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Article

Functional oral intake scale in toddlers: how much does it correlate with dysphagia severity? An observational cross sectional study

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Abstract

Background: The Functional Oral Intake Scale (FOIS) is a seven-point observer-reliable, valid rating scale that can be used without adding to the patient's workload. It was designed for stroke patients but is now used by adults and children. For newborns, a special scale was created. Toddlers are the transition from infant to adult swallowing. So the current study's goal is to assess the screening accuracy of the FOIS as an objective indicator of dysphagia in toddlers. *Methods*: A cross sectional study of 123 toddlers attending dysphagia clinic in phoniatrics unit, Otorhinolaryngology (ORL) department, Alexandria main university hospital. Swallowing assessment of these patients was conducted by bedside swallowing assessment including functional oral intake scale and instrumental evaluation by videofluoroscopy. Another 123 healthy toddlers were assessed by FOIS as control. Two experienced clinicians scored the toddlers twice for each form of FOIS. VFSS was performed to assess swallowing of these patients.
Results: Both Intra rater and inter-rater reliability were high with ICC= 0.984* and 0.946* respectively. Chi-square test showed a statistically significant difference of FOIS scores between cases and control group. There was a strong negative correlation between FOIS and PAS score in fluids with Pearson correlation coefficient (r=0.293 at p<0.001 while for semisolids and solids equally (r=0.424) while no correlation between FOIS score and total residue score. The cut off point for detection of aspiration at ≤5 using FOIS had high sensitivity 71.1 % in predicting aspiration of fluids with 43.6% specificity

(AUC=0.617), with semisolids and solids 42.1 Positive predictive value (PPV) and 72.3 negative predictive value (NPV), (AUC= 0.754) with higher sensitivity than fluids (84.6%) and lower specificity (40.9 %). On the other hand, FOIS was very poor in predicting pharyngeal residue. It was highly sensitive in detecting the oral phase dysphagia 91.3 but low specificity 19.5, (AUC = 0.715*) (95% CI of 0.618-0.812). *Conclusion*: FOIS has high screening power of oropharyngeal dysphagia in toddlers, with high prediction of fluids and semisolids aspiration but not pharyngeal residue. It was also highly predictive of oral phase dysphagia.

Keywords: deglutition, functional oral intake scale, toddlers, dysphagia

Introduction

Feeding and deglutition are developmental phenomena involving highly complex interactions that begin in embryologic and fetal periods and continue throughout infancy and early childhood. (1, 2).

The functional oral intake scale (FOIS) is a measure with high reliability, validity, and sensitivity to change for determining and monitoring the oral intake range of patients, it was initially developed in 2005 to assess oral intake of patients with neurogenic dysphagia by Crary et al.(3)

It is a seven-tiered ordinal scale that analyses oral food and beverage consumption. Levels 1–3 contain a variety of non-oral feeding options, whereas levels 4–7 include a variety of oral feeding options. It is the most widely used scale for assessing the range of oral intake by dysphagia patients, and it is utilized in both clinical and research contexts.(4, 5)

Patients with amyotrophic lateral sclerosis, head and neck cancer, Parkinson's disease, and pediatric patients were also assessed for their oral intake level by this scale.(4, 6-8)

The direct application of the FOIS to infants and toddlers was challenging, as they are developing rapidly and will experience an expansion of the oral diet with age (9-11).

Coppens et al.(12) modified the FOIS for the evaluation of infants subjected to esophageal atresia repair by reducing the FOIS levels from seven to five stages to reflect the food expansion status (12) and its validity was proved in another study in 2019.

The regular FOIS rather than the modified form for infants was used in this current study in toddlers a s a descriptive tool of the oral intake level in this particular age group who constitute the transitional phase between infant and adult form of feeding with very rapid progression in oral motor skills this age and rapid expansion of oral intake with variety of textures ad consistencies Videofluoroscopy is the gold standard in objective assessment of oropharyngeal dysphagia. Objectively assessing the oral phase of swallowing which can affect the functionality and textures taken orally and the pharyngeal phase which indicates the safety of the swallow, and not just in pediatric patients.(13-17)

By Penetration aspiration scale score (PAS score) (18) which is an ordinal scale of the severity and depth of the swallow developed by Rosenbeck et al in 1996 . Also some important findings are assessed by VFSS which can affect the safety of the swallow including delayed trigger of swallow reflex and pharyngeal residue.

Contrast-material not entering the airway is scored 1, while penetration can be scored from 2 to 5. Score 2 is given if contrast material remains above the vocal folds but no residue is visible, while score 3 is given if visible residue remains. If contrast material contacts the vocal folds but is ejected from the airway penetration this is scored 4, while if there is no ejection of material and residue is visible, penetration is scored 5.

