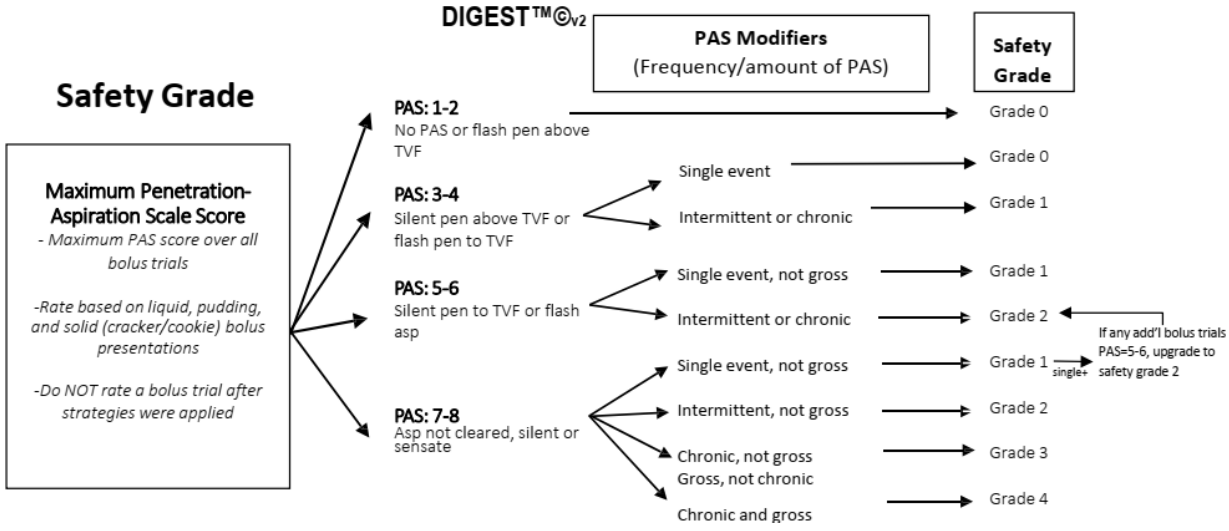
Since creation of the DIGEST method, our team has conducted various clinical research studies to understand how DIGEST performs in certain clinical scenarios and how it relates to other measures and factors. Table 2 provides a quick summary of the research we have conducted using DIGEST to date.

TABLE 2. SUMMARY OF THE INVESTIGATORS' PUBLISHED WORK USING THE DIGEST METHODOLOGY IN CLINICAL RESEARCH

Summary of published work using DIGEST™
• Developed and validated DIGEST[1], • Described improved sensitivity and specificity of DIGEST to grade pharyngeal dysphagia relative to clinical CTCAE[5], • Reported DIGEST sensitive to differences in swallowing muscle RT dose[6] • Reported DIGEST sensitive to differences in longitudinal change after RT or primary surgery[6,7] • Validated binary split of DIGEST grade ≥2 as RT dose-dependent and QOL altering[1,6] • Demonstrated DIGEST is sensitive to change after swallowing therapy[8] • Demonstrated feasibility of clinically implementing DIGEST, and expected relationships between DIGEST grades with MBS recommendations (i.e., diet, swallow strategies) supporting the notion of clinical utility. • Demonstrated reliability and confidence improved after training manual in multi-site pilot study.
Abbreviations: DIGEST, Dynamic Imaging Grade of Swallowing Toxicity; CTCAE, Common Criteria for Adverse Events; RT, radiotherapy ; QOL, quality of life

DIGEST™ SAFETY GRADE

FIGURE 2. DIGEST™ (VERSION 2) SAFETY GRADE FLOWCHART



DIGEST assigns a Safety Grade [S] on a 5-point scale:

- Grade 0 = normal
- Grade 1 = mild
- Grade 2 = moderate
- Grade 3 = severe
- Grade 4 = life threatening or profound impairment

Follow these basic steps to assign the **DIGEST Safety Grade:**

1. **Score PAS on each bolus trial** in standard MBS protocol (see Section MBS Bolus Protocol for details of the bolus protocol)
    a. Rate only liquid, pudding, cracker/cookie trials in lateral/mid-sagittal field of view (FOV)
    b. Do not rate PAS on a bolus trial after strategies are applied
2. Select the **maximum PAS** across all bolus trials in the MBS. Max PAS is condensed into four groups:
    a. PAS 1-2
    b. PAS 3-4
    c. PAS 5-6
    d. PAS 7-8
3. If max PAS is 3 or higher, then select **PAS modifiers**
    a. PAS **frequency** modifier is selected to describe the **frequency** of which the max PAS range or "bin" event(s) occurred (i.e., the frequency of PAS 3-4, PAS 5-6, or PAS 7-8 events)
    b. PAS **amount** modifier is selected to describe the **amount** of barium on or below the vocal cord on max PAS on the worst performance for any single bolus
4. Assign Safety Grade
    a. Use DIGEST flow chart (Figure 2) to select the Safety grade based on the steps above

SCORING PAS FOR DIGEST™

PAS, for DIGEST, is scored for each bolus level **not** for each swallow of a given bolus. That is, for DIGEST, the rater scores PAS at the bolus level rather than the individual swallow level. This means that PAS is taken based on the depth of airway entry, response and clearance of the bolus from the airway over all attempts to swallow a given bolus trial regardless of the number of swallows per bolus.

A few scenarios of bolus-level PAS scoring are detailed to better illustrate **bolus-level scoring**:

- Scenario: A person swallows 4 times to get down a single sip of thin liquid, the liquid touches the vocal cords at some point in the course of those swallows but is fully cleared from the laryngeal vestibule by the end of those swallows.
    - Rating: The cup sip thin liquid trial would be scored as PAS 4.
- Scenario: A person swallows 3 times to get down a 10mL trial of thin liquid, the liquid penetrates without clearing the laryngeal vestibule on the first swallow, the liquid slips below the vocal folds without response during the 2nd swallow, then coughs but doesn't clear the bolus from the tracheal airway.
    - Rating: The 10 mL trial would be scored as PAS 7.

Page 1 of the DIGEST forms gives the rater a place to track PAS for each bolus (Appendix).

TABLE 3. PENETRATION ASPIRATION SCALE SCORE[2]

Penetration-Aspiration Scale Score Definitions[2]
1. Material does not enter the airway
2. Material enters the airway, remains above the vocal folds, and is ejected from the airway
3. Material enters the airway, remains above the vocal folds, and is **not** ejected from the airway
4. Material enters the airway, contacts the vocal folds, and is ejected from the airway
5. Material enters the airway, contacts the vocal folds, and is **not** ejected from the airway
6. Material enters the airway, passes below the vocal folds, and is ejected into the larynx or out of the airway
7. Material enters the airway, passes below the vocal folds, and is **not** ejected from the trachea despite effort
8. Material enters the airway, passes below the vocal folds, and no effort is made to eject

Reprinted with permission from: Springer Nature: Dysphagia, A penetration-aspiration scale, Rosenbek JC, et al, 1996.

WHEN PAS IS MESSY

PAS ratings can be challenging at times. For DIGEST, it is critical to avoid over or under-assigning PAS ratings in order to avoid over or under-rating DIGEST severity. Several common clinical situations are described below.

Delayed penetration/aspiration events on residue

This challenge occurs when new bolus is seen in the airway in a delayed fashion, typically noted after fluoroscopy has been turned off, then resumed for the next bolus trial. When DIGEST rating, the clinician may adjust previous PAS rating based on what happens with residue on subsequent fluoro images (before the next bolus is swallowed). Our raters often refer to this as **'confirmatory evidence' of delayed airway entry**. Delayed airway entry is typically attributed to the immediate preceding bolus trial when it is detected before the next bolus trial is swallowed. This allows PAS ratings to most closely approximate the real world scenario, in which swallows do not typically occur in isolation, and ensures under-grading does not occur by ignoring these episodes of delayed airway entry. While important to capture this airway entry to enable accurate severity grading, it is also essential not to assign the delayed airway entry twice (that is, do not assign to both the old and new bolus). Some examples to better illustrate this concept of grading PAS when there is "confirmatory evidence" of delayed airway entry:

- Scenario: The 1st cup sip of thin barium yields a PAS 3, fluoroscopy goes off, and when fluoroscopy resumes in anticipation of the next cup sip of thin barium the vocal cords are now seen to be outlined with barium.
    - Rating: This will change the 1st cup sip score to a PAS 5.
- Scenario: The 1st trial of 10mL thin liquid yields a PAS 5 rating, fluoroscopy goes off, and when fluoroscopy resumes there is new barium seen in the trachea (prior to swallowing the next bolus trial).
    - Rating: This will change the 1st trial of thin liquid barium to PAS 8

It is not always fully clear which bolus to assign an aspiration event, particularly if there is residue in the airway already when a new bolus is given. Don't split hairs on this. It is critical only that you assign that aspiration event once, but not double count it (i.e., do not assign it to the old and new bolus trials, just assign it to one of the two bolus trials). As a general rule of thumb, when unclear which bolus trial to attribute the aspiration event, it is typically assigned to the new bolus; unless it is 100% clear that the new bolus did not enter the airway during or after the swallow.

