The Development of a Standardized Videofluoroscopic Swallow Study Barium Mixing Protocol: A Consensus-Based Approach

Création d'un protocole standardisé de mélanges de baryum pour l'évaluation de la déglutition par vidéofluoroscopie : une approche fondée sur le consensus

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Abstract

Videofluoroscopic swallow assessments are considered the gold standard for dysphagia evaluation. Despite widespread use in clinical and research settings, standardization of barium mixing protocols is lacking. This study compared current barium mixing protocols across four Canadian acute care centres and aimed to establish standard consensus-based protocols for select target textures (i.e., thin liquid, nectar thick liquid, honey thick liquid, puree, and solid) feasible for clinical and research implementation. A representative speech-language pathologist at each site responded to an online questionnaire regarding their current barium mixing protocols. Each liquid protocol was assessed for accuracy in meeting its target using the International Dysphagia Diet Standardisation Initiative Flow Test. Early consensus was reached to use pudding and a biscuit as targets for puree and solid textures, respectively. The mixing protocols which met these criteria moved through the iterative feedback process with participating sites, identifying the protocol considered most accurate and feasible. Survey data identified use of common products across institutions, but barium mixing protocols differed. Flow Test results eliminated liquid mixing protocols that failed to align with our criteria. Acceptable liquid, puree, and solid protocols were reviewed by sites for feasibility of mixing, perceived accuracy, and visibility on imaging. Through this process, a single consensus-based barium mixing protocol was established for each target texture. Reproducibility for each final protocol was established by two sites. The iterative review process, clinician feedback, and Flow Test results successfully established barium mixing protocols for several textures which have the potential for widespread implementation.

Abrégé

L'évaluation de la déglutition par vidéofluoroscopie est considérée comme l'examen de référence pour l'évaluation de la dysphagie. En dépit de son utilisation répandue en clinique et en recherche, un manque de standardisation des protocoles utilisés pour créer les mélanges de baryum demeure. Dans le cadre de la présente étude, les protocoles utilisés par quatre établissements de soins aigus canadiens pour créer les mélanges de baryum ont été comparés dans le but d'établir des protocoles standardisés et fondés sur le consensus pouvant être utilisés en clinique et en recherche pour obtenir des textures et consistances spécifiques (liquide clair, liquide nectar, liquide miel, purée et solide). Quatre orthophonistes représentant chacun des quatre établissements participants ont répondu à un questionnaire en ligne portant sur les protocoles utilisés dans leur établissement pour créer les mélanges de baryum. Les mélanges de liquide obtenus en utilisant les protocoles de chaque établissement ont été soumis au test d'écoulement de l'Initiative internationale de standardisation des diètes pour la dysphagie afin de déterminer la capacité de chacun à produire les consistances cibles. Un premier consensus a été atteint concernant l'utilisation de pouding et d'un biscuit pour les textures « purée » et « solide », respectivement. Les protocoles de mélanges qui respectaient ces critères ont ensuite été soumis à un processus itératif de rétroactions auprès des établissements participants afin d'identifier les protocoles les plus précis et les plus réalisables. Les données du questionnaire ont révélé que, même si les mêmes produits étaient employés d'un établissement à l'autre, les protocoles utilisés pour mélanger le baryum à ces produits différaient entre ces derniers. Les résultats au test d'écoulement ont permis d'éliminer les protocoles produisant des mélanges qui ne répondaient pas à nos critères. La faisabilité des protocoles acceptables, la précision perçue des consistances de liquides et des textures de purées et de solides obtenus avec ces protocoles et la visibilité des consistances et textures pendant la vidéofluoroscopie ont été évaluées par les établissements participants. Au travers de ce processus fondé sur le consensus, un seul protocole de mélange de baryum a été retenu pour chaque consistance et texture ciblée. La reproductibilité des protocoles finaux a été vérifiée par deux des établissements. Le processus itératif, les rétroactions des cliniciens et les résultats au test d'écoulement ont permis d'établir des protocoles de mélanges de baryum pour plusieurs textures et consistances, lesquels sont susceptibles d'être utilisés à grande échelle.

