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Original Article

Consistency between Schedule for Oral-Motor Assessment – Persian and Fluoroscopic Barium Swallow Study

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ABSTRACT

Background: A swallowing disorder is one of the most common problems in the pediatric population. Schedule for Oral-Motor Assessment (SOMA) has become one of the best methods for the assessment of swallowing disorders in the pediatric population. In this study, we evaluated the sensitivity, specificity, and consistency of SOMA by fluoroscopic barium swallow study.
Methods: This is a descriptive-analytical study. SOMA was assessed on 52 children with swallowing problems. The children were 6 to 48 months and had been referred for a fluoroscopic barium swallow. We analyzed sensitivity; specificity, positive predictive value, and negative predictive value of SOMA, with the fluoroscopic barium swallow as the gold standard. For the evaluation of the correlations among variables, Cronbach's coefficient alpha was calculated.
Results: In this study 6 parts of SOMA had 0-25% sensitivity, 90-97% specificity, 0-66% positive predictive value, 84-87% negative predictive value, 78-86% compatibility percent and 0.06-0.17 kappa value. Internal consistency was 0.93 using Cronbach's coefficient alpha.
Conclusion: The results of this study suggest that SOMA is valid for the evaluating of swallowing disorders. It can use as a screening test and as a complementary method to fluoroscopic barium swallow.

Introduction

Pediatric swallowing disorders can arise from various causes, including gastroesophageal reflux, respiratory problems [1], neuromuscular conditions, premature birth, craniofacial abnormalities, and pulmonary ailments [2]. Feeding disorders can often be associated with prematurity and the complications that may result from it [3, 4]. Premature infants, in particular, may not have fully developed the coordination between sucking, swallowing, and breathing [5]. During swallowing, symptoms like upper airway noises, apnea, and cyanosis while feeding can indicate aspiration [1].

The ability to transition from oral feeding to oral nutrition is one of the most intricate skills in infants and children that must be achieved. It also stands as one of the criteria for discharging children from the hospital. The assessment of swallowing disorders is of utmost importance to ensure the appropriate nourishment intake and prevent complications such as weight loss, malnutrition, dehydration, aspiration pneumonia, and, in some severe cases, even death [6, 7]. If left unaddressed, swallowing disorders can lead to growth failure over time [3].

A fluoroscopic barium swallow is a highly effective technique for evaluating dysphagia and swallowing

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disorders [4-12]. This imaging study assesses anatomy and movement in the oral, pharyngeal, and esophageal phases. It is considered the gold standard for evaluating the dynamic processes of swallowing in children [2, 4, 6, 10].

To design an appropriate treatment plan for children with feeding disorders, performing a comprehensive assessment beyond instrumental assessment alone is essential. This is primarily due to the limitations of instrumental assessments, especially in adequately evaluating the oral phase of feeding. Certain aspects of the child's feeding process, such as the interaction between the child and mother as caregiver, posture, and positioning during feeding, patient motivation, the efficiency of intact feeding reflexes, environmental effects, and fatigue during eating, cannot be fully assessed through a barium swallow study alone. These aspects require more time and careful observation. Instrumental evaluation of swallowing can complement the overall feeding evaluation, especially when an aspiration disorder is confirmed [13].

The fluoroscopic barium swallow study (FBSS) is widely considered the gold standard for evaluating swallowing disorders. However, it has its limitations. Not all clinics offer FBSS, and there can be long waiting lists for this procedure. Additionally, FBSS requires specialized technicians, is an invasive procedure, and exposes patients to radiation, which cannot be repeated as frequently as needed [1]. Furthermore, some children may experience fear and resistance during the procedure, impacting the evaluation results. Barium contrast alters food taste and can lead to crying and resistance among children [8]. Instrumental evaluation methods like FBSS also have limitations in assessing sensory-motor oral function and the caregiver's feeding skills. Tools like the Schedule for Oral-Motor Assessment (SOMA) by Reilly et al. (1995) have been developed to address these limitations. SOMA is a validated and reliable scale designed to objectively assess oral-motor function in infants aged 8 to 24 months [12, 14-16].