On-the-Cusp PAS Ratings

While PAS definitions are clearly outlined with anatomic reference points, it can be difficult at times to differentiate between PAS scores. For example, is it PAS 2 vs 3; is it PAS 4 vs 6? Remember, DIGEST is a clinical tool – intended to be pragmatic and big picture. While each swallow is rated for PAS, the DIGEST rating should converge on the overall impression of severity.

In those instances where one is unsure as to which PAS to assign for a given bolus (e.g., is it a PAS 2 or PAS 3?), it is advisable to review 2 or 3 times, then make your best clinical determination. Ask yourself, "could I convince an audience of 100 that I see residue on the epiglottis or the bolus touch the vocal folds, etc?" Relevant questions on review may include:

- Does the penetration merely coat the aryepiglottic folds or does it enter the laryngeal vestibule?
- Is there a clear pattern across other swallows that may suggest one score over the other?

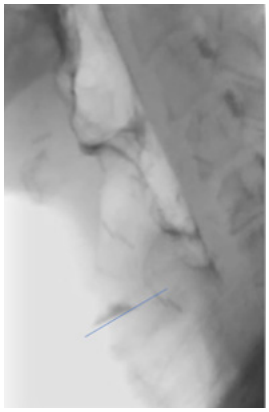
Review 2 to 3 times (ask is it clinically meaningful), rate, move on.

PAS 4, 5 or 6?

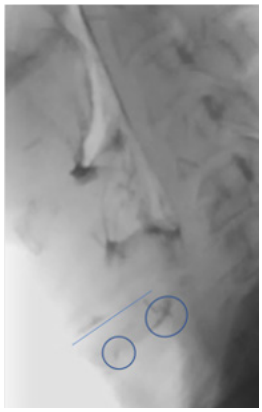
Defining depth of bolus entry within the laryngeal vestibule and tracheal air column can be tricky. This is particularly important when trying to decide whether the rating for a bolus is PAS 4, 5, or 6. The primary distinction between these ratings is often whether the bolus has reached the level of the vocal cords (VC) or has fallen below the VC. For this rating, ask yourself if the location of the liquid is along the vocal fold surface or has dropped below the vocal folds peeking into the tracheal air column. The top of the tracheal air column is used to designate the line where the bolus has fallen below the VC. This means if you observe:

a. a drop or line of barium visible along the surface of the vocal fold → the bolus reached the level of the vocal folds (PAS 4 or 5)

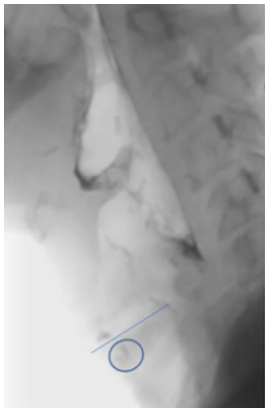
b. a drip of portion of barium entering into the top of the tracheal air column just below the surface of the vocal cords → below the vocal folds (PAS 6+)



a. Lining the vocal cord surface PAS 4 or 5



b. Below the vocal cord Breaches the tracheal column PAS 6 if ejected



c. Below the vocal cord Breaches the tracheal column PAS 6 if ejected

The following scenarios provide examples for selecting the correct PAS rating when deciding between PAS 4, 5 , or 6:

- Scenario: The bolus reaches the top of the vocal folds stays above the tracheal air column, and is ejected out of the laryngeal vestibule by a spontaneous cough or second swallow.
  - Rating: PAS 4
- Scenario: The bolus reaches the top of the vocal folds stays above the tracheal air column, and is not ejected out of the laryngeal vestibule.
  - Rating: PAS 5

- Scenario: The bolus lines the level of the vocal folds and momentarily drops just below the VC into the top of the tracheal air column before it is ejected above the vocal folds either from a spontaneous cough or second swallow
    - Rating: PAS 6
- Scenario: The bolus drips over the arytenoids from the piriform sinus into the top of the tracheal air column before it is ejected above the vocal folds either from a spontaneous cough or second swallow
    - Rating: PAS 6

"Cued Coughs" and Otherwise

DIGEST ratings are based on uncompensated swallows. For this reason, the SLP or clinician performing the MBS should avoid overly eager application of strategies or cues to the patient. Bolus trials are rated for PAS and PR up to the point that the clinician cues a strategy. This rule is designed to enable the DIGEST score to best reflect how the patient swallows when you (the clinician) are not watching or coaching.

- Scenario: Patient is presented with a cup sip of thin liquid. The patient swallows 3 times to clear the bolus through the oropharynx. On the first swallow, penetration is evident. During the second swallow, liquid settles on the true vocal cords, the clinician then cues the patient to clear their throat effectively clearing the bolus from the laryngeal vestibule.
    - Rating: PAS score 5.
- Scenario: Patient is presented with a 10ml trial of thin liquid. The patient swallows 3 times to clear the bolus through the pharynx. On the first swallow, liquid penetrates into the laryngeal vestibule. The patient spontaneously swallows a second time and liquid passes below the true vocal cords without response. The clinician then cues the patient to cough clearing the bolus back into the laryngeal vestibule.
    - Rating: PAS score 8.

APPLYING PAS MODIFIERS

PAS modifiers are a critical component to select the correct Safety Grade. PAS modifiers were developed to acknowledge the fact that the maximum PAS score alone does not give the complete picture of safety impairment. That is, a single PAS 8 in trace amounts is very different than multiple PAS 8 over an entire MBS.

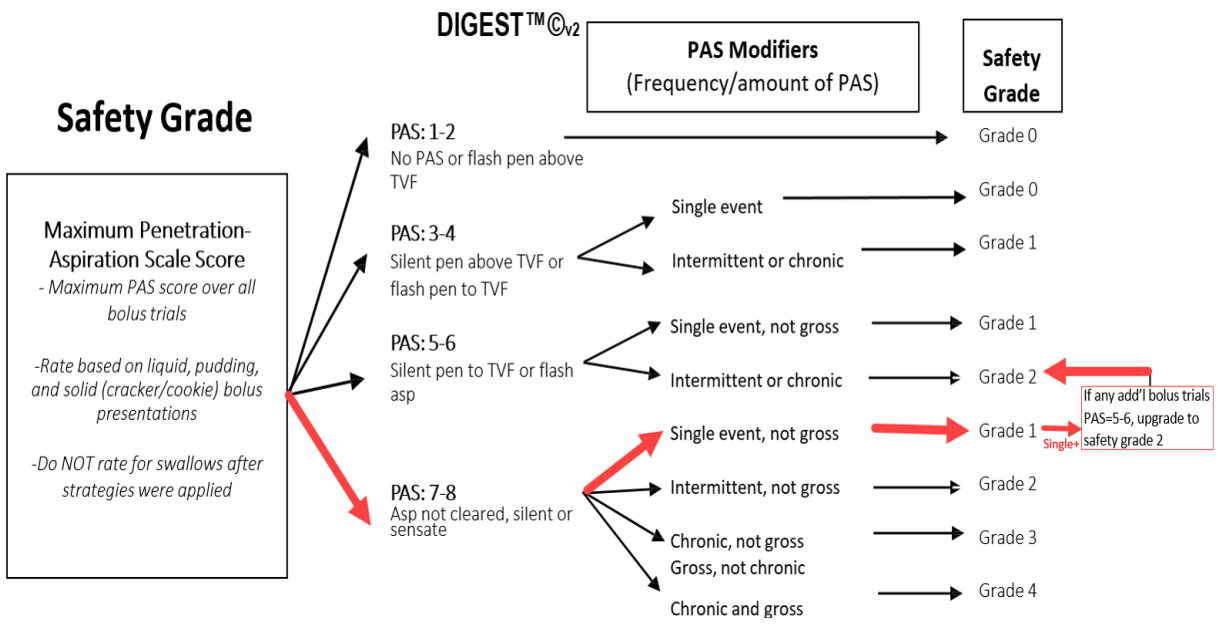
Consequently, if the max PAS observed during an MBS is PAS 7 or PAS 8, using the DIGEST method, the Safety Grade could be mild (grade 1), moderate (grade 2), severe (grade 3), or life threatening/profound (grade 4) depending on the frequency and amount of aspiration events that are detected.