The videofluoroscopic swallow (VFS) procedure is considered a gold standard of dysphagia assessment (Martin-Harris et al., 2021). The VFS provides an objective means of analyzing swallow physiology and bolus clearance by observing ingestion of barium-infused solids and liquids under fluoroscopic visualization. Yet, despite widespread utilization of the VFS to assess swallow physiology, clinical practice guidelines are only emerging with limited detail in the standardization of this procedure (Boaden et al., 2020). As such, aspects of assessment protocols vary across institutions and even amongst individual clinicians within the same institution, thereby limiting comparisons of patient swallowing statuses (Power et al., 2006).

Fortunately, in recent years there have been several evidence-based recommendations to standardize the conduct and analysis of the VFS assessment (Martin-Harris et al., 2020, 2021). For example, the optimal pulse rate of the radiation beam at 30 frames per second is now considered essential to ensure adequate visualization of swallow physiology and bolus movement while staying within a safe radiation exposure level (Bonilha et al., 2013). Likewise, several psychometrically validated tools are now available by which to rate the VFS findings. The Penetration-Aspiration Scale is an 8-point ordinal classification of airway safety that captures the depth of bolus invasion into the airway (Rosenbek et al., 1996). The Modified Barium Swallow Impairment Profile offers a systematic sequence of texture administration and a validated and reliable rating schema of 17 physiological components of the swallow. These components derive two overall swallow physiology impairment scores: for the oral phase and the pharyngeal phase of swallowing (Martin-Harris et al., 2008). The Dynamic Imaging Grade of Swallowing Toxicity derives an overall severity grade for pharyngeal dysphagia along a 5-point scale based on combined ratings of pharyngeal swallow efficiency and airway safety (Hutcheson et al., 2017). The Analysis of Swallow Physiology: Events, Kinematics and Timing Method evaluates the physiological impairments of the swallow and provides normative values for healthy swallows across a variety of textures (Steele et al., 2019). As a complement to these perceptual ratings, there are now objective digital measurement tools that quantify biomechanical features of the swallow, such as the pharyngeal constriction ratio (Leonard et al., 2011) and pharyngoesophageal segment opening (Leonard & Kendall, 2019). Together these standardized protocols have greatly enhanced the reliability and validity in the interpretation of VFS assessment findings.

The accuracy of these standardized ratings is dependent on the VFS protocol execution and specifically the reproducibility of the bolus textures used as testing stimuli (Martin-Harris et al., 2021). To date, there are no universal standards regarding which textures should be included or how their barium counterparts are prepared (Peladeau-Pigeon & Steele, 2013). In the United States, clinicians have addressed this variability in part with the utilization of the FDA-approved Varibar line of barium contrast products (Martin-Harris et al., 2021). The Varibar products offer a variety of prepared liquids (thin, nectar, thin honey, honey) and one food texture (pudding), each prepared to a 40% weight/volume concentration of barium sulfate (VARIBAR barium sulfate 40% weight/volume, Bracco Diagnostics, Inc., Monroe Township, NJ). The Varibar products enable not only a reproducible series of barium-infused textures but also sufficient contrast visualization during VFS.

Unfortunately, these commercially standardized barium-infused textures are not readily available outside the United States. As such, clinicians are often left to their own means to standardize VFS texture stimuli. These efforts have the potential to be disjointed and can unintentionally lead to different protocols. In fact, recent studies from the United Kingdom and Australia have shown this to be the case. In the United Kingdom, VFS procedures related to texture selection, preparation, and administration varied both within and between institutions (Benfield et al., 2021). Likewise in Australia, VFS liquid barium preparations across multiple institutions were not well matched to their target liquid textures in relation to density, viscosity, and yield stress (Cichero et al., 1997, 2000). The addition of varying amounts of barium to target liquids and foods has the potential to unknowingly alter their thickness, density, and/or viscosity (Baron & Alexander, 2003; Cichero et al., 2000; Steele et al., 2013). Importantly, protocols that produce inaccurate target texture prototypes or produce inconsistent texture stimuli during the VFS administration may yield inaccurate and unreliable VFS findings. Not even standardized rating protocols can salvage these VFS findings. Therefore, the accuracy of the VFS assessment is firmly dependent on reliable and accurate barium mixing protocols.