Aspiration is a more severe event than penetration: it can be scored from 6 to 8 according to whether aspirated material is partially or totally expelled from the airway (score 6), subglottic residue is visible despite the patient's effort (score 7) or aspiration occurs without the patient's attempt to expel contrast material (score 8).(18)

Another abnormality seen on VFSS is epiglottic undercoating which occurs when material penetrates underneath the epiglottis above the laryngeal vestibule.(16) Deteriorated swallowing can be also displayed by a swallow reflex delayed more than 1 sec.(16)

On VFSS some patients show a normal swallowing process in the first few swallows but, as feeding progresses, abnormalities appear. On the other hand, certain patients may have greater difficulty during first few swallows and, as they become more organized, improve their function with additional swallows. Thus, during the procedure, multiple swallows have always to be examined.(19)

The aim of the current study was to detect the screening power of FOIS to detect oropharyngeal dysphagia in pediatric population specifically the toddler age group and to assess its predictive validity of pharyngeal phase abnormalities namely aspiration of both fluids, semisolids and detecting pharyngeal residue and also oral phase abnormalities. Another aim was to assess functional oral intake scale by both 5 and 7 point forms and describe which was more beneficial in toddlers with dysphagia.

Materials and methods

Ethical approval for the study was obtained from Alexandria medical school ethical committee approved the study with IRB NO: 00012098.

Study design

A cross sectional study of 123 toddlers attending dysphagia clinic in Alexandria main university hospital and 123 toddlers attending the otorhinolaryngology clinic without current complaint or any previous history of feeding or swallowing problems or any neurological complaints, weight loss or failure to thrive.

The following inclusion criteria were applied to potential subjects with suspected dysphagia

(1) Participation in the VFSS to evaluate a swallowing disorder at age of toddlers from 12 months up to 36 months old in the duration from October 2020 to June 2021 complaining of dysphagia and Exclusion of children below one year old and children above 36 months old presenting to dysphagia

(2) Recording of the dietary status at the time of the VFSS by 2 separate clinicians and all parents of children included in the study were asked thoroughly to assess the child's developmental level in feeding of consistencies and restriction of certain textures were asked . Each clinician scored both 5 point and 7 point forms of FOIS twice.

Dysphagia evaluation

- All patients in the study group underwent a full history taking and oral motor examination followed by VFSS on the same day. Oropharyngeal phases of swallowing were assessed: oral phase was scored affected or not affected while pharyngeal phase affection and severity was described by 2 scales: PAS score and total residue score.
- Swallowing was evaluated directly with nine bolus challenges, three of each consistency (liquid and pudding and solid) of approximately 5 cc volume each, presented. Each bolus challenge was evaluated for the presence of penetration or aspiration, and was scored using the Penetration–Aspiration Scale (PAS). Penetration was defined as PAS 2–5 and aspiration was defined as PAS 6–8. The worst PAS out of all bolus challenges in all consistencies was used for analysis Residue presence was scored using a residue scale of 0, 1, 2, or 3. Total residue score was a scale of 0= no residue with any consistency, 1= residue with single consistency, 2= residue in 2 consistencies. 3 is residue with all 3 consistencies introduced.

Validity testing

1. Cross-validity (20) was determined by comparing the FOIS scores with the categorical ratings of swallowing impairment/aspiration severity and on the basis of the presence of swallowing impairment/aspiration determined by the VFSS (20) plus correlation
2. Clinical validity (21). Was established by comparing results of score of cases versus healthy controls

Reliability testing

Intra rater reliability: (22) Was established by reassessment of FOIS once before VFSS and once after by the same clinician.

Inter-rater Reliability:(23) The toddlers' caregivers were interviewed by a nutritionist, who recorded the type, amount, and consistency of food and liquid intakes, tube dependency, and total nutrient intake. Two clinicians with >2 years of experience in swallowing therapy reviewed the FOIS levels.

Intra class correlation coefficient (ICC) (24) was calculated, The ICCs were classified using a system suggested by McGraw and Wong11 as follows: (1) less than 0.75 poor, 0.75 to less than 0.90 moderate agreement, 0.90 or greater high agreement.

Statistical analysis

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. **(**Armonk, NY: IBM Corp**).**Significance of the obtained results was judged at the 5% level. To assess cross-validity, Spearman's ϱ-test was used to assess correlations between the FOIS for toddlers with swallowing impairments and aspiration severity ratings. We used Cramer's V (dichotomized data) to determine the association between the FOIS for infants and the presence or absence of swallowing impairment and aspiration**.** Clinical validity was tested by chi square test. Reliability was assessed intra class correlation coefficient.(24)

Results

I. Reliability assessment of scoring of FOIS in toddlers:

High Intra rater reliability was found with ICC= 0.984* and high Inter rater reliability with ICC = 0.946*

II. Validity assessment of FOIS in toddler FOIS

There was a statistically significant difference between the cases and control group in the scores of FOIS as 4.9 % of cases had score 1, while none of the control group children scored 0. Both groups did not score 2 or 3. 10.6 % of cases group scored 4 while none scored 4 in the control group. 46.3 % of cases scored 5, while only 13.3 % of control group had this score. 36.6 % of cases scored 6 while 50 % of control scored 6. 1.6 % of cases scored 2 while 36.7 % of control group scored 7. The biggest percentage of cases had score 5, 6 while the biggest percent of control had score 6, 7. All control group had only scores 5, 6, 7 and none of them scored 1, 2, 3, 4.as shown in **table (1).**

Table (1): The modified functional oral intake scale for infants according (12)