PAS FREQUENCY MODIFIER

PAS frequency modifier is required if the max PAS is 3 or higher. The PAS frequency modifier describes how frequently the rater assigned PAS scores within the max PAS "bin" over the entire MBS. Bins here refer to the specific grouping in the flowsheet and are outlined below:

- PAS 1-2
- PAS 3-4
- PAS 5-6
- PAS 7-8

FIGURE 3. SINGLE+ SAFETY GRADE FLOWCHART



PAS frequency modifiers are defined as:

- **Single event:** only 1 bolus trial with max PAS range or bin (3-4 or 5-6 or 7-8) assigned
    a. **Single+:** Denotes special scenario when a single PAS 7-8 is accompanied by additional PAS 5-6 that will upgrade from S1 to S2 as highlighted in Figure 3.
- **Intermittent:** max PAS range or bin (PAS 3-4 or 5-6 or 7-8) assigned on multiple but <50% of bolus trials on a single consistency
- **Chronic:** max PAS range or bin (PAS 3-4 or 5-6 or 7-8) assigned on majority of thin liquid trials (≥ 50% of thins) OR more than one consistency

The following scenarios provide examples for selecting the frequency modifier for PAS:

- Scenario: The max PAS is 3-4, and PAS 3 or 4 was observed on only 1 bolus trial.
    - Rating: Frequency modifier = single.
- Scenario: The max PAS is 3-4, and PAS 3 or 4 was observed on 2 of 6 total thin liquid trials but no other bolus types.
    - Rating: Frequency modifier = intermittent.
- Scenario: The max PAS is 3-4 and PAS 3 or 4 was observed on 5 of 6 total thin liquid trials.
    - Rating: Frequency modifier = chronic
- Scenario: The max PAS is 3-4, and PAS 3 or 4 was observed on 2 of 6 thin liquid trials and ALSO 1 of 3 pudding trials. Note: PAS 3-4 on both thin and pudding makes frequency chronic by way of >1 consistency.
    - Rating: Frequency modifier = chronic
- Scenario: The max PAS is 3-4, and PAS 3 or 4 was observed on 2 of 6 thin liquid trials and ALSO 1 of 3 nectar thick liquid trials. Note: PAS 3-4 on both thin and thick liquid makes frequency chronic by way of >1 consistency.
    - Rating: Frequency modifier = chronic.

PAS AMOUNT MODIFIER

PAS amount modifier is required if the max PAS is 5 or higher. The amount of PAS modifier identifies the amount of barium on or below the true vocal folds based on worst performance of any single bolus. Amount of PAS is based on the total amount of bolus on or below the vocal folds relative to total amount of bolus entering the pharynx over all swallows of the bolus.

PAS amount modifiers are outlined below:

- **Trace:** resembling faint coating; droplets, or trickle of barium on or below the true vocal folds
- **Neither:** neither trace nor gross; and
- **Gross:** >25% of bolus volume across all attempts to swallow a given bolus

TABLE 4. EXAMPLES OF ASSIGNING PAS FREQUENCY MODIFIERS AND DIGEST™ SAFETY GRADE

	Ex. 1	Ex. 2	Ex. 3	Ex. 4	Ex. 5	Ex. 6	Ex. 7	Ex. 8	Ex. 9	Ex. 10	Ex. 11	Ex. 12	Ex. 13	Ex. 14
Bolus 1: 5-mL thin	3	5	2	1	5	5	3	3	3	5	7	3	3	8
Bolus 2: 5-mL thin	4	4	3	2	4	4	4	4	4	8	8	4	4	5
Bolus 3: 10-mL thin	3	5	2	1	6	6	2	7	7	5	7	2	2	5
Bolus 4: 10-mL thin	3	5	1	1	5	3	2	2	2	7	Skipped	2	2	Skipped
Bolus 5: Cup thin	8	8	1	2	6	3	3	8	8	8	8	8	8	7
Bolus 6: Cup thin	2	2	1	3	2	2	5	5	Skipped	Skipped	Skipped	5	5	Skipped
Bolus 7: pudding	1	1	1	3	1	1	1	1	1	1	3	1	1	3
Bolus 8: pudding	1	1	1	1	1	1	1	1	1	1	Skipped	8	8	3
Bolus 9: solid	1	1	1	1	1	1	1	1	1	1	1	1	1	3
Bolus 10: solid	1	1	1	1	1	1	1	1	1	1	Skipped	1	1	3
Max PAS	**7-8**	**7-8**	**3-4**	**3-4**	**5-6**	**5-6**	**5-6**	**7-8**	**7-8**	**7-8**	**7-8**	**7-8**	**7-8**	**7-8**
PAS modifier-Frequency	**Single**	**Single+**	**Single**	**Chronic**	**Chronic**	**Intermittent**	**Single**	**Intermittent**	**Intermittent**	**Chronic**	**Chronic**	**Chronic**	**Chronic**	**Chronic**
PAS modifier-Amount	**Not gross**	**Not gross**	**N/A**	**N/A**	**Not gross**	**Not gross**	**Not gross**	**Not gross**	**Gross**	**Not gross**	**Gross**	**Not gross**	**Gross**	**Not gross**
Safety grade*	**1**	**2**	**0**	**1**	**2**	**2**	**1**	**2**	**3**	**3**	**4**	**3**	**4**	**3**
Explanation	Single PAS7-8	Single PAS7-8 with additional PAS5-6	Single PAS3-4	PAS3-4 on >1 consistency (thin and pudding)	PAS5-6 on 4 of 6 (>50%) thins	PAS5-6 on 2 of 6 (<50% but more than once) thins	Single PAS5-6	PAS7-8 on 2 of 6 (<50% on 1 consistency) thins	PAS7-8 on 2 of 5 (<50% on 1 consistency) thins but gross	PAS7-8 on 3 of 5 (≥50% thins) but not gross	PAS7-8 on 3 of 4 (≥50%) thin and gross	PAS7-8 on >1 consistency (thin and pudding) but not gross	PAS7-8 on >1 consistency (thin and pudding) and gross	PAS7-8 on 2 of 4 (50%) thins in setting of skipped trials

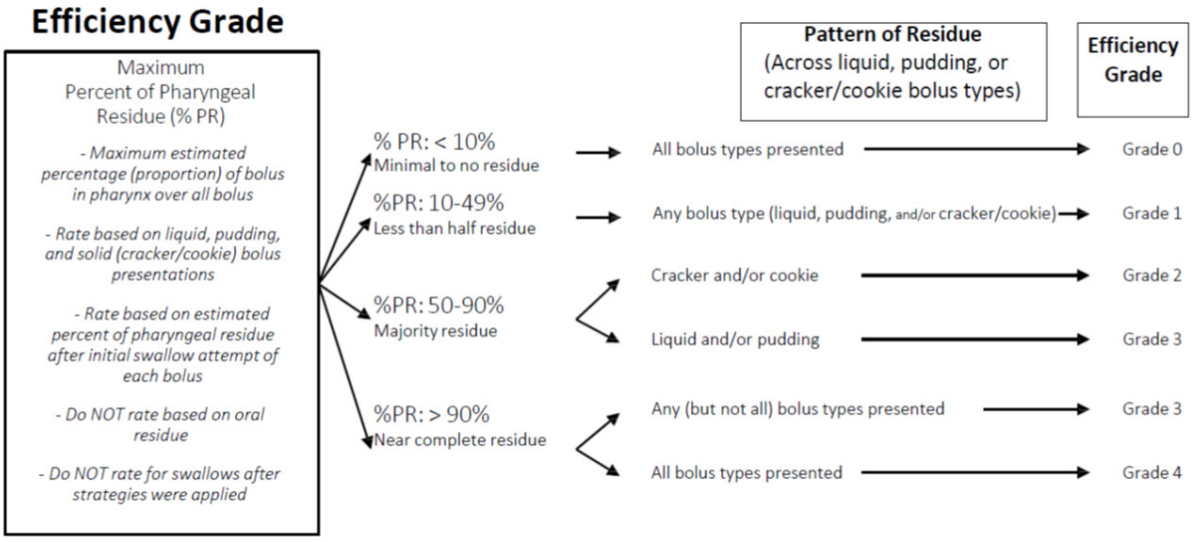
SAFETY GRADE SELECTION

Once Max PAS is identified and any necessary frequency and amount modifiers are then applied, the Safety Grade can be selected on the DIGEST flow sheet. (Figure 2)

DIGEST™ EFFICIENCY GRADE

DIGEST assigns an Efficiency Grade [E] on a 5-point scale based on patterns of residue over all bolus trials. The rater estimates percent residue remaining in the entirety of the pharynx after the initial swallow of each bolus [<10%, 10-49%, 50-90%, >90%], then assigns the Efficiency Grade using the flowsheet in *Figure 4*.

FIGURE 4. DIGEST (VERSION 2) EFFICIENCY GRADE FLOWCHART



DIGEST assigns an Efficiency Grade [E] on a 5-point scale:

- Grade 0 = normal
- Grade 1 = mild
- Grade 2 = moderate
- Grade 3 = severe
- Grade 4 = life threatening or profound impairment

Follow these basic steps to assign the **DIGEST™ Efficiency Grade:**

1. **Score pharyngeal residue** (PR) on each bolus trial in the standard MBS protocol
    a. Rate only liquid, pudding, cracker/cookie trials in lateral/mid-sagittal FOV
    b. Estimate residue based on what you see enter and exit the pharynx after the **first or primary swallow** of a given bolus
    c. Do not rate PR once strategies have been applied
2. Select the maximum PR **across all bolus trials** in the MBS. Max PR is condensed into one of four groups:
    a. Residue <10%
    b. Residue 10-49%
    c. Residue 50-90%
    d. Residue >90%
3. If max **PR ≥50%**, then select **PR modifiers**

4. Assign Efficiency Grade

    a. Use DIGEST flow chart to select the Efficiency Grade based on the steps above (Figure 4).

ESTIMATING PERCENT RESIDUE

The rater estimates the percent residue of a bolus after the initial attempt to swallow that particular bolus. Do not rate after additional spontaneous or cued swallows. The time point at which the rater estimates percent residue for DIGEST is operationalized to match the timing that one rates residue on MBSImP™© to harmonize measures as much as possible[9].