The global issue of the lack of standardized barium mixing protocols is further compounded by inconsistent rheological properties and nomenclature of the target textures themselves (Cichero et al., 2013). One may argue that without first establishing predetermined texture properties that align with a shared nomenclature, it would be challenging for multiple institutions to implement and adhere to common barium mixing protocols. In an attempt to address this matter, the International Dysphagia Diet Standardization Initiative (IDDSI) offered a framework for standardization of diet textures. The IDDSI nomenclature

operationalized the preparation and corresponding labels for a wide spectrum of clinically relevant textures from liquid to solid in an attempt to bridge this gap (Cichero et al., 2017). This framework provides both nomenclature and an 8-level scale (0–7) in its classification of food and liquid consistencies. Specifically, solid textures are classified from *liquidized* (Level 3) to *regular* (Level 7) based on particle size, response to fork pressure, and spoon tilt tests (Cichero et al., 2017). Liquid consistencies range from *thin* (Level 0) to *extremely thick* (Level 4) based on the results of a standardized Flow Test (Cichero et al., 2017). The Flow Test is a simple, cost-effective, and reliable means of ensuring liquid textures are prepared according to a preset target thickness. Fluids in question are placed in a 10-ml syringe and undergo a gravity flow test through the syringe for 10 s. The amount of fluid remaining following this time interval determines the IDDSI level. Specifically, between 0 and 1 ml remaining represents *thin*–Level 0, 1 to 4 ml remaining represents *slightly thick*–Level 1, 4 to 8 ml remaining represents a *mildly thick*–Level 2, 8 to 10 ml represents a *moderately thick*–Level 3, 10 ml (i.e., all fluid remaining) represents *extremely thick*–Level 4 (Cichero et al., 2017). Such a test has utility in not only clinical and research settings but also can be easily and independently applied by patients themselves as part of their own self-care.

The University Health Network/University of Toronto Swallowing Lab routinely engages in multisite research collaborations. As such, it was considered critical for our research team to develop harmonized VFS barium mixing protocols that could be feasibly and reliably implemented across various participating research sites. Based on previous findings suggesting the risk for variation across institutions regarding how VFS barium textures were prepared, we needed to ensure a standardized approach by our participating study sites. Therefore, in response to a primarily research agenda, namely the PRO-ACTIVE trial (ClinicalTrials.gov, 2018; Martino et al., 2021), we sought to establish a consensus-based barium mixing protocol that utilized the IDDSI framework for each of the target VFS textures. Our aim was to ensure that the derived protocols were considered efficient and feasible in both the research and clinical settings and would be perceptually judged to provide adequate visualization on videofluoroscopy. Furthermore, because we were preparing for a multisite study that included several U.S. sites, all of whom were using the same commercial Varibar barium products, we aligned our target textures accordingly.

Methods

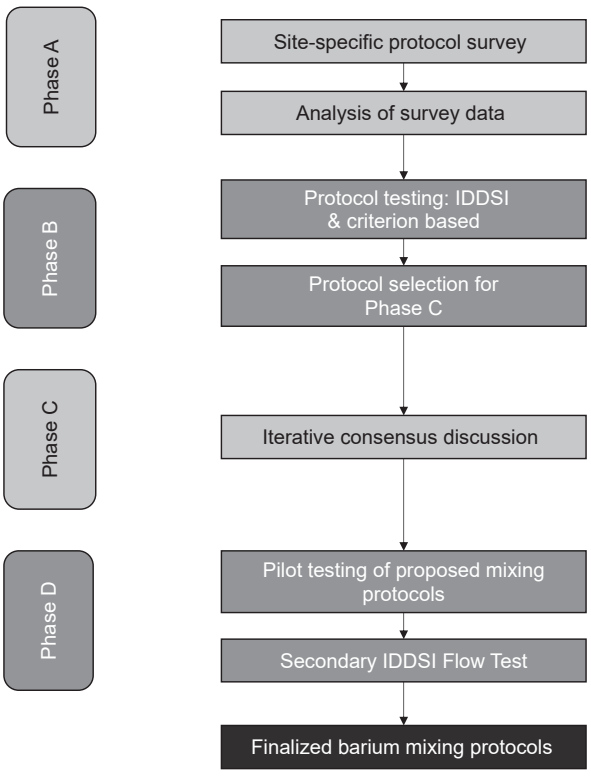
As part of this process, we utilized a collaborative iterative approach, ensuring that the values and opinions of clinicians at all participating Canadian research sites were considered in the final selection of textures and barium mixing protocols. Our iterative approach was a repetitive forward sequential process whereby clinician feedback was shared and received with clinicians across participating sites in real time.