Romano et al. conducted a systematic review of 1787 studies to compare the Clinical Swallow Assessment (CSA) diagnostic accuracy with the video-fluoroscopic swallow study (VFSS) in individuals with swallowing dysfunction, both in children and adults. Their review found that CSA had a sensitivity of 71% and specificity of 76% as a diagnostic test for evaluating aspiration in cases of dysphagia [1].

Another study by Sheppard et al. evaluated the Dysphagia Disorder survey (DDS) in a group of 654 individuals aged 8 to 85 with intellectual and developmental disabilities. They assessed the internal consistency of DDS and its subscales using Cronbach's coefficient alpha. This investigation demonstrated that DDS is valid and reliable for identifying swallowing and feeding disorders in children and adults with developmental disabilities [17].

The research was conducted due to the lack of standardized instruments and a universal agreement on the standard method for evaluating swallowing disorders worldwide. As clinical guidelines for assessing the swallowing process exist, the available instruments are not standardized and may vary across countries. In the context of this study, the aim was to evaluate the consistency between the SOMA and the fluoroscopic barium swallow study, assess the internal consistency of SOMA for detecting swallowing disorders, and determine the sensitivity, specificity, positive predictive value, and negative predictive value of SOMA when compared to FBSS, which is considered the gold standard for assessing swallowing disorders.

Methods

This was an analytical-descriptive study conducted with the approval of the study protocol by the local ethics committee at the University of Social Welfare and Rehabilitation Sciences in Tehran, Iran (IR.USWR.REC.1395.316). The study included 52 children aged 6 to 48 months, consisting of 23 girls and 29 boys, with mean ages of 18.2 months and 11.3 months, respectively. Parents of all the children provided signed consent forms before the study.

The study's inclusion criteria encompassed children with feeding disorders who met the following conditions: gestational age of ≥36 weeks, birth weight exceeding 1500 grams, age within the range of 6 to 48 months, and having a prescription for a barium swallow study, which were referred to the Radiology Center of Children's Medical Center. Children in poor general health and those whose parents were not interested in participating were excluded from the study.

In this study, all participants underwent a FBSS performed by an expert Pediatric Radiologist. Liquid barium sulfate was used as the contrast medium. To prepare the contrast, three packages of barium sulfate, totaling 135 grams, were dissolved in 500 milliliters of dextrose water (5%) and administered to the children via their milk bottles. The quantity was adjusted based on the child's age and the standard amount for bottle-feeding. During the procedure, the children reclined on a bed until their stomachs were adequately filled with barium.

The FBSS captured the swallowing process in both lateral and anteroposterior views. The assessment included the evaluation of oral residue, examination of the pharyngeal phase, which encompassed the assessment of the swallowing reflex, identification of residues in the nasopharynx due to swallowing muscle discoordination, detection of aspiration, examination of the upper esophageal sphincter opening, and measurement of the passage duration in the pharynx.

A highly skilled speech therapist evaluated the children's feeding disorders using the SOMA method. SOMA is a well-established and reliable approach for assessing oral-motor function in pediatric patients with dysphagia [8]. Previous studies have indicated that SOMA exhibits favorable reliability, including an intra-class correlation coefficient (ICC) of 0.48 and a reasonably sensitive kappa coefficient for test-retest agreement [15] .The essential characteristics of a reliable assessment tool encompass reliability, validity, and responsiveness. Dependability denotes the extent to which an assessment tool lacks random errors. Analyzing internal consistency reliability usually involves employing Cronbach's coefficient α, while approaches like test-retest and inter-observer reliability are utilized to assess reliability.

Validity assesses whether a test accurately measures what it intends to measure. This validity can be confirmed through a strong correlation between the assessment tool and an established criterion, often called concurrent validity. In cases where a gold standard is unavailable, validity can be established by evaluating the extent to which the assessment tool correlates with others that measure related constructs, known as convergent validity. On the other hand, Responsiveness evaluates an assessment tool's ability to detect changes that occur over time. A responsive measure is essential for documenting clinical changes and conducting outcome studies.