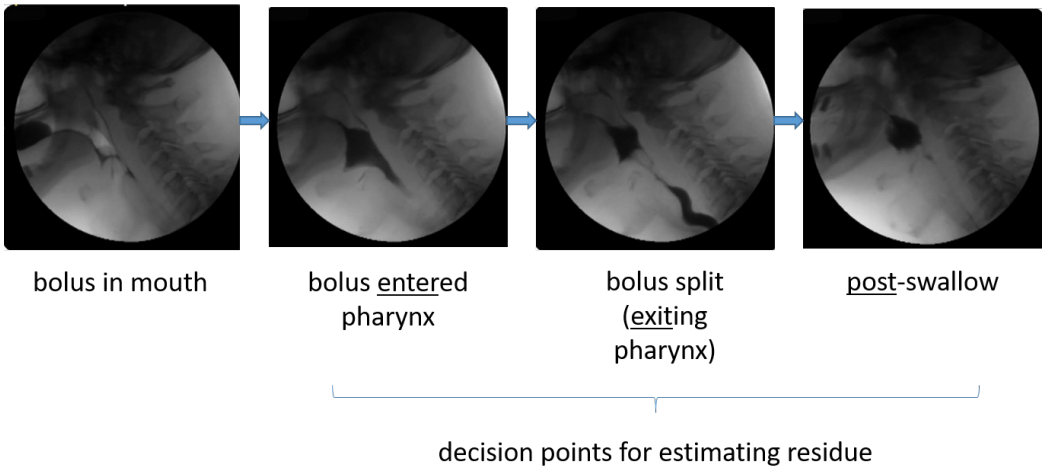
To estimate percent residue for DIGEST, raters should focus on 2 parameters:

1. What **enters**? -- What amount of bolus enters the pharynx?
2. What **exits?** -- What amount of bolus exits the pharynx?

% pharyngeal residue = total bolus entering pharynx (100%) – total bolus exiting pharynx

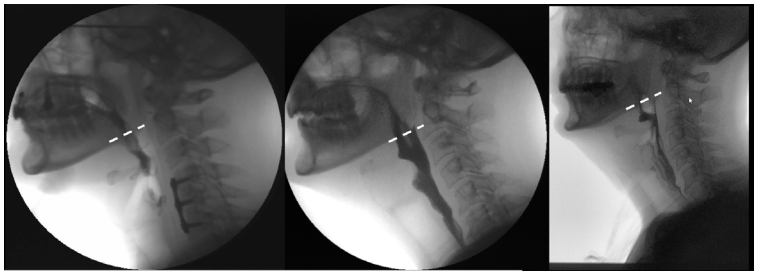
When first estimating residue, it can be helpful to use frame-by-frame review or to toggle back and forth to compare what entered and exited the pharynx. There are several key points in the swallow that can assist in estimating percent residue, as shown in Figure 5. The bolus that remains in the mouth (whether piecemeal or due to oral impairment) does not count toward the total bolus entering the pharynx. Percent residue is often first estimated at the peak of the swallow where the bolus separates or breaks apart, the "bolus break." This often allows the clearest view of the portion that will remain vs the portion that is going to clear into the esophagus. The rater should then watch where the bolus settles post-swallow to make the final estimation of percent residue.

FIGURE 5. DECISION POINTS FOR ESTIMATING PHARYNGEAL RESIDUE



At what point is the bolus considered to have entered the pharynx? For DIGEST, the bolus is assumed to enter the pharynx when it passes the ramus of the mandible.

FIGURE 6. ANATOMIC BOUNDARY FOR BOLUS ENTRY INTO THE PHARYNX



Where does residue count?

Residue in ANY portion of the laryngopharynx after the initial swallow attempt should be included in the estimate of PR, including the nasopharyngeal, oropharyngeal, laryngeal, and/or hypopharyngeal regions.

How is the 'initial swallow' defined?

Initial is defined as 'first,' but just like PAS can get messy. Several clinical scenarios exist that can make it difficult to sometimes choose the "initial" swallow. Current operating rules for these scenarios are as follows:

- On those swallows where there is **difficulty with oral bolus propulsion** to the pharynx and preparatory or pumping swallow(s) are first elicited without actual bolus material transferred to the pharynx, do not count the first swallow(s) prior to bolus transfer, rather rate the first attempt at swallowing the bolus once it has reached the level of the pharynx after oral bolus transit to the pharynx. This would be considered the 'primary swallow' for rating residue.
- On **piecemeal swallows** where only a small amount of the bolus enters the pharynx on the first portion, rate the first swallow of bolus material transferred to the pharynx.
- When a small amount of **premature oral bolus loss** occurs yielding a spontaneous swallow (prior to onset of oral bolus transit), consider the subsequent initial purposeful swallow with oral transit of the bolus to the pharynx as the primary swallow, and rate the primary swallow.
- In those instances where **no bolus enters the pharynx** during the course of the swallow, pharyngeal efficiency cannot be rated.

Examples of deciding which swallow to rate as the "initial" for a given bolus:

- Scenario: Bolus in the mouth, no movement of the tongue to propel the bolus. Swallow of saliva, then intentional initiation of bolus swallow.
  - Rating: Do not rate the 1st saliva swallow, rate the 1st bolus swallow attempt.
- Scenario: Piecemeal swallow with small volume bolus on 1st swallow.
  - Rating: Assign efficiency from the 1st bolus swallow.
- Scenario: Patient attempts to initiate swallow but no bolus enters pharynx due to oral impairment and/or expectoration.
  - Rating: Do not rate efficiency.

"ON-THE-CUSP" BETWEEN PHARYNGEAL RESIDUE RATINGS?

Sometimes, raters are undecided (or "on the cusp") between 2 residue bins – e.g., *is it 0-9% or is 10-49% residue?* In this scenario, the rater should review the bolus trial 2 or 3 times asking key questions:

1. What entered the pharynx?
2. What exited the pharynx?
3. What did the split look like at the bolus break?
4. What did the split look like when the residual bolus settled in the pharynx post-swallow?

Then, reflect on overall clinical impression – does it look more like mild or more like moderate residue? Clinical impression is relevant with DIGEST, as it is a pragmatic clinical and research tool. In those cases where it is difficult to score residue (or PAS) on a single bolus, decisions may be made within the greater context of overall swallow presentation. While each swallow is assessed separately to derive

the DIGEST grade, the final grade is intended to be representative of a gestalt impression of severity. Hence, should a question arise that impacts final severity grade, one should take into consideration corresponding clinical impression. This is even more important when the question arises for grading PAS or residue for a bolus that is a deciding bolus for the final severity DIGEST score.

- For example, if you are on the cusp between a residue rating on an individual bolus trial and this score will change the overall Dysphagia Grade from a D1 to a D2 – ask yourself, is the overall clinical impression of the patient's swallow more a mild or a moderate level dysphagia?
- For example, if you are on the cusp between a residue rating on an individual bolus trial and this score will change the overall Dysphagia Grade from a D2 to a D3 – ask yourself, is the overall clinical impression of the patient's swallow more a moderate or a severe level dysphagia?
- Review 2 to 3 times, rate, move on.

APPLYING PHARYNGEAL RESIDUE MODIFIERS

The pharyngeal residue modifier is used to describe the pattern of higher grade residue across bolus types. That is, how often was the maximum residue bin of 50-89% residue or >90% residue observed across the 3 broad categories of bolus types – liquid (any liquid – thin or thick), pudding, or cookie/cracker.

To apply PR modifiers, the bolus types are considered as follows:

- Liquid (IDDSI equivalent 0 to 3)
- Pudding (IDDSI equivalent 4)
- Cracker/Cookie (IDDSI equivalent 7)

Pharyngeal Residue modifiers are applied once the max percent residue rating for any single bolus trial has been identified, and defined as follows:

- If maximum residue is < 10% on all bolus types → Efficiency Grade = 0
- If maximum residue is 10-49% on any bolus type → Efficiency Grade = 1
- If maximum residue is 50-89%, then the rater must select modifiers, defined by which bolus type(s) had this % residue:
  - Liquid and/or Pudding → Efficiency Grade = 3
  - Cracker/Cookie → Efficiency Grade = 2
- If the maximum residue is >90%, then the rater must select modifiers, defined by whether >90% of residue happened on:
  - Any, but not all, bolus types presented → Efficiency Grade = 3
  - All bolus types presented → Efficiency Grade = 4

When maximum residue is >90%, skipped bolus trials become more common. For example, if a patient had 100% residue with pudding that had to be expectorated, the examiner may skip the cracker/cookie trial. Or, if on the first bolus trial of thin liquids a complete stricture is observed with 100% bolus residue, the examiner may terminate the MBS after a single bolus administration. The following scenarios may help the rater select ANY or ALL appropriately, particularly in the setting of skipped bolus trials.