Site Selection

Eligible sites were those which independently prepared their barium texture stimuli and were collaborators in research with our Central-VFS Lab (C-VFS), which is a branch of our University Health Network/University of Toronto Swallowing Lab. Four Canadian acute care hospital sites participated in this study: London Health Sciences Centre, Montreal Jewish General Hospital, and University Health Network (comprising Toronto Western Hospital and Princess Margaret Cancer Centre). To promote anonymity, sites have been randomly assigned the numeric labels 1, 2, 3 and 4. Ethical review and approval was received from the University of Toronto's Office of Research Ethics (Protocol 42864).

Our iterative feedback process is depicted in **Figure 1** and described below.

Figure 1



Visual Depiction of Iterative Feedback Process

Study Phase A

A questionnaire was developed by researchers at the C-VFS with the aim of collecting information regarding existing VFS barium mixing practices at each of the participating sites. As all sites had previously reported one standard protocol used at their respective institutions, the self-administered online questionnaire was circulated by email to participating sites for completion by one representative speech-language pathologist (S-LP) at each site. The representatives selected from Sites 1 and 2 were S-LPs involved in the initial development and implementation of their site-specific barium mixing protocols. This information was not available for the S-LPs at Sites 3 and 4, therefore all S-LPs involved in our research were sent the questionnaire and self-selected a representative to respond to the survey. Textures of interest were thin liquids, nectar thick liquids, honey thick liquids, puree/pudding solids, and cookie/cracker solids. Although our current research protocol only required standardization of thin liquids, puree, and solids, we expanded our interest to include nectar thick liquids and honey thick liquids, as these are common therapeutic interventions that may be implemented during VFS. Survey content focused on site-specific details related to their preparation of our target VFS textures, such as texture labels, liquid and food products, barium products, and mixing protocols. Survey responses were aggregated and compared descriptively to identify similarities and differences in barium mixing practices across sites. In cases where sites used different measurement units (i.e., grams vs. millilitres), conversions were made to the unit most commonly employed across sites. Mathematical conversions were used wherever possible, however in instances where product densities were not available, conversions were manually carried out using a weighing scale.

Study Phase B

The protocol for each target texture from each site was prepared and tested in a similar manner at the C-VFS. To assess the three liquid thickness textures, we used the IDDSI Flow Test (Cichero et al., 2017). All liquids and barium products were kept at room temperature throughout the entire testing process, which was approximately 20 min in length. The flow test was completed immediately after mixing and was repeated three times per protocol to ensure accuracy. As outlined by IDDSI guidelines, testing was completed using a BD 10 ml Leur-Lok Tip syringe (IDDSI, 2019). The IDDSI level values were assigned as per guidelines: thin liquid (*thin*–Level 0), nectar thick liquid (*mildly thick*–Level 2), and honey thick liquid (*moderately thick*–Level 3; United States IDDSI Reference Group, 2021). Liquid protocols which yielded the target IDDSI level on at least two of the three flow test trials were moved forward to Study Phase C. The duration of the flow test with water is benchmarked to be approximately 7 s; as such, this was used as a target for thin liquid barium protocols as this would represent the thinnest form of thin (IDDSI, n.d.). Likewise, for the puree texture we targeted the Varibar pudding thick texture. Only puree texture protocols which met this criterion were moved forward to Study Phase C. For the solid texture, we selected a digestive cookie as the target.

Study Phase C

All accepted mixing protocols from Study Phase B were put through an iterative consensus generating process with S-LPs from the participating sites. Feedback was sought regarding feasibility of protocol execution, visualization during VFS, and perception of the best match to its target texture from the sites which provided the protocols. All S-LPs contacted in Study Phase A were invited to provide this feedback and to elaborate if they had concerns with their current protocols. Iterative feedback was collected through email communication and/or teleconference. The consensus for the final barium mixing protocol for each of the proposed textures was guided by S-LP feedback and the IDDSI Flow Test results derived from the C-VFS.