	Intake
Level 1	Nothing by mouth
Level 2	Tube dependent with minimal attempts of food or liquids
Level 3	Tube dependent with consistent oral intake of food or liquids
Levels 4–6	Expansion of oral diet not reached[a]
Level 7	Expansion of oral diet reached[a]

[a]*Normal expansion of oral diet was considered reached when introduction of solid foods in pureed form started before 9 months of age and the introduction of mashed foods and soft lumps started before 12 months of age*

Table 2: The seven point functional oral intake scale according to Crary Et al.(3)

Level 1	**Nothing by mouth**
Level 2	Tube-dependent with minimal attempts of food or liquids
Level 3	Tube-dependent with consistent oral intake of food or liquids
Level 4	Total oral diet of a single consistency
Level 5	Total oral diet with multiple consistencies but requiring special preparations or compensations
Level 6	Total oral diet with multiple consistencies without special preparation but with specific food limitations
Level 7	Total oral diet with no restrictions

Table 3: Comparison between medical and healthy group in FOIS scales

FOIS	Cases (n = 123)		Normal children (n = 120)		χ^2	p
	No	%.	No	%.		
1	6	4.9	0	0.0	82.494*	<0.001*
2	0	0	0	0		
3	0	0	0	0		
4	13	10.6	0	0.0		
5	57	46.3	16	13.3		
6	45	36.6	60	50.0		
7	2	1.6	44	36.7		

χ^2: **Chi square test**

p: p value for comparing between the studied groups

*: Statistically significant at $p \leq 0.05$

On comparing the result of 7 point versus modified 5 point form for children. Score 1 was similar in both group with 4.9 % of the studied population, 2 and 3 were not scored in this study by both

scales, score 4, 5, 6 was equivalent to score 4 (expansion of oral diet not reached) in the modified form and score 7 was equivalent to score 5 (expansion of oral diet reached) in the modified form.

In the present study, the studied group were 123 toddlers complaining of dysphagia of different etiologies and underwent the full evaluation protocol fitting the criteria for the study. The commonest etiology found in this age group was predominantly neurogenic 60.2 % then GIT etiology 15.4 % followed by the aero digestive group 13.8 % of this age category and finally the genetics group 10.6 %. FOIS score of these children were 46.3 % of the studied sample scored 5, 36.6 % scored 6. 10.6 % score 4. 4.9 % scored 1, 1.6 % scored 7 and none scored 2 or 3.

On examination and assessment by VFSS: 62.6 % had abnormal oral phase while only 37.4 % had normal oral phase. While 90 % of the studied toddlers had affected oesophageal phase.

On assessment of pharyngeal phase 78.9 % had delayed trigger of swallow reflex and 78% had premature spillage mainly with fluids. 86.9 % of the swallowing studies had residue: Location of residue was 80.5 % in vallecula and 15.4 % in pyriform fossae and 87.9 % were trace to mild residue, 10.3 % had moderate residue and 1.9 % had severe residue as shown in **table 4.**

Table (4): comparison between the scoring by the clinician of 5 point versus 7 point FOIS:

FOIS	Number	Percentage
1	6	4.9
2	0	0
3	0	0
4	13	10.6
5	57	46.3
6	45	36.6
7	2	1.6
FOIS		
1	**6**	**4.9%**
2	**0**	**0 %**
3	**0**	**0 %**
4	**115**	**93.5 %**
5	**2**	**1.6 %**

Only 1.6 % of the toddlers in our study had normal swallow PAS score 1, while 21.1 % had the same score but with different consistencies (semisolid and solid). Penetration: with fluids: 61.8 % with fluids and 68.3 %with semisolids and solids .Aspiration percentage in the studied sample: 36.6 %had aspiration with fluids, and 10.6 % had aspiration with semisolids and solids Residue: 76.4 % had residue with fluids and 82.1 had residue with semisolid and solid. Both semisolids and solids scored the same results in our studied sample in both PAS score and residue scoring as shown in **table 5.**

Table (5): Distribution of the studied sample according to different parameters in medical group of toddlers: (n = 123)

	No	%
Oral phase		
Abnormal	77	62.6
Normal	46	37.4
Pharyngeal phase		
Trigger of swallow reflex		
Not delayed	26	21.1
Delayed	97	78.9
Premature spillage		
No	27	22.0
Yes	96	78.0
Location of residue		
Vallecula	99	80.5
Pyriform	19	15.4

There was no statistically significant correlation between FOIS score and PAS score of fluids however the majority of those children with penetration and aspiration and even PAS score 1, were with scores 5 and 6. FOIS score 1 was with 1.3 %of those with penetration and 11.1 % of children aspirating with fluids. There was a statistically significant correlation between PAS score of semisolid and solid and FOIS scale as shown in **table 6**.