Guidance on rating ANY versus ALL modifiers when max residue is >90%:

- Scenario: If all 3 bolus types were given (liquid, pureed/pudding, cracker/cookie) >90% was observed on 1 or 2 bolus types but not all 3 (e.g., >90% on liquid and pudding but not cracker,or pudding and cracker but not liquid)

- Rating: PR modifier = "Any"

- Scenario: >90% was observed on all 3 bolus types (i.e., >90% on liquid, pureed/pudding, and cracker/cookie)
  - Rating: PR modifier = "All"

If only 2 bolus types were given (e.g., liquid, and pureed/pudding given, cracker/cookie skipped):

- Scenario: >90% on 1 of 2 bolus types but not both (e.g., >90% on liquid but not pureed/pudding, or >90% on pureed/pudding but not liquid)
  - Rating: PR modifier = "Any"

- Scenario: >90% was observed on both bolus types (e.g., >90% on liquid and pureed/pudding)
  - Rating: PR modifier = "All"

If only 1 bolus type was given (e.g., liquid only, pureed/pudding and cracker/cookie skipped):

- Scenario: >90% on any one liquid trial when other bolus types skipped
  - Rating: PR modifier = "All"

Remember that for PR modifiers, "liquid" denotes ANY liquid consistency, so if there is >90% residue on honey thick liquid (if administered), but <90% residue on thin or nectar, "liquid" bolus type is still categorized as >90% residue.

TABLE 5. EXAMPLES OF ASSIGNING EFFICIENCY MODIFIERS AND DIGEST™

	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5	Scenario 6	Scenario 7	Scenario 8	Scenario 9	Scenario 10
Bolus 1: 5-mL thin	0-9%	0-9%	0-9%	0-9%	0-9%	0-9%	50-90%	10-49%	>90%	10-49%
Bolus 2: 5-mL thin	0-9%	0-9%	0-9%	0-9%	0-9%	10-49%	10-49%	0-9%	Skipped	10-49%
Bolus 3: 10-mL thin	0-9%	0-9%	0-9%	0-9%	0-9%	50-90%	10-49%	10-49%	Skipped	50-90%
Bolus 4: 10-mL thin	0-9%	0-9%	0-9%	0-9%	0-9%	10-49%	10-49%	0-9%	Skipped	Skipped
Bolus 5: Cup thin	0-9%	0-9%	0-9%	10-49%	10-49%	10-49%	10-49%	0-9%	Skipped	>90%
Bolus 6: Cup thin	0-9%	0-9%	0-9%	10-49%	0-9%	10-49%	0-9%	0-9%	Skipped	Skipped
Bolus 7: pudding	0-9%	0-9%	10-49%	10-49%	50-90%	50-90%	10-49%	>90%	Skipped	>90%
Bolus 8: pudding	0-9%	0-9%	0-9%	10-49%	Skipped	10-49%	50-90%	50-90%	Skipped	Skipped
Bolus 9: solid	0-9%	10-49%	10-49%	10-49%	50-90%	Skipped	>90%	Skipped	Skipped	Skipped
Bolus 10: solid	0-9%	0-9%	Skipped	50-90%	Skipped	Skipped	>90%	Skipped	Skipped	Skipped
Max PR	**0-9%**	**10-49%**	**10-49%**	**50-90%**	**50-90%**	**50-90%**	**>90%**	**>90%**	**>90%**	**>90%**
Efficiency modifier	**All**	**Any**	**Any**	**Solid**	**Liquid or pudding**	**Liquid or pudding**	**Any**	**Any**	**All**	**All**
Efficiency grade	**0**	**1**	**1**	**2**	**3**	**3**	**3**	**3**	**4**	**4**
Explanation		10-49% occurred on 1 of 3 consistencies (solid)	10-49% occurred on 2 of 3 consistencies (pudding and solid)	50-90% residue occurred on solids only	50-90% residue occurred on pudding bolus	50-90% residue occurred on liquids and pudding	>90% residue occurred only on 1 of 3 bolus types tested (cracker but not liquid or pudding)	>90% residue occurred only on 1 of 2 bolus types tested (pudding but not liquid)	>90% residue occurred on the only bolus type tested (liquid)	>90% residue occurred on all bolus types tested (liquid and pudding)

DIGEST™ EFFICIENCY GRADE SELECTION

Once maximum pharyngeal residue is identified, and pattern of residue modifier is then applied, the rater then assigns the efficiency grade using the DIGEST flow sheet.

DIGEST™ GRADE

Once Safety and Efficiency Grades have been selected, the rater then assigns an overall DIGEST grade of Pharyngeal Dysphagia [D] on a 5-point scale as outlined below:

- Grade 0 = normal
- Grade 1 = mild
- Grade 2 = moderate
- Grade 3 = severe
- Grade 4 = life threatening or profound impairment

The rater selects the overall DIGEST grade [D] using the grid or rubric in Table 6. After the Safety [S] and Efficiency [E] Grades are determined, the overall or summary DIGEST Grade is identified simply based on their interaction as shown in Table 6. As with its two contributing constructs (DIGEST-Safety and DIGEST-Efficiency Grades), the overall DIGEST grade is a 5-point ordinal scale of dysphagia severity compatible with CTCAE framework, where 0=normal, 1=mild, 2=moderate, 3=severe, and 4=life-threatening/profound. Table 7 summarizes the Safety and Efficiency profiles that contribute to overall DIGEST grades. Figure 7 shows the process of moving through the Safety and Efficiency flowcharts then using the DIGEST rubric to derive the overall DIGEST grade.

TABLE 6. OVERALL DIGEST™ GRADE RUBRIC (BASED ON SAFETY [S] AND EFFICIENCY [E] GRADES)

	S0	S1	S2	S3	S4
E0	0	1	2	3	3
E1	1	1	2	3	3
E2	1	2	2	3	3
E3	2	2	3	3	4
E4	3	3	3	4	4

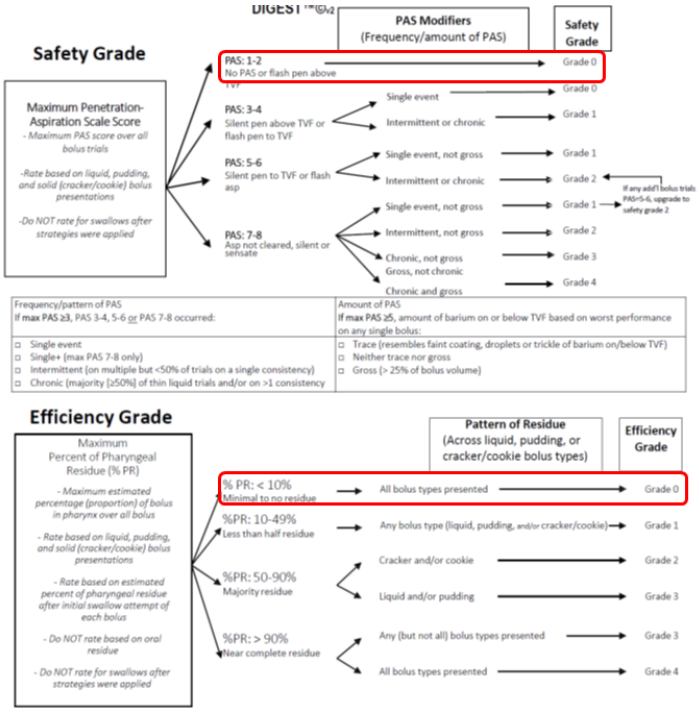
Various combinations of Safety and Efficiency impairment can result in the same overall DIGEST grade as summarized in Table 7.

TABLE 7. DIGEST SAFETY AND EFFICIENCY COMBINATIONS

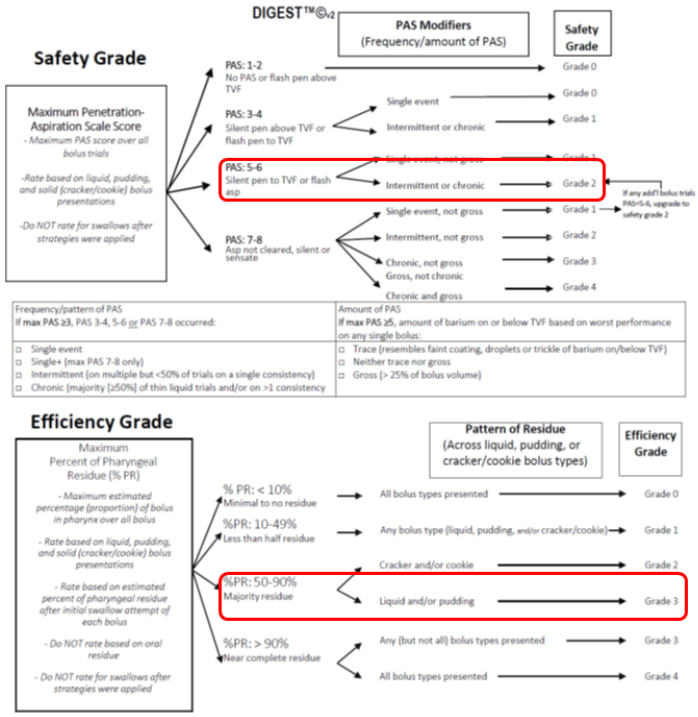
DIGEST	CTCAE	Safety Grade	Efficiency Grade	Safety	&	Efficiency
0	No toxicity	S0	E0	Safe	&	Efficient
1	Mild	S0	E1-E2	Safe	&	Mildly to moderately inefficient
		S1	E0-E1	Mildly unsafe	&	Efficient or mildly inefficient
2	Moderate	S0	E3	Safe	&	Severly inefficient
		S1	E2-E3	Mildly unsafe	&	Moderately to severly inefficient
		S2	E0-E2	Moderately unsafe	&	Efficient or mildly to moderately inefficient
3	Severe	S0-S1	E4	Safe or mildly unsafe	&	Profoundly inefficient
		S2	E3-E4	Moderately unsafe	&	Severely to profoundly inefficient
		S3	E0-E3	Severly unsafe	&	Efficient or mildly to severly inefficient
		S4	E0-E2	Profoundly unsafe	&	Efficient or mildly to moderately inefficient
4	Life-threatening	S3	E4	Severly unsafe	&	Profoundly inefficient
		S4	E3-E4	Profoundly unsafe	&	Severly to profoundly inefficient

Reprinted by permission from John Wiley and Sons: Cancer, Dynamic Imaging Grade of Swallowing Toxicity (DIGEST): Scale development and validation, Hutcheson KA, et al, 2016.