Study Phase D

The final barium mixing protocol for each texture underwent independent pilot testing by two of the four participating sites. Utilizing local resources, each site evaluated feasibility of recipe execution, visualization during VFS, and reproducibility using the IDDSI Flow Test. Sites were instructed to mix the allotted quantities of the base and barium products in a measuring cup with a teaspoon until a homogenous mixture was formed. This step sought to ensure that the barium mixing protocol was both feasible in the clinical setting and stable across test trials. A post hoc weight/volume analysis was carried out with the finalized protocols.

Results

Study Phase A

Survey responses were received from all participating sites providing details of their original barium mixing protocols (**Table 1**). All sites had institution standard protocols for each of the target textures, namely thin liquid, nectar thick liquid, honey thick liquid, pudding/puree, and cracker/cookie. Additional textures were reported by some sites and included pudding thick liquid (one site), prepackaged peaches (two sites), and bread (two sites). We considered these additional textures to be therapeutic

Table 1

Original Barium Mixing Protocols Across Participating Sites by Target Texture

Texture	Participating site			
	1	2	3	4
Thin liquid	120 ml water 120 ml Polibar Plus Barium Sulfate Suspension prediluted (~50% w/v)	135 ml water 45 ml Polibar Plus Barium Sulfate Suspension	155 ml[a] water 163.8 ml[a] Polibar Plus Barium Sulfate Suspension	60 ml water 60 ml Polibar Plus Barium Sulfate Suspension
Nectar thick liquid	120 ml Sysco nectar thick liquid 10 ml water 15 g EZ HD Barium Sulfate Powder	120 ml Sysco nectar thick liquid 40 ml water 64 g EZ HD Barium Sulfate Powder	120 ml Sysco nectar thick liquid 48 g EZ HD Barium Sulfate Powder	120 ml Oasis Nutrisolution Hydra nectar thick liquid 19 g[b] EZ HD Barium Sulfate Powder
Honey thick liquid	120 ml Sysco nectar thick liquid 25 g EZ HD Barium Sulfate Powder	120 ml Sysco nectar thick liquid 48 g EZ HD Barium Sulfate Powder	120 ml Sysco honey thick liquid 48 g EZ HD Barium Sulfate Powder	120 ml Oasis Nutrisolution Hydra honey thick liquid 19 g[b] EZ HD Barium Sulfate Powder
Puree	~64 g[c] Apple Blend packets 15 g EZ HD Barium Sulfate Powder	113 g Leah Orchard Applesnax 46 g EZ HD Barium Sulfate Powder	99 g Jell-O pudding 40 g EZ HD Barium Sulfate Powder	105 g[d] Leah Orchard Applesnax 19 g[b] EZ HD Barium Sulfate Powder
Solid	Peak Freans Digestive Cookie Puree barium mixture	Peak Freans Social Cookie Barium Paste (Sysco Honey thick liquid [no measurement provided] + 3–4 spoonfuls of EZ HD Barium Sulfate Powder)	Social Tea Cookie Puree barium mixture	Leclerc 1905 Tradition Social Tea Cookie 4 g Esobar Barium Sulfate Esophageal Cream

Note. w/v = weight/volume.
[a] Conversion made to millilitres from grams. [b] Manually converted to grams from provided measurement (1.5 rounded teaspoons). [c] Manually converted to grams from provided measurement (4 packets). [d] Manually converted to grams from provided measurement (120 ml).

and not part of the site standard core diagnostic protocol, therefore they were not included in this study.

Across all sites, a common nomenclature was used for liquids, namely thin liquid, nectar thick liquid, and honey thick liquid. Also, the base and barium products used to yield these target textures were similar. Specifically, water was used as a base for thin liquid barium textures and a prethickened liquid was the base for all thickened liquid protocols. Likewise, the same barium products were utilized across sites for the liquid and pudding/puree textures. All sites also used a digestive cookie to represent their solid texture.