Table (6): Distribution of the studied sample according to PAS and residue in toddler (n = 123)

	Fluids		Semisolid		Solid	
	No	%.	No	%.	No	%.
PAS						
1	2	1.6	26	21.1	26	21.1
2	7	5.7	16	13.0	16	13.0
3	9	7.3	44	35.8	44	35.8
4	20	16.3	6	4.9	6	4.9
5	40	32.5	18	14.6	18	14.6
6	3	2.4	0	0.0	0	0.0
7	29	23.6	6	4.9	6	4.9
8	13	10.6	7	5.7	7	5.7
Normal 1	2	1.6	26	21.1	26	21.1
2 - 5 penetration	76	61.8	84	68.3	84	68.3

6 - 8 aspiration	45	36.6	13	10.6	13	10.6
Residue						
No	29	23.6	22	17.9	22	17.9
Yes	94	76.4	101	82.1	101	82.1

Correlation between FOIS and swallowing assessment by VFSS by PAS score and total residue score was assessed by Pearson correlation coefficient. There was a statistically significant negative correlation between FOIS and PAS score with all consistencies but there was no correlation between FOIS and total residue score as shown in table 6.

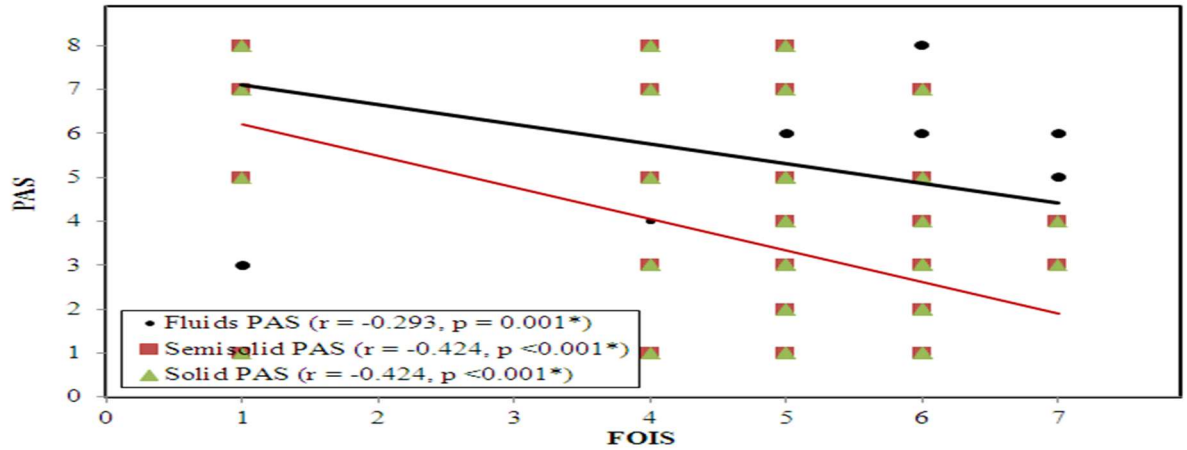

Figure (1):Correlation between FOIS and PAS score in VFSS

Table (7): Relation between PAS and FOIS in toddler (n = 123)

FOIS	Fluids PAS						Semisolid PAS						Solid PAS					
	Normal (n =2)		2 - 5 penetration (n=76)		6 - 8 aspiration (n =45)		Normal (n =26)		2 - 5 penetration (n=84)		6 - 8 aspiration (n =13)		Normal (n =26)		2 - 5 penetration (n=84)		6 - 8 aspiration (n =13)	
	No	%.	No	%.	No	%.	No	%.	No	%.	No	%.	No	%.	No	%.	No	%.
1	0	0	1	1.3	5	11.1	1	3.8	1	1.2	4	30.8	1	3.8	1	1.2	4	30.8
4	0	0	6	7.9	7	15.6	2	7.7	8	9.5	3	23.1	2	7.7	8	9.5	3	23.1
5	1	50	36	47.4	20	44.4	10	38.5	43	51.2	4	30.8	10	38.5	43	51.2	4	30.8
6	1	50	32	42.1	12	26.7	13	50.0	30	35.7	2	15.4	13	50.0	30	35.7	2	15.4
7	0	0	1	1.3	1	2.2	0	0.0	2	2.4	0	0.0	0	0.0	2	2.4	0	0.0
χ^2 (MC p)	12.215 (0.124)						18.697* (0.007*)						18.697* (0.007*)					

χ^2: **Chi square test** MC: **Monte Carlo**

*: Statistically significant at $p \leq 0.05$

Regarding accuracy of FOIS score in predicting aspiration, the ROC for evaluating its discriminatory capacity for aspiration of fluids showed an AUC of 0.617 (95% CI of 0.511 – 0.723). The cut off point for detection of aspiration at ≤5 using FOIS with higher sensitivity than specificity 71.1 % sensitivity and 43.6 % specificity with 42.1 positive predictive value and 72.3 negative predictive value. As shown in **table 8**.