FIGURE 7. EXAMPLES OF SAFETY, EFFICIENCY AND OVERALL DIGEST GRADING USING FLOWSHEETS AND RUBRIC



	S0	S1	S2	S3	S4
E0	0	1	2	3	3
E1	1	1	2	3	3
E2	1	2	2	3	3
E3	2	2	3	3	4
E4	3	3	3	4	4



	S0	S1	S2	S3	S4
E0	0	1	2	3	3
E1	1	1	2	3	3
E2	1	2	2	3	3
E3	2	2	3	3	4
E4	3	3	3	4	4

DESCRIBING DIGEST™ GRADE IN CLINICAL NOTES

To provide a complete profile of the pharyngeal swallow, we suggest that clinical notes document DIGEST grade by identifying all components (D: S, E).

- For example, the impression statement in the MBS note might read *"Mild pharyngeal dysphagia [DIGEST Grade 1: S0, E1] impacting efficiency but not safety of pharyngeal bolus clearance."*

This style of documentation is recommended to provide an immediate "big picture" summary of the pharyngeal dysphagia. Other observations and physiologic summary should then describe the pathophysiology of the dysphagia in varying levels of detail (to continue with the above example, e.g., characterized by reduced pharyngeal constriction yielding <50% vallecular residue).

- Additional examples, to illustrate:
  - *Moderate pharyngeal dysphagia [DIGEST grade 2: S1, E3] impacting efficiency more than safety of pharyngeal bolus clearance, characterized by reduced laryngeal vestibule closure yielding silent laryngeal penetration of liquids and incomplete pharyngeal constriction yielding >50% pharyngeal residue with solids.*
  - *Severe pharyngeal dysphagia [DIGEST grade 3: S2, E3] impacting both safety and efficiency of pharyngeal bolus clearance resulting in intermittent silent aspiration of thin liquids and >90% pharyngeal residue with particulate solids.*
  - *Severe pharyngeal dysphagia [DIGEST grade 3: S3, E1] impacting safety more than efficiency of pharyngeal bolus clearance, resulting in chronic silent aspiration of liquids and mild pharyngeal residue.*

PROFILING PHARYNGEAL DYSPHAGIA USING DIGEST™

While DIGEST provides an overall grade of pharyngeal dysphagia severity by considering impairments in both Safety and Efficiency, the S and E grades together can be considered a "profile" in and of themselves. The DIGEST profile is intended to give a quick summary of the pattern of impairment. This is similar to the idea of GRBAS[11] rating in voice or TNM classification for cancer. For example, a familiar rater might know quickly that G3 R0 B3 A0 S0 voice disorder is more likely vocal fold paralysis and G3 R0 B0 A1 S3 is more likely muscle tension dysphonia by a "quick glance" at the profile. Likewise, a quick glance at different TNM profiles for stage III head and neck cancer (e.g., T3 N0 M0 versus T1 N1 M0) quickly gives a big picture summary of the clinical scenario. The S by E profile of DIGEST is intended to do the same.

- For example, a moderate DIGEST grade 2: S1 E3 specifies that inefficiency is the primary issue with only mildly impaired safety (S1) yet severe inefficiency (E3). In contrast, a moderate DIGEST grade 2: S2 E0 suggests that safety (S2) impairment is the primary issue with intact pharyngeal efficiency (E0). This can assist not only in understanding the etiology of the dysphagia, but also in forecasting potential recourse for prioritizing therapy.

MBS ACQUISITION PARAMETERS

Valid use of DIGEST assumes adherence to a standard MBS clinical protocol and recording capability to review the MBS video after acquisition.

FOV (Field of View) - must provide adequate visualization of the oral cavity, pharynx, tracheal airway, and upper esophagus – sufficient to grade PAS and PR on each bolus trial. Adequate resolution is a requisite.

How long should fluoroscopy remain on during each bolus administration? – Fluoroscopy should remain on until the bolus and swallowing structures come to rest after all attempts to swallow or clear the bolus.

Recording - Frame by frame capability is strongly preferred. Audio recording is mandatory. Audio is necessary to hear clinician cues, as bolus rating stops if or when the patient is cued to perform a compensatory technique (e.g., "clear your throat"), Audio is necessary to help adequately identify bolus trials (e.g., thin liquid versus nectar thick liquid).

The developers use the TIMS Medical® system (Foresight Imaging, Chelmsford, MA, https://tims.com/tims-dicom-system/speechpathology/) that allows for high resolution image capture at 30 frames per second in accordance with the DICOM (Digital Imaging and Communications in Medicine)[12] standard, and allows for remote review and analysis via TIMS DICOM Review System (TDRS). This system is by no means required for application of DIGEST, but the image quality, user interface, and review functions streamline analysis. The minimum frame or pulse rate to reliably acquire DIGEST has not been tested, but there are data to suggest differences in judgements of swallowing impairment and treatment recommendations when comparing even small differences in pulse rate (e.g., 30 pulse per seconds to a simulated 15 pps).[12] For this reason, we advocate for 30 pulse/frame per second standard at this time.

MBS BOLUS PROTOCOL

The DIGEST grade is based on **patterns** of bolus clearance. For this reason, use of a standard bolus protocol is extremely important to avoid misgrading. Using a bolus protocol with too few thin liquid trials (less than 5) may misrepresent safety impairment by not allowing adequate sampling to discriminate between single, intermittent, or chronic frequency modifiers. The error can go either way, over or under, although most often results in an over-grading of impairment (assigning too high a grade of impairment).

DIGEST is derived by grading PAS and PR on each bolus trial in a standard clinical protocol that includes 3 bolus types .The MBS bolus protocol used in the validation study for DIGEST included the VARIBAR® line as the current industry standard for contrast agents in the United States developed specifically for MBS testing standard barium contrast agents (Bracco Diagnostic Inc., Monroe, NJ, https://imaging.bracco.com/us-en/products/fluoroscopy/varibar) aligning to International Dysphagia Diet Standardisation Initiative (IDDSI, https://iddsi.org/framework/)[13] as follows:

- Liquid: Thin (IDDSI level 0 equivalent);
    - Nectar (IDDSI level 2 equivalent) and/or Honey (IDDSI Level 3 equivalent) as clinically indicated (rated for PAS and PR when given)
- Pureed/Pudding (IDDSI level 4 equivalent)
- Cracker/Cookie (IDDSI level 7 equivalent)

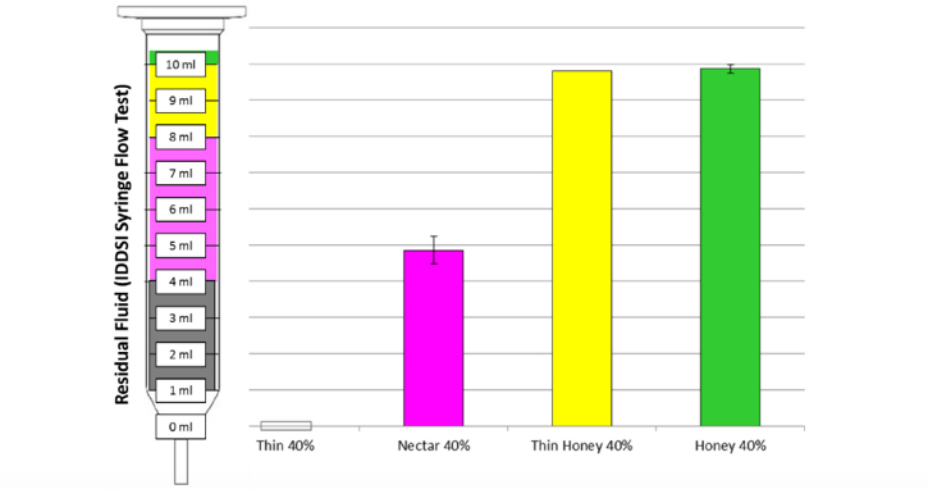
The standard bolus protocol (all administered in lateral/mid-sagittal plane) used in the validation sample for DIGEST was[1]:

- 2 trials 5 mL thin liquid VARIBAR® (IDDSI level 0 equivalent)
- 2 trials 10 mL thin liquid VARIBAR® (IDDSI level 0 equivalent)
- 2 trials self-administered cup sips thin liquid VARIBAR® (IDDSI level 0 equivalent)
- 2 trials VARIBAR® pudding (IDDSI level 4 equivalent)
- 2 trials ¼ cracker dipped in VARIBAR® pudding (IDDSI level 7 equivalent)
- VARIBAR® Nectar thick liquid (IDDSI level 2 equivalent), as clinically indicated
- Honey thick liquid (IDDSI level 3 equivalent, VARIBAR® Thin Honey), as clinically indicated

FIGURE 8. VARIBAR® BARIUM PRODUCTS DESCRIBED BY CORRESPONDING IDDSI LEVELS[13]

Varibar Product	IDDSI Syringe Flow Test Result (ml)		IDDSI Result (Level # and Name)
	Mean	Standard Deviation	
Thin 40%	0.0	0.0	Level 0 - Thin
Nectar 40%	4.9	0.4	Level 2 - Mildly-thick
Thin Honey 40%	9.8	0.0	Level 3 - Moderately-thick
Honey 40%	9.9	0.1	Level 4 - Extremely-thick

Table 2. IDDSI Syringe Flow Test results for Bracco Varibar® barium products.