Differences in product use across sites were also identified. Specifically, three of four sites utilized an undiluted form of the Polibar Plus Barium Sulfate for their thin liquid protocol, whereas another site used a prediluted version of this product. Also, three of four sites utilized the Sysco brand of thickened liquid, whereas the fourth site used an institution-specific product (Oasis). Two sites utilized nectar thick liquid as a base for the honey thick liquid barium solutions, whereas the other two sites used the honey thick liquid as their base. While one mixing protocol was the same between two sites, one site used it to represent nectar thick liquids, the other site to represent honey thick liquids. Three of four sites used applesauce as

their base for puree texture, whereas one site used store-bought pudding. Two sites coated their cookie/cracker solid with barium using their puree barium texture, whereas the other sites used a commercial barium cream or a paste developed specifically for the cookie/cracker texture. In sum, despite some similarities across sites regarding base and target products, the barium mixing protocols for each of the target textures were different across all four sites.

Study Phase B

The IDDSI scores for each liquid protocol from each site are depicted in **Table 2** and described below.

Thin Liquids

Although protocols from all sites scored within the desired IDDSI level, the protocol provided by Site 4 was consistently found to have residual fluid within the syringe at the end of each trial. The residual fluid was less than 1 ml, thus still qualifying as an IDDSI Level 0. Site 3 had a thin liquid protocol which required the entire 10 s testing interval for the barium solution to completely clear from the syringe, whereas thin liquid protocols from Sites 1 and 2 achieved full clearance of the liquid within 8 s. Given that the protocols from Sites 1 and 2 required the shortest time interval to clear the syringe and as such represented the thinnest form of thin liquids, they were moved forward for further consideration.

Nectar Thick Liquids

In contrast, the recipes for nectar thick liquids did not yield the same IDDSI score across all sites. Specifically, the protocol provided by Site 3 was consistently outside of the IDDSI Flow Test criteria; therefore it was not moved forward for consideration. The nectar thick liquid protocol provided by Site 4 could not be tested centrally due to product unavailability. The protocol provided by Site 2 was within the desired IDDSI range across all three iterations and the protocol provided by Site 1 was within this range on two of three iterations. As such, both of these protocols were carried forward to Phase C.

Honey Thick Liquids

Similar to those for thin liquid, the honey thick liquid protocols provided by Sites 1, 2, and 3 were within the accepted IDDSI standard across all three replication trials, thus were moved forward for consideration. Again, the fourth protocol could not be tested due to product unavailability.

Puree

The target for this texture was intended to align with the Varibar pudding texture, therefore only protocols with pudding were moved forward for consideration. The protocol provided by Site 3 met this criterion, as it was the only target to use pudding as a base consistency. All other sites used applesauce as their base for their puree texture.

Solids

All sites utilized a digestive cookie for their solid texture, albeit from varying brands, coated with barium-infused material. Two of four sites coated the solid with their puree barium counterpart, while one site developed a separate barium paste mixture specific for this purpose and another site used a prepackaged barium cream. All digestive cookie brands were carried forward, with the intention to coat the cookie with the finalized puree barium counterpart, to ensure feasibility and accessibility of products across all sites.

Study Phase C

From each of the four participating sites, between one and four clinicians provided feedback regarding their current mixing protocols which had been carried forward to this phase.

Thin Liquids

Of the two mixing protocols considered, the Site 1 mixing protocol was reported to have inconsistent visibility

Table 2

Flow Levels for Original Barium Liquid Protocols by Site

Liquid texture	Participating site			
	1	2	3	4
Thin	Level 0 [a]	Level 0 [a]	Level 0	Level 0
Nectar thick	Level 2 [a]	Level 2 [a]	Level 3	- [b]
Honey thick	Level 3 [a]	Level 3 [a]	Level 3 [a]	- [b]

Note. Flow Test results reflect the level achieved on the majority of trials (≥ 2 of 3 trials).
[a] Protocols which aligned to study target moved forward to Study Phase C. [b] Protocols not tested due to product unavailability at central research site.

during VFS and therefore was eliminated. The other protocol, from Site 2, met this criterion and was carried forward for pilot testing.

Nectar Thick Liquids

Of the two mixing protocols considered, clinicians voiced concern that the protocol provided by Site 2 yielded a (perceptually) thinner consistency than the target texture, despite falling within the target IDDSI standard on testing. No concerns were voiced for the other protocol, provided by Site 1, therefore it was carried forward for pilot testing.