Table (8): Correlation between FOIS and PAS score in VFSS

Toddler	FOIS	
	r	p
Fluids PAS	-0.293	0.001*
Semisolid PAS	-0.424	<0.001*
Solid PAS	-0.424	<0.001*
Total residue	-0.156	0.084

r: Pearson coefficient

Table (9): Accuracy of FOIS in predicting aspiration of fluids

	AUC	P	95% C.I	Cut off	Sensitivity	Specificity	PPV	NPV
FOIS	0.617*	0.031*	0.511 – 0.723	≤5	71.1	43.6	42.1	72.3

AUC: Area Under a Curve p value: Probability value
CI: Confidence Intervals NPV: Negative predictive value
PPV: Positive predictive value *: Statistically significant at $p \leq 0.05$

Table (10): Accuracy of FOIS in predicting aspiration with semisolids and solids

	AUC	P	95% C.I	Cut off	Sensitivity	Specificity	PPV	NPV
FOIS	0.754*	0.003*	0.594 – 0.913	≤5	84.6	40.9	14.5	95.7

AUC: Area Under a Curve p value: Probability value
CI: Confidence Intervals NPV: Negative predictive value
PPV: Positive predictive value *: Statistically significant at $p \leq 0.05$

Table (11) Accuracy of FOIS in predicting total residue

	AUC	P	95% C.I	Cut off	Sensitivity	Specificity	PPV	NPV
FOIS	0.582	0.227	0.456-0.709					

AUC: Area Under a Curve p value: Probability value
CI: Confidence Intervals NPV: Negative predictive value
PPV: Positive predictive value *: Statistically significant at $p \leq 0.05$

Table 12. Accuracy of FOIS in predicting oral phase affection

	AUC	P	95% C.I	Cut off	Sensitivity	Specificity	PPV	NPV
FOIS	0.715*	<0.001*	0.618-0.812	≤5	91.3	19.5	40.4	78.9

AUC: Area Under a Curve p value: Probability value

CI: Confidence Intervals NPV: Negative predictive value

PPV: Positive predictive value *: Statistically significant at p ≤ 0.05

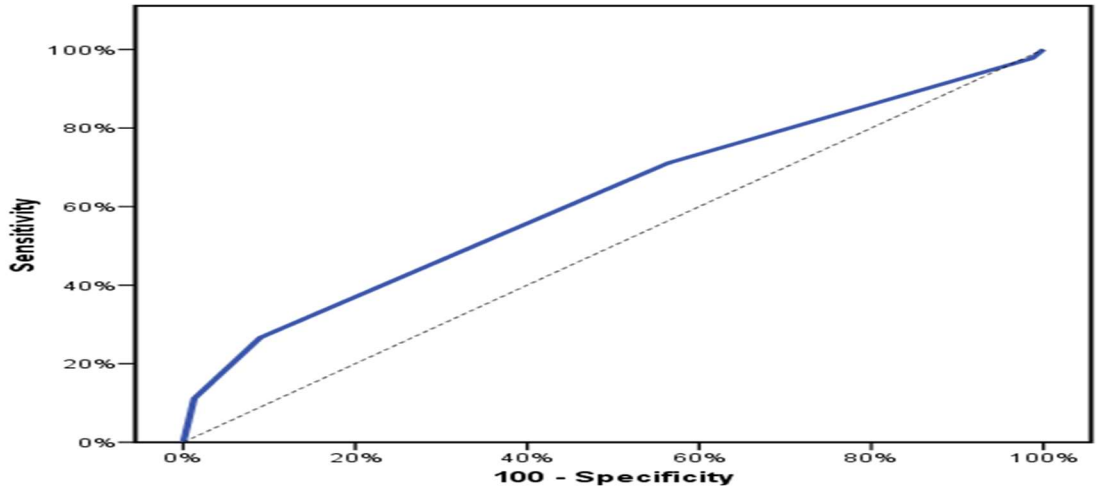

Figure (2): ROC curve for different parameters to predict Fluids PAS aspiration (6 - 8)

Regarding accuracy of FOIS score in predicting aspiration, the ROC for evaluating its discriminatory capacity for aspiration of semisolids and solids showed an AUC of 0.754* (95% CI of 0.594 – 0.913). The cut off point for detection of aspiration at ≤5 using FOIS with higher sensitivity than specificity 84.6 sensitivity and 40.9 % specificity with 14.5 positive predictive value and 95.7 negative predictive value.

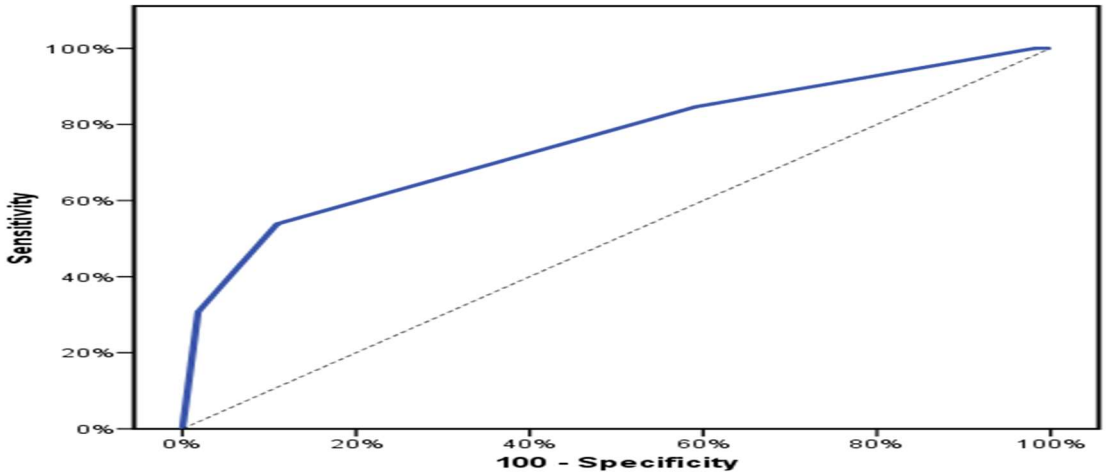

Figure (3): ROC curve for different parameters to predict Semisolid PAS aspiration (6 - 8)

Regarding accuracy of FOIS score in predicting residue with different consistencies, the ROC for evaluating its discriminatory capacity for detection of residue showed an AUC of 0.582 (95% CI of 0.456-0.709) as shown in table 8.