Five types of food (yogurt, cream cheese, cooked rice, biscuits, water, and milk) were tested on the children. Parents were trained to feed their infants easily without hindering the observation of the speech-language pathologist. This training is necessary because some infants may not eat when they are in the presence of strangers. If any food was found to be unsuitable for consumption, the test was conducted with other types of food.

To assess each food category as described, the speech-language pathologist observed the specific type of food and evaluated it using the SOMA test. The pathologist then assigned a score based on this assessment. This SOMA test scoring system is designed to detect oral-motor dysfunction. To classify oral-motor function as normal or abnormal using SOMA, the child's score is compared to predefined cutoff scores for the test [8, 17-19]. If a patient's score falls below the cutoff point, it is considered abnormal. These cutoff scores are tailored for use with Iranian children. When a child could not complete the test categories for a specific food type, the same food was presented again for evaluation.

Each of the five food types was assessed three times. Children had the option to feed themselves if they preferred. During the observation process, the child was positioned comfortably, except the fifth part, where the child was held in their mother's arms. The selection of these five food types aimed to align with the local culture and ensure their availability for testing.

The five types of food used in the study were as follows: low-fat yogurt (puree), cream cheese (semisolid), cooked rice (solid), biscuits (crackers), water (in a liquid cup), and milk (breastfeeding or bottle-fed). A teaspoon was employed for yogurt, cream cheese, and cooked rice, while a glass cup was used for water and milk, or breastfeeding/bottle-feeding was performed according to the child's habits. The assessment process took a minimum of 20 minutes per child. Importantly, none of the examiners, including the speech-language pathologist, radiology technician, and pediatric radiologist, knew the results obtained by the other examiners [12].

Statistical Analysis

The results were analyzed using SPSS 17.0 software running on the XP Windows version. A sample size of 50 individuals with 80% statistical power and a 5% test error rate was required for the study. Barium swallow imaging was considered the gold standard method for diagnosing swallowing disorders. To assess SOMA's convergent validity, the study examined the associations between total scores in both categories of SOMA and infants' eating performance using Spearman's rank correlation. The test's internal consistency was evaluated for reliability using Cronbach's coefficient alpha. The consistency among findings in the six parts of SOMA and FBSS was assessed using kappa value analysis. Statistical significance was defined as a p-value less than 0.05. Sensitivity, specificity, and negative and positive predictive values of the six components of SOMA were calculated individually.

Results

In this study, 78.8% of the children had a history of hospitalization, 15.4% experienced respiratory distress while eating, and 23.1% had experience of non-oral eating. Additionally, 19.2% of children would get tired while eating, 28.8% had an eating duration of more than 30 minutes, and 19.2% exhibited growth retardation. The most frequently clinically diagnosed diseases, according to the FBSS findings, are presented in Table 1.

Table 1: Clinical evaluation of children who participated in this research

Clinical evaluation	Patients number (%)
Gastroesophageal reflux	38 (73.07%)
Discoordination of swallowing muscles	8 (15.38%)
Complete normal	4 (7.69%)
Other	2 (3.84%)
Total	52 (100%)

Based on the information in Table 1, the findings of the SOMA test revealed that 11.5% of patients had swallowing dysfunction when consuming puree food, 3.8% of patients exhibited swallowing dysfunction when consuming semisolid food, 9.6% of patients displayed swallowing dysfunction when consuming solid food, 5.8% of patients experienced swallowing dysfunction when consuming liquid from a bottle or through breast-feeding, and 1.9% of patients encountered swallowing dysfunction when consuming liquid from a cup.

Based on the information in Table 2, the reliability and consistency between the first part of SOMA (puree food, such as yogurt) and FBSS, with kappa=0.17, was 80%. In this case, the sensitivity rate was 25%, the specificity rate was 90%, the positive predictive value rate was 33%, and the negative predictive value rate was 86%.

Similarly, the reliability and consistency between the second part of SOMA (semisolid food, like cream cheese) and FBSS, with kappa=0.14, was 84%. Here, the sensitivity was 12%, the specificity was 97%, the positive predictive value was 5%, and the negative predictive value was 86%.