Honey Thick Liquids

No concerns were voiced by the clinicians for any of these protocols. The same protocol was utilized by Sites 2 and 3, although there was a difference in target representation. Specifically, Site 2 labelled this protocol as a honey thick liquid and Site 3 labelled it as a nectar thick liquid. To align with our goal to meet IDDSI standards, this protocol was carried forward for pilot testing as a honey thick liquid.

Puree

Only the protocol from Site 3 met the target texture of pudding. No concerns were voiced by clinicians for this protocol; therefore it was carried forward for pilot testing.

Solids

Given that the variation of the solid item was largely by brand, and not the actual texture, it was proposed that each site continue with their current choice of digestive cookie brand and coat it with the same designate puree barium counterpart.

Study Phase D

The pilot testing of the new consensus-based barium mixing protocols yielded the same IDDSI Flow Test results for all target fluids, confirming successful duplication with locally available thickened liquid (i.e., Sysco thickened liquid and Oasis Hydra thickened liquid). Successful duplication of target textures coupled with positive feedback from all sites regarding the perceived feasibility and clinical acceptability of the proposed barium mixing protocols derived final consensus for these protocols (see **Table 3**). The protocols were shared with all participating sites for local implementation.

Discussion

Despite recent critical strides in the standardization of many aspects of the VFS assessment, there remains no common protocol by which to prepare the texture stimuli administered during this procedure. Our results offer insight into the practice patterns of VFS conduct in Canadian academic centres and the variability that persists. This study specifically targeted this gap using a reiterative consensus-based approach aimed to standardize a multisite research VFS protocol. This process successfully derived common barium mixing protocols for three liquid and two food textures for implementation at the participating research sites, despite the fact that at the onset each site had been utilizing different barium mixing protocols. The reiterative consensus process was successful in not only generating a harmonized and feasible protocol across all sites, but one that also aligned with published IDDSI guidelines and three Bracco Varibar texture equivalents (thin liquid, nectar thick liquid, and pudding).

Table 3

Final Barium Mixing Protocol by Target Texture

Texture	Base product (quantity)	Barium product (quantity)	Weight/volume (%)
Thin liquid	Water (135 ml)	Polibar Plus Barium Sulfate Suspension 105% (45 ml)	26
Nectar thick liquid	Sysco Nectar thick liquid (120 ml) Water (10 ml)	EZ HD Barium Sulfate Powder (15 g)	11
Honey thick liquid	Sysco Nectar thick liquid (120 ml)	EZ HD Barium Sulfate Powder (48 g)	36
Puree	Pudding cup (99 g)	EZ HD Barium Sulfate Powder (40 g)	41
Solid	Digestive cookie	Puree barium solution (thin coating)	

Given that our protocol was considered feasible and appropriate at multiple Canadian institutions, each with originally varying mixing protocols, it may generalize to additional sites. Originally, three of the participating sites were using approximate measures for ingredients, and of these, one site also reported inconsistent visibility of their original thin liquid barium texture during their VFS exam. This suggests that variability in mixing ratios may alter visibility of the target texture and while sites may have institution-wide barium mixing protocols, there can be variability in its execution in standard practice. Our final mixing protocols used specific quantities in an effort to limit variability. Our findings have shown that varying concentrations of barium to base solutions not only impacts visibility, but also the viscosity of the product itself. This finding was most evident in our Flow Test values of the nectar thick liquid protocols provided. Others have also found the addition of barium to thickened liquids resulted in further thickening of the original product (Park et al., 2019; Steele et al., 2013). Varied amounts of barium have also been found to impact temporal measures of the swallow, where more barium increases pharyngeal transit time and upper esophageal sphincter opening duration (Dantas et al., 1989; Stokely et al., 2014). Therefore, utilization of consistent barium mixing protocols ensures the reliability of VFS findings. Clinically, this is particularly important as VFS findings are used in patient care not only to evaluate a patient's swallowing impairment, but also to guide therapeutic interventions and nutritional management (Martin-Harris et al., 2020).