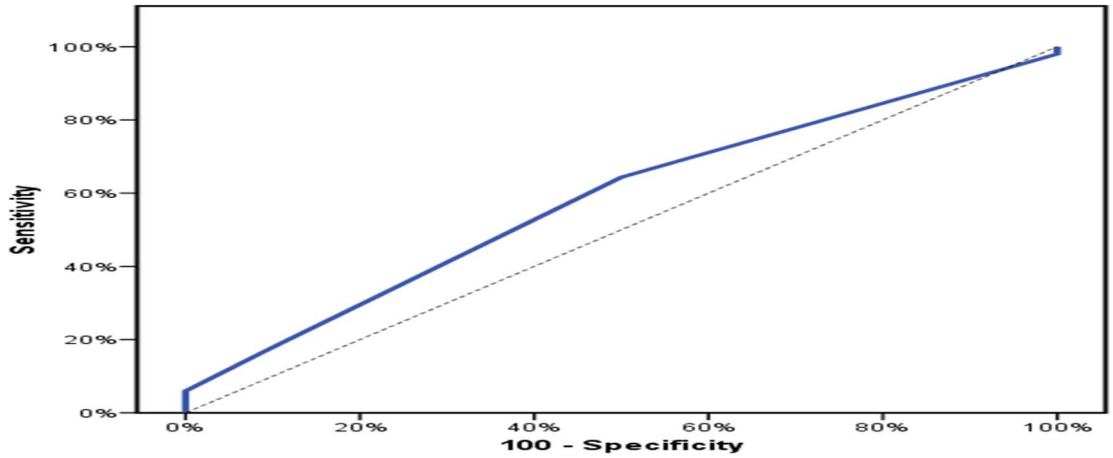

Figure (4): ROC curve for different parameters to predict Total residue (no residue vs 1 or 2 or 3 residue)

Regarding accuracy of FOIS score in predicting oral phase affection, the ROC for evaluating its discriminatory capacity showed an AUC of 0.715* (95% CI of 0.618-0.812). The cut off point for detection of aspiration at ≤5 using FOIS with higher sensitivity than specificity 91.3 sensitivity and 19.5 % specificity with 40.4 positive predictive value and 78.9 negative predictive value.

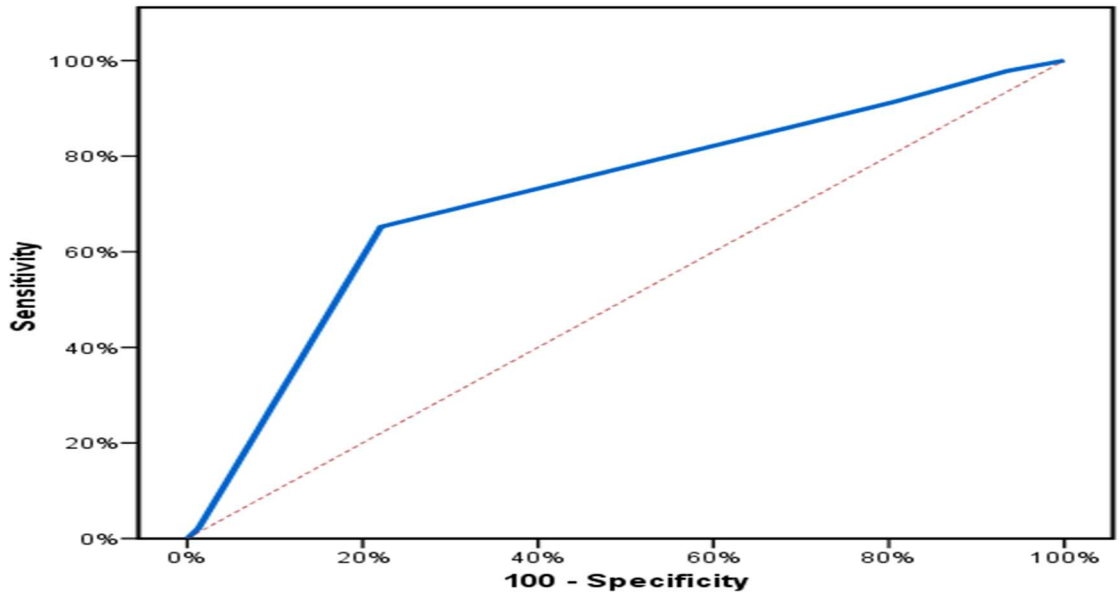

Figure (5): ROC curve of FOIS to predict oral phase affection.