For both the third part of SOMA (solid food, e.g., cooked rice) and the fourth part (cracker food, as a biscuit) compared to FBSS, the reliability and consistency were the same, with kappa=0.04. The reliability in both cases was 78%, sensitivity was 12%, specificity was

Table 2: Comparison between all parts of Schedule for Oral-Motor Assessment (SOMA) and fluoroscopic barium swallow study (FBSS)

FBSS	First part of SOMA		Second part of SOMA		Third and fourth parts of SOMA		Fifth part of SOMA		Sixth part of SOMA	
	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal
Abnormal	2	4	1	1	1	4	2	1	0	1
Normal	6	40	7	43	7	40	6	43	8	43

SOMA: Schedule for Oral-Motor Assessment; FBSS: fluoroscopic barium swallow study

90%, positive predictive value was 20%, and negative predictive value was 85%.

In the fifth part of SOMA (liquid, as water in a cup) compared to FBSS, the reliability and consistency, with kappa=0.3, was 86%. Sensitivity was 25%, specificity was 97%, positive predictive value was 66%, and negative predictive value was 87%.

Compared to barium swallow imaging, the sixth part of SOMA (breast or bottle-fed) had a kappa value of 0.03, with a reliability and consistency rate of 82%. However, the sensitivity was 0%, specificity was 97%, positive predictive value was 0%, and negative predictive value was 84%.

The first part of SOMAdemonstrated the highest consistency, while the sixth part of SOMA exhibited the lowest consistency in diagnosing oral-motor dysfunction. The internal consistency reliability of SOMA, assessed by Cronbach's coefficient alpha, was determined to be 0.93.

Discussion

Instrumental evaluations, such as barium swallow imaging, are effective in diagnosing aspiration but may not be a universal assessment method for swallowing disorders in children. While respiratory aspiration due to oral-motor dysfunction can be less severe, it is often overlooked in clinical settings [20].To ensure proper treatment for all potential causes of swallowing disorders, a comprehensive method for assessing abnormalities throughout the entire swallowing process is necessary.

The primary objective of this research was to assess the consistency between SOMA and barium swallow results. The findings revealed that 73.07% of children exhibited gastroesophageal reflux during the barium swallow, a statistic consistent with the results of Nelson et al. as cited by Arodsen. The high prevalence of gastroesophageal reflux is attributed to various factors, including the anatomy of the gastrointestinal tract, liquid digestion function, low esophageal capacity, and the length of the subdiaphragmatic esophagus [13].

In the current study, 42.2% of children without cerebral palsy displayed oral-motor dysfunction. This result aligns with the work of Skuse et al., who employed the SOMA method on 127 children with cerebral palsy aged 12 to 42 months, revealing abnormal oral-motor function in these individuals [18]. Additionally, Rogress et al., as cited in Juko et al., utilized VFSS to evaluate 90 children with cerebral palsy, reporting that 98% of patients exhibited abnormalities in the oral phase, 99% in the pharyngeal phase, and 38% experienced aspiration [14].

Our analysis did not reveal a significant correlation between the SOMA findings and barium swallow, as indicated by the kappa values ranging from 0.03 to 0.17. However, the results of this study demonstrated that the reliability and consistency between all types of SOMA and FBSS exceeded 80%, which is consistent with the findings of Juko et al. regarding the consistency between SOMA and VFSS in the pharyngeal phase (kappa=0.105, P=0.509).

Significant compatibility between the SOMA findings and barium swallow was observed in the 82% to 86% range, which aligns with the study conducted by Juko et al. [8]. The findings also indicated consistency between SOMA and the evaluation of the oral phase through VFSS (kappa=0.419, P=0.023) [8].

In our comparison between SOMA and barium swallow, the diagnostic results revealed a sensitivity ranging from 0% to 25%, specificity values between 90% and 97%, positive predictive values between 0% and 66%, and negative predictive values between 84% and 87%. These results are consistent with the study by Juko et al., which reported a specificity of 66.6%. Still, there is a discrepancy in sensitivity compared to their findings of 87.5% and a positive predictive value of 95.4% [8].

Additionally, the sensitivity of the SOMA test in this study does not align with the results of Skuse et al.'s research, which reported a sensitivity of more than 85% and a positive predictive value of more than 90%. This difference could be attributed to the smaller sample size in the latter study [18].