FAQS ABOUT THE MBS ACQUISITION PARAMETERS FOR DIGEST™

Q: Can I grade DIGEST when I deviate from the standard bolus protocol?

Yes. DIGEST was designed with the reality of clinical testing in mind. Skipped bolus trials in the case of very extreme dysphagia (e.g., grade 4) were expected, and the rating criteria are scalable to these scenarios. However, overly conservative stopping rules, frequent deviations from the bolus protocol, and over-cuing can all threaten the validity of the DIGEST score. Thus, deviations from the clinical protocol should be reserved for extreme scenarios (e.g., complete/near complete stricture, gross/chronic aspiration, medically fragile patient).

- DIGEST validity typically maintains even with skipped boluses in a truly severe-profound dysphagia, frail or medically compromised patient, or clearly identified fully obstructive stricture.

A general rule of thumb when making the decision to deviate from the standard bolus protocol is to ask if additional relevant information or "deciding" PAS or PR scores might be achieved by stringently adhering to the standard bolus protocol, and if these counterbalance or outweigh perceived risk with proceeding.

Q: Do you grade DIGEST from AP/coronal plane?

While we routinely obtain an AP image for physiologic and structural data (e.g., pharyngeal constriction, UES opening), DIGEST ™ ratings are taken only in the lateral plane.

Q: Do I grade the first bolus given?

Yes.

Q: Do I grade PAS and PR on thickened liquid trials?

Thickened liquid trials of VARIBAR® Nectar (IDDSI 2 equivalent) and VARIBAR® thin honey (IDDSI 3 equivalent), when tested, were included in the DIGEST rating when the method was developed and validated. The thickened liquid bolus trials, however, were only administered when clinically indicated.

Note that thickened liquid bolus trials are considered "additional consistencies" when grading frequency of max PAS. Thus, these are sometimes deciding bolus trials that are relevant in determining whether max PAS is "chronic" (e.g., if PAS 7-8 is observed on both thin and nectar, it is considered "chronic").

Thickened liquids are considered "liquids" when applying the PR modifier for pattern of pharyngeal residue. (e.g., residue >=50% with thickened liquid when administered would result in DIGEST efficiency grade 3)

Q: Do additional bolus trials count toward DIGEST?

No. Only liquids, pureed/pudding, and cracker/cookie contribute to DIGEST. Additional bolus trials would be tested only to provide further clinical information or when requested by the patient or clinician – the results from these bolus trials are described as a "qualitative" result and do not contribute to DIGEST grade.

Q: Do I grade PAS and PR on swallows where strategies were applied?

Yes, you may grade PAS and PR on swallows where strategies were applied **if** you are able to obtain these ratings for the given bolus **before** the strategy has been implemented.

Some examples to illustrate:

- Scenario: The individual swallows, and after several swallows is cued by the clinician for a throat clear.
  - Rating: Rate the PR after the initial swallow and rate PAS up until that throat clear cue.
- Scenario: The individual is cued to tuck his chin and then swallow.
  - Rating: Do not rate for either PAS or PR (since there are no swallows of that bolus before the chin tuck was instructed).

Q: Do I score penetration/aspiration or residue from a liquid wash?

No. Do not score the liquid wash trial when it is given as a compensation to clear residue of an earlier bolus.

Q: Can you use DIGEST with other bolus protocols?

DIGEST has not been validated for a bolus protocol other than the one described in this manual. If adapting DIGEST grading to other protocols, the users should attempt, at a minimum, to have at least 5 thin liquid bolus trials (without compensation), a pureed/pudding, and cracker/cookie bolus type.

Q: I standardly include thickened liquids in my bolus protocol. Should I include their ratings in my DIGEST grading?

Yes, include the thick liquid ratings in your DIGEST grade. Emerging data suggest a high level of agreement between DIGEST grades taken from bolus protocols with or without the standard inclusion of thickened liquids (in IDDSI level 2-3 range).

Q: I standardly include a thin liquid sequential swallow in my bolus protocol. Should I include this rating in my DIGEST grading?

This question is under investigation. A standard sequential swallow task was not included in the bolus protocol for the original DIGEST validation study. Sequential swallows are currently defined in our studies as the continuous elevation of the hyolaryngeal complex without resumption of breathing between multiple swallows of a bolus. Residue would be rated after the 1st swallow and PAS would be rated after all swallows are completed for the sequential trial.

Q: What are the stopping rules for your bolus protocol?

There were no defined stopping rules in the development and validation sample used for DIGEST. Clinical MBS videos were used. The clinicians were all instructed to deviate from the standard clinical bolus protocol using their clinical judgement, typically only in the setting of truly severe/profound dysphagia or poor patient tolerance of the examination. Overly conservative stopping rules, such as skipping subsequent thin liquid trials after an initial observation of aspiration, may over-grade safety impairment.

DIGEST™ RECAP

In summary, DIGEST is:

- a CTCAE compatible method to grade the severity of pharyngeal phase dysphagia from MBS
- based on patterns of bolus clearance through the pharynx
- designed for real-time clinical use
- designed for research as an outcome measure of pharyngeal dysphagia severity

DIGEST does NOT:

- measure timing of swallow
- measure physiology of swallow
- measure oral preparatory or oral transit impairment
- measure compensation

FAQS

Q: Can you use DIGEST outside of HNC populations?

It depends. This is likely population specific. The reliability and validity of DIGEST has not been published outside of head and neck cancer populations at this time. DIGEST likely provides a valid measure of dysphagia severity when the swallowing problem results in pharyngeal residue and/or laryngeal penetration/aspiration, but the reliability and validity of DIGEST must be confirmed in other populations.

DIGEST also rates severity of dysphagia based on clearance of the bolus through the pharynx. If the manifestations of dysphagia do not result in penetration, aspiration, or pharyngeal residue, the DIGEST criteria is not likely to yield a valid grade for the population at hand (even if it proves reliable in that population).

Another critical factor is whether the clinician can safely obtain an adequate sampling of swallows to achieve a valid dysphagia summary score in a population of interest. Remember that DIGEST was developed and validated in a population that is considered to often tolerate aspiration for lengthy periods of time potentially without either awareness or ill-health effects. In our clinical practice, we use the DIGEST method on all MBS in our oncology setting, including non-head and neck cancer populations. The context of a medically fragile patient admitted with a diagnosis of leukemia post stem cell transplant, however, is vastly different than that of an ambulatory, disease free head and neck cancer survivor. Both patients may demonstrate a severe pharyngeal dysphagia, but the first may yield a D3 grade with a recommendation for temporary NPO and alternate nutrition, and the next a D3 with an oral diet recommendation despite similar DIGEST grades.

Q: What about oral dysphagia?

DIGEST does not measure oral dysphagia.

DIGEST was developed to grade severity of pharyngeal phase dysphagia and does not assess the oral preparatory or oral transit phases of swallowing. Oral dysphagia should be evaluated and commented on separately. Oral impairment will typically only impact the DIGEST grade if oral impairment yields penetration/aspiration or pharyngeal residue at some point during the course of the swallow.

Q: How many times should I watch a clip frame-by-frame before making a decision?

Several times at most – in our practical practice. This is often 2-3 times, then move on. You may find you want to review a few more times if the swallow is a defining swallow, in other words, if a particular bolus trial will determine the grade, and that's okay. Overall, view, review, and move on.

Q: How does DIGEST impact clinical management? For instance, does someone with Grade 3 or Grade 4 DIGEST always need a feeding tube?

DIGEST provides clinicians with reproducible criteria to assign a severity grade to the pharyngeal swallow based on the results of the MBS. The DIGEST grade should contribute to clinical decision making, and the S by E profile may help the clinician prioritize therapy, but clinical recommendations should always be applied within the full context of the patient scenario and pathophysiology of the dysphagia. Clinical decision-making will vary based on health and frailty, nutritional status, pulmonary health, and patient ability to compensate for the dysphagia. Pathophysiology of the dysphagia must also drive therapy plans. Sound clinical interpretation, taking into consideration concomitant factors, is paramount.