Discussion

In adults with dysphagia, the FOIS has been reported to correlate significantly with the Food Intake Level scale (25, 26), swallowing item of the Functional Assessment Measure (27), Mann Assessment of Swallowing Ability.(28, 29) modified Barthel Index,(30) modified Rankin scale(31), and dysphagia and aspiration during a video fluoroscopic swallowing study (VFSS)(32)

Despite the wide use of the FOIS to evaluate dysphagia and assess oral intake recovery in adults.(33). FOIS was modified into a scale for children by removing 2 item levels to generate a 5-point scale. FOIS for children showed adequate reliability and validity and could be appropriate for documenting children's eating abilities and evaluating the effectiveness of interventions.(34)

In the present study the reliability of scoring the FOIS was assessed by 2 clinicians. Intra rater ICC= 0.984*Inter rater reliability ICC = 0.946*. These results math with the results of the inter-rater reliability of the FOIS for infants which was high (95.5% absolute agreement) among the 201 evaluated infants in a study in 2019 for the psychometric properties of FOIS for infants.(34) And the Interrater reliability was high, with perfect agreement on 85% of ratings. Kappa statistics ranged from .86 to .91 in a study of the initial psychometric properties of the 7 point FOIS.(3)

The scores most frequently used for objective evaluation of dysphagia severity are the Penetration-Aspiration-Scale (PAS)(18) the Secretion Severity Rating Scale (SSRS)(35) and the FOIS scale.(3)

These scores allow for monitoring of swallowing ability and security over time there was a statistically significant difference between the cases and control group in the scores of FOIS as 4.9 % of cases had score 1, while none of the control group children scored 1. Both groups did not score 2 or 3. 10.6 % of cases group scored 4 while none scored 4 in the control group. 46.3 % of cases scored 5, while only 13.3 % of control group had this score. 36.6 % of cases scored 6 while 50 % of control scored 6. 1.6 % of cases scored 2 while 36.7 % of control group scored 7. The biggest percentage of cases had score 5, 6 while the biggest percent of control had score 6, 7. All control group had only scores 5, 6, 7 and none of them scored 1,2,34. The FOIS was strongly associated with indicators of

dysphagia. However, associations with postural control, wakefulness, age and diagnosis highlights that tube feeding may be attributed to other issues than dysphagia.(36)

In comparing the studied group if scored by adult FOIS versus modified FOIS for children: Score 1 was similar in both group with 4.9 % of the studied population, 2 and 3 were not scored in this study by both scales, score 4, 5, 6 was equivalent to score 4 (expansion of oral diet not reached) in the modified form and score 7 was equivalent to score 5 (expansion of oral diet reached) in the modified form. The adult form was more descriptive of the developmental level of feeding skills in this age group especially none of the control group scored 4 while 10.6 % of children with dysphagia had this score. Score 5 was more than score 6 in the dysphagic patients while score 6 was much more than score 5 in control group so this descriptive variance made the adult form more expressive of the development rather than the safety of the swallow. In a study to evaluate reliability and validity of the children form of FOIS. The FOIS for children showed adequate reliability and validity and could be appropriate for documenting children's eating abilities and evaluating the effectiveness of interventions.(34)

In the present study, the studied group were 123 toddlers complaining of dysphagia of different etiologies and underwent the full evaluation protocol fitting the criteria for the study. The commonest etiology found in this age group was predominantly neurogenic 60.2 % then GIT etiology 15.4 % followed by the aero digestive group 13.8 % of this age category and finally the genetics group 10.6 %. FOIS score of these children were 46.3 % of the studied sample scored 5, 36.6 % scored 6. 10.6 % score 4. 4.9 % scored 1, 1.6 % scored 7 and none scored 2 or 3.

On examination and assessment by VFSS: 62.6 % had abnormal oral phase while only 37.4 % had normal oral phase. While 90 % of the studied toddlers had affected oesophageal phase. On assessment of pharyngeal phase 78.9 % had delayed trigger of swallow reflex and 78% had premature spillage mainly with fluids. 86.9 % of the swallowing studies had residue: Location of residue was 80.5 % in vallecula and 15.4 % in pyriform fossae and 87.9 % were trace to mild residue, 10.3 % had moderate residue and 1.9 % had severe residue.

17.9 % did not have any residue with either fluids or semisolids, 5.7 % had residue with single consistency and 76.4 % had residue with both consistencies introduced. Only 1.6 % of the toddlers in our study had normal swallow PAS score 1, while 21.1 % had the same score but with different consistencies (semisolid and solid).Penetration: with fluids: 61.8 % with fluids and 68.3 %with semisolids and solids .Aspiration percentage in the studied sample: 36.6 %had aspiration with fluids, and 10.6 % had aspiration with semisolids and solids Residue: 76.4 % had residue with fluids and 82.1 had residue with semisolid and solid. Both semisolids and solids scored the same results in our studied sample in both PAS score and residue scoring

There was no statistically significant correlation between FOIS score and PAS score of fluids however the majority of those children with penetration and aspiration and even PAS score 1, were with scores 5 and 6. FOIS score 1 was with 1.3 %of those with penetration and 11.1 % of children aspirating with fluids. There was a statistically significant correlation between PAS score of semisolid and solid and FOIS scale.