Accurate representation of a patient's swallow is crucial to accurately chart change in swallow status as patients transition to different institutions throughout their healthcare journey. For our research agenda, standardization of the VFS protocol was necessary for the launch of our multisite, international PRO-ACTIVE study, in which patients at each site undergo VFS at three different time points throughout their participation (ClinicalTrials.gov, 2018; Martino et al., 2021). Likewise, there was a need for standardization of the VFS protocol within the clinical research setting.

Our findings are especially relevant for clinical sites without access to commercially prepared and therefore standardized weight/volume VFS products such as Varibar. Although the published weight/volume standard of barium products is declared to be 40% (Martin-Harris et al., 2017) there has been a recent call for considering 20% in the clinical setting (Stokely et al., 2014). This transition has been driven by the increased pharyngeal coating effect of the higher barium concentrations (Peladeau-Pigeon & Steele, 2013; Steele et al., 2013). While our thin liquid and honey thick liquid protocols both fall within the 20% to 40% range, the nectar thick liquid falls below this range. Despite this lower weight/volume level, visualization was not reportedly compromised. Further research will be beneficial to objectively evaluate if the lower weight/volume level has any impact on visibility and if this can successfully be generalized to other barium textures.

While other studies evaluated the stability of barium target textures with their mealtime equivalent (Barbon & Steele, 2019; Cichero et al., 2000; Park et al., 2019), our study is the first to utilize existing barium mixing protocols across multiple institutions in an attempt to harmonize to a common protocol. The methodology and derived protocol were anchored by a pragmatic goal to balance reproducibility and validity of target textures with perceived feasibility and clinical utility. Our use of prethickened liquids instead of thickening agents was intentional to maintain ease of execution. The goal set for each target texture was to identify a barium mixing protocol that was feasible, yielded a product that was easily visible on VFS across multiple sites, and was reproducible for clinicians with high clinical and research demands. The feasibility of our final protocols is supported by successful implementation of the barium mixing protocol in over 600 VFSs conducted at three Canadian sites to date in the PRO-ACTIVE trial.

Although we successfully harmonized barium mixing protocols across all our research sites, also meeting the IDDSI standards, there were notable limitations that deserve mention. Namely, with emphasis on feasibility, we intentionally limited products to those available to sites. For example, the thickened liquids utilized by one site was not available at other sites and as such did not qualify for central testing. While this site was able to fully implement the protocols for the thin liquid, puree, and solid as necessary for our PRO-ACTIVE study research protocol, their nectar thick liquid and honey thick liquid protocols were implemented using a locally available thickened liquid brand. Despite this variation in base thickened liquid product, this site independently conducted the IDDSI Flow Test using their locally available brand of thickened liquid and found it to be compliant with our final standard for both the nectar thick and honey thick liquid protocols. Despite these promising results, it is unclear if similar testing conditions were maintained during this site's independent IDDSI Flow Test, as such execution of a standardized testing process would be of benefit to ensure consistency of results. Furthermore, although IDDSI testing for each protocol was completed after mixing at room temperature, we did not measure the temperature of the final product. Our testing interval, however, was approximately 20 min, reflecting our typical total VFS testing time from when products were prepared

to administration. Although protocols can be stable for up to 3 hours after preparation (Barbon & Steele, 2019), further research to evaluate the generalizability of our results over time and at varying temperatures would be warranted.

Another important limitation to note is of the IDDSI Flow Test itself. Although it evaluates gravitational flow of a given fluid, this feature might not be all that impacts bolus movement in the aerodigestive tract. Specifically, as the liquid bolus is propelled through the oropharynx it undergoes constant manipulation and deformation in addition to lubrication from saliva. These processes can alter bolus flow (Nicosia, 2012). Hence, while the IDDSI Flow Test was a useful tool in evaluating and comparing barium mixing protocols across different sites, it may not necessarily capture the large variation in fluid properties that occur during swallowing. Finally, despite variability in the barium weight/volume concentrations, clinicians did report adequate visualization of all textures, however empirical testing is needed to validate these perceptions.

Conclusion

Overall, this study resulted in successful development of a harmonized consensus-based barium mixing protocol for a variety of commonly utilized textures for the VFS assessment. The final textures derived by these protocols aligned with the IDDSI criteria and were feasible and reliable for clinical and research settings.

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