Romano et al. evaluated the accuracy of the Clinical Swallowing Assessment (CSA) diagnostic test compared to VFSS, and their findings indicated a sensitivity ranging from 21% to 93% and specificity between 46% and 93% for the diagnostic test [1]. It's worth noting that the specificity of the diagnostic test was more consistent than sensitivity, which is in line with the results of our study.

Sheppard et al. (2014) evaluated the Dysphagia Disorder Survey (DDS) and reported a kappa value ranging from 0.53 to 0.71. They found a sensitivity of 88%, a specificity of 85%, a positive predictive value of 61%, and a negative predictive value of 96%. Their study concluded that DDS is a valid and reliable tool for identifying swallowing and feeding disorders in children and adults with developmental disabilities. These results are consistent with our study's specificity and positive predictive value [21].

The present study found that the sixth part of SOMA, which involves liquid drinking from a cup, had the lowest agreement based on a kappa value (0.03). This result is consistent with the findings of Reilly et al. In Reilly et al.'s study, which focused on oral-motor dysfunction in children with organic and non-organic failure to thrive, the sixth part of SOMA or the oral-motor challenge categories (OMC) was not utilized. This decision was based on previous research indicating that liquid foods had lower sensitivity in diagnosing abnormalities, and direct observation alone was not considered a suitable evaluation method [19].

According to Ferketich and following Nunnally's guidelines, a Cronbach's coefficient alpha of 0.7 is considered adequate for instruments in the early stages of development. In contrast, Cronbach's coefficient alpha of 0.8 is recommended for more advanced tools. In this research, the Cronbach's coefficient alpha for SOMA was 0.93, indicating excellent internal consistency [22]. This level of internal consistency is similar to the study conducted by Sheppard et al. (2014), where they assessed the internal consistency of the DDS and its subscales using Cronbach's coefficient alpha [21].

Fluoroscopic barium swallow studies have limitations, particularly when assessing the oral phase of swallowing. This method only uses liquid food for evaluation, which may not fully represent the complexity of oral-motor function during eating and drinking. Additionally, introducing a child to a new environment and using unfamiliar substances like barium can lead to fear and discomfort, potentially causing the child to cry or resist the procedure. In some cases, parents may need to feed barium to the child with some force, which can affect the natural swallowing process.

Furthermore, there are constraints related to radiation exposure. To minimize radiation exposure, the duration of the fluoroscopic examination is limited. The exposure period should not exceed two minutes, and the evaluation should ideally be completed within 1-2 minutes. This limited time frame can make it challenging to assess the oral phase of swallowing thoroughly.

This research aimed to assess the clinical utility of SOMA in examining dysphagia, with a particular focus on the oral phase. While SOMA is effective for evaluating the oral phase of swallowing, it may be less suitable for identifying abnormalities or aspiration during the pharyngeal phase, which can be challenging to assess. Nevertheless, SOMA, in combination with barium swallow imaging, can provide valuable insights into various stages of the swallowing process, assisting therapists in diagnosing and managing swallowing disorders.

This study revealed good agreement between barium swallow imaging and SOMA findings regarding consistency, specificity, and negative predictive value. The results suggest that SOMA can be a valuable alternative for children who may have difficulty cooperating with barium swallow imaging.

Several limitations should be taken into account when interpreting our findings. These include the relatively small sample size and the short-term follow-up in our study. Furthermore, our study was conducted at a single center, which may limit the generalizability of the results. Further research with a larger sample size and multi-center studies are warranted to support these findings more robustly.

Conclusion

This study's findings indicate good compatibility in terms of consistency percentage, specificity, and negative predictive value between barium swallow imaging and SOMA. Additionally, SOMA demonstrates excellent internal consistency. Furthermore, SOMA is particularly useful for assessing children with limited cooperation for barium swallow imaging. It is a valuable tool for diagnosing oral-phase swallowing disorders, while barium swallow imaging is well-suited for diagnosing aspiration during swallowing. Consequently, these two tools complement each other in evaluating swallowing disorders.

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Conflict of Interest: None declared.

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