Correlation between FOIS and swallowing assessment by VFSS by PAS score and total residue score was assessed by Pearson correlation coefficient. There was a statistically significant negative correlation between FOIS and PAS score with all consistencies as the greater the FOIS score the more safely and efficiently the swallowing is while the more PAS scores the less safe the swallowing becomes.(37) but there was no correlation between FOIS and total residue score., Significant

associations were identified between the FOIS for children and aspiration severity ($P < 0.001$, $r = 0.315$) and dysphagia severity ($P < 0.001$, $r = 0.287$).(34)

Regarding calculating the accuracy of FOIS score in predicting residue with different consistencies in our study, the ROC for evaluating its discriminatory capacity for detection of residue showed an AUC of 0.582 (95% CI of 0.456-0.709). The FOIS had adequate reliability, validity, and sensitivity to change in functional oral intake which is mainly based on oropharyngeal safety and efficacy.(3) but there was no correlation between FOIS and total residue score. In a study in 2020, there were no significant correlations for FOIS with Pooling score or PAS. There were significant differences between objective assessments (P-score/PAS) and functional measure (FOIS) for identifying patients as pathological; although the positive predictive values were high, the negative predictive values were very low. Although pharyngeal residues are significantly associated with the presence of penetration-aspiration during endoscopy, the real intake modalities are not correlated with objective assessments of swallowing disorders. Therefore, clinicians need to implement a comprehensive approach to assess dysphagia.(38)

Regarding accuracy of FOIS score in predicting aspiration, the ROC for evaluating its discriminatory capacity for aspiration of fluids showed an AUC of 0.617 (95% CI of 0.511 – 0.723). The cut off point for detection of aspiration at ≤5 using FOIS with higher sensitivity than specificity 71.1 % sensitivity and 43.6 % specificity with 42.1 positive predictive value and 72.3 negative predictive value while Regarding accuracy of FOIS score in predicting aspiration, the ROC for evaluating its discriminatory capacity for aspiration of semisolids and solids showed an AUC of 0.754* (95% CI of 0.594 – 0.913). The cut off point for detection of aspiration at ≤5 using FOIS with higher sensitivity than specificity 84.6 sensitivity and 40.9 % specificity with 14.5 positive predictive value and 95.7 negative predictive value. These results were equivalent to the results of cross validation of the original FOIS.(3) and VFSS a significant correlation between FOIS-G and the PAS score in FEES was found.(39)

Significantly lower FOIS scores were detected among patients with penetration/ aspiration (PAS > 2) and penetration (PAS > 2 ≤ 5) for all consistencies ($p < .01$), aspiration (PAS > 5) of liquids and semisolids ($p < .001$), residue in the pyriform sinuses (YPRSRS > 3) with semisolids ($p < .001$) and solids ($p = .02$), and malnutrition (BMI ≤ 18.5; $p = .019$). FOIS-It appears as a valid tool to assess functional oral intake against FEES' measures of swallowing safety and efficiency and nutritional status in patients with OD of etiological heterogeneity.(40)

While in assessing in our study, the accuracy of prediction of FOIS for oral phase affection by VFSS, the ROC for evaluating its discriminatory capacity showed an AUC of 0.715* (95% CI of 0.618-0.812). The cut off point for detection of aspiration at ≤5 using FOIS with higher sensitivity than specificity 91.3 sensitivity and 19.5 % specificity with 40.4 positive predictive value and 78.9 negative predictive value. In previous studies, FOIS was found to be a useful tool with which to document clinical change and may be appropriate as an independent measure of functional oral intake (18)

Our study though had some limitations including that we did not test how much the difference between the 5 point form and 7 point form of the scale affected the clinicians' decisions of feeding of the assessed patients or their swallowing rehabilitation plan, however patients who were put on alternative or complementary mode of feeding scored the same in both forms (1, 2, 3) so this did not affect the safety of swallow decision. Another limitation was that the clinicians performing the instrumental assessment proposed according to the results of the study new FOIS recommendations

to be followed by the patients, this was not reported in our study, neither the effect of swallowing rehabilitation on FOIS scores to assess its prognostic power of improvement of oropharyngeal dysphagia, this was not the scope of our current study, yet it would be important to continue research in this field.

Conclusion

Both initial 7 point form and modified 5 point children from of FOIS can be used as an objective tool of assessment of functional oral intake in pediatric population specifically in toddlers. Toddlers is the age of complete transition from the infant form of feeding to the adult form of feeding. The 7 point FOIS form was more descriptive to the developmental level of feeding rather than the safety of the swallowing with a strong correlation between the FOIS and PAS score of swallowing safety in toddler population. FOIS has high screening power of dysphagia in toddler age group with high prediction of fluids and semisolids aspiration but not pharyngeal residue. It was also highly predictive of oral phase dysphagia.

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Abbreviations

ORL	:	Oto Rhino Laryngology
FEES	:	flexible endoscopic evaluation of swallowing
VFSS	:	Video fluoroscopic swallowing study
ASHA	:	American speech and hearing association
PAS	:	Penetration Aspiration Scale score
FOIS	:	Functional oral intake scale
ICC	:	Intra class correlation coefficient.
GIT	:	gastro intestinal tract
p value	:	Probability value
CI	:	Confidence Intervals
NPV	:	Negative predictive value
PPV	:	Positive predictive value
AUC	:	Area under the curve

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