RESEARCH APPLICATION

DIGEST is a clinician-rated measure of the functionality of uncompensated pharyngeal bolus transit on videofluoroscopy, readily applicable in the clinical setting. As a reliable, validated, ordinal, MBS grade of pharyngeal stage dysphagia compatible with the NCI's CTCAE toxicity grading system, it also offers a streamlined MBS measure sensitive to the needs of oncology trials that increasingly incorporate clinician-graded (so called "objective") measures of functional outcomes. In research trials, our preferred approach is to pair DIGEST with complementary functional measures of oral intake (e.g., PSS-HN[14] or the Functional Oral Intake Scale[15]) and patient-reported swallowing outcome questionnaires (e.g., MDADI[13] or the 10-item Eating Assessment Tool[18]). Depending on the research question, we may also pair DIGEST with other measures from the MBS to understand the pathophysiology of the dysphagia. Options include, among others, MBSImP[9], CASM[17,18], PCR[19], ASPEKT[20], and SwallowTail.

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DIGEST™ RATING FORM

Pt ID:
MBS date:
Clinician/Rater:

Instructions:

1. Score Penetration-Aspiration Scale (PAS) and percent residue for each bolus trial in Table 1 (Page 1).
2. Assign Safety and Efficiency Grades (circle your response on Page 2).
3. Assign DIGEST score (circle your response on Page 2).

Penetration-Aspiration Scale (PAS)

I. When to rate PAS: Assign a PAS rating for each bolus trial based on all swallow attempts for that bolus

II. PAS Scores (Rosenbek, 1996):

1 Material does not enter the airway
2 Material enters the airway, remains above the vocal folds, and is ejected (no residue)
3 Material enters the airway, remains above the vocal folds and is NOT ejected from the airway (visible residue remains)
4 Material enters the airway, contacts the vocal folds, and is ejected from the airway (no residue)
5 Material enters the airway, contacts the vocal folds and is NOT ejected from the airway, (visible residue remains)
6 Material enters the airway, passes below the vocal folds and is ejected into the larynx or out of the airway (no subglottic residue visible)
7 Material enters the airway, passes below the vocal folds, and is NOT ejected from the trachea despite effort (visible subglottic residue)
8 Material enters the airway, passes below the vocal folds, and NO effort is made to eject the material (visible subglottic residue)

Do not score penetration/aspiration for a bolus trial after strategies are cued (*e.g.*, cued throat clear, chin tuck, *etc*).

Source: Rosenbek, J. C., Robbins, J. A., Roecker, E. B., Coyle, J. L., & Wood, J. L. (1996). A penetration-aspiration scale. *Dysphagia, 11*(2), 93-98.

Pharyngeal Residue

When to rate residue: Judge pharyngeal residue after the completion of the 1st swallow. The amount of residue after the initial/primary swallow is the basis for the score, regardless of how much residue is left after any additional clearing swallows or strategies. Watch what enters and exits the pharynx. Estimate the proportion of what entered the pharynx that remains in the pharynx (not clearing thru the cervical esophagus) after the first swallow. The first swallow is the initial or primary swallow of a bolus after oral transfer (not spill) to the pharynx. Entry to the pharynx is defined as bolus passing the ramus of the mandible. Do not include residue from prior bolus trials in the estimation of residue. In instances where new bolus and prior residue are indistinguishable, again watch the amount of new bolus entering pharynx and amount of bolus exiting pharynx to derive the proportion remaining.

Start Time/ Frame MM: SS		Penetration/Aspiration	PAS Amount t=trace n=neither g=gross	Pharyngeal Residue	Not evaluable	Not given
	Thin	□1 □2 □3 □4 □5 □6 □7 □8	□t □n □g	□0-9% □10-49% □50-90% □>90%		
	Thin	□1 □2 □3 □4 □5 □6 □7 □8	□t □n □g	□0-9% □10-49% □50-90% □>90%		
	Thin	□1 □2 □3 □4 □5 □6 □7 □8	□t □n □g	□0-9% □10-49% □50-90% □>90%		
	Thin	□1 □2 □3 □4 □5 □6 □7 □8	□t □n □g	□0-9% □10-49% □50-90% □>90%		
	Thin	□1 □2 □3 □4 □5 □6 □7 □8	□t □n □g	□0-9% □10-49% □50-90% □>90%		
	Thin	□1 □2 □3 □4 □5 □6 □7 □8	□t □n □g	□0-9% □10-49% □50-90% □>90%		
	Nectar	□1 □2 □3 □4 □5 □6 □7 □8	□t □n □g	□0-9% □10-49% □50-90% □>90%		
	Nectar	□1 □2 □3 □4 □5 □6 □7 □8	□t □n □g	□0-9% □10-49% □50-90% □>90%		
	Nectar	□1 □2 □3 □4 □5 □6 □7 □8	□t □n □g	□0-9% □10-49% □50-90% □>90%		
	Honey	□1 □2 □3 □4 □5 □6 □7 □8	□t □n □g	□0-9% □10-49% □50-90% □>90%		
	Honey	□1 □2 □3 □4 □5 □6 □7 □8	□t □n □g	□0-9% □10-49% □50-90% □>90%		
	Honey	□1 □2 □3 □4 □5 □6 □7 □8	□t □n □g	□0-9% □10-49% □50-90% □>90%		
	Pudding	□1 □2 □3 □4 □5 □6 □7 □8	□t □n □g	□0-9% □10-49% □50-90% □>90%		
	Pudding	□1 □2 □3 □4 □5 □6 □7 □8	□t □n □g	□0-9% □10-49% □50-90% □>90%		
	Cracker	□1 □2 □3 □4 □5 □6 □7 □8	□t □n □g	□0-9% □10-49% □50-90% □>90%		
	Cracker	□1 □2 □3 □4 □5 □6 □7 □8	□t □n □g	□0-9% □10-49% □50-90% □>90%		
	MAX	□1 □2 □3 □4 □5 □6 □7 □8	□t □n □g	□0-9% □10-49% □50-90% □>90%		

Project: Rater: Video Identifier: _____

DIGEST™©v2

Safety Grade

Maximum Penetration-Aspiration Scale Score

- Maximum PAS score over all bolus trials

-Rate based on liquid, pudding, and solid (cracker/cookie) bolus presentations

-Do NOT rate for swallows after strategies were applied

PAS Modifiers (Frequency/amount of PAS)		Safety Grade
PAS: 1-2 No PAS or flash pen above TVF		Grade 0
PAS: 3-4 Silent pen above TVF or flash pen to TVF	Single event	Grade 0
	Intermittent or chronic	Grade 1
PAS: 5-6 Silent pen to TVF or flash asp	Single event, not gross	Grade 1
	Intermittent or chronic	Grade 2
	Single event, not gross	Grade 1 (single+ → If any add'l bolus trials PAS=5-6, upgrade to safety grade 2)
PAS: 7-8 Asp not cleared, silent or sensate	Intermittent, not gross	Grade 2
	Chronic, not gross	Grade 3
	Gross, not chronic	Grade 4
	Chronic and gross	Grade 4

Frequency/pattern of PAS If **max PAS ≥3**, PAS 3-4, 5-6 or PAS 7-8 occurred:	Amount of PAS **If max PAS ≥5**, amount of barium on or below TVF based on worst performance on any single bolus:
□ Single event □ Single+ (max PAS 7-8 only) □ Intermittent (on multiple but <50% of trials on a single consistency) □ Chronic (majority [≥50%] of thin liquid trials and/or on >1 consistency	□ Trace (resembles faint coating, droplets or trickle of barium on/below TVF) □ Neither trace nor gross □ Gross (> 25% of bolus volume)

Efficiency Grade

Maximum Percent of Pharyngeal Residue (% PR)

- Maximum estimated percentage (proportion) of bolus residue in pharynx over all bolus trials

- Rate based on liquid, pudding, and solid (cracker/cookie) bolus presentations

- Rate based on estimated percent of pharyngeal residue after initial swallow attempt of each bolus

- Do NOT rate based on oral residue

- Do NOT rate for swallows after strategies were applied

	Pattern of Residue (Across liquid, pudding, or cracker/cookie bolus types)	Efficiency Grade
% PR: < 10% Minimal to no residue	All bolus types presented	Grade 0
%PR: 10-49% Less than half residue	Any bolus type (liquid, pudding, and/or cracker/cookie)	Grade 1
%PR: 50-90% Majority residue	Solids only (cracker and/or cookie)	Grade 2
	Liquid and/or pudding	Grade 3
%PR: > 90% Near complete residue	Any (but not all) bolus types presented	Grade 3
	All bolus types presented	Grade 4

DIGEST Score (Interaction of Assigned Safety and Efficiency Grades)					
	S0	S1	S2	S3	S4
E0	0	1	2	3	3
E1	1	1	2	3	3
E2	1	2	2	3	3
E3	2	2	3	3	4
E4	3	3	3	4	4

1 = Mild 2 = Moderate 3 = Severe 4 = Life threatening

NOTES

THE UNIVERSITY OF TEXAS
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