

# Initial Psychometric Assessment of a Functional Oral Intake Scale for Dysphagia in Stroke Patients

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**ABSTRACT.** Crary MA, Carnaby Mann GD, Groher ME. Initial psychometric assessment of a functional oral intake scale for dysphagia in stroke patients. *Arch Phys Med Rehabil* 2005;86:1516-20.

**Objective:** To report on the development and psychometric evaluation of a clinical scale to document change in functional oral intake of food and liquid in stroke patients.

**Design:** Validity and reliability study.

**Setting:** Tertiary care, academic medical center, metropolitan stroke unit.

**Participants:** Acute stroke patients (N=302).

**Interventions:** Not applicable.

**Main Outcome Measures:** Interrater reliability, validity, and sensitivity to change assessments were completed on a 7-point ordinal scale—the Functional Oral Intake Scale (FOIS)—developed to document the functional level of oral intake of food and liquid in stroke patients. Interrater reliability was drawn from FOIS ratings applied to dietary information from patient medical charts. Consensual validity was estimated by rankings from judges against predefined scale scores. Criterion validity was evaluated by comparison to the Modified Rankin Scale, the Modified Barthel Index, and Mann Assessment of Swallowing Ability. Cross-validation was assessed via comparison to 2 physiologic measures of swallowing function. Change in functional oral intake over time was assessed descriptively by applying the scale to dietary information from a cohort of 302 acute stroke patients followed up for 6 months.

**Results:** Interrater reliability was high, with perfect agreement on 85% of ratings. Kappa statistics ranged from .86 to .91. Consensual validity was high (.90). Criterion validity was high at onset and 1 month poststroke. Significant associations were identified between the FOIS and stroke handicap scales. The FOIS was significantly associated with 2 physiologic measures of swallowing. Scores on the FOIS from the cohort of stroke patients showed a shift toward increased oral intake over a 6-month period.

**Conclusions:** The FOIS had adequate reliability, validity, and sensitivity to change in functional oral intake. These findings suggest that the FOIS may be appropriate for estimating and documenting change in the functional eating abilities of stroke patients over time.

**Key Words:** Dysphagia; Food intake; Recovery of function; Rehabilitation; Stroke; Water intake.

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**D**YSPHAGIA, OR SWALLOWING difficulty, is highly prevalent among acute stroke patients. Some estimates suggest that nearly 65% of stroke survivors suffer some degree of impairment in the ability to swallow.<sup>1</sup> This limitation in the ability to safely ingest adequate amounts of food and liquid places the patient with acute stroke at risk for poor nutrition and hydration and/or for complications such as aspiration-related pneumonia.<sup>2,3</sup> Moreover, dysphagia and related complications increase length of acute stay and are associated with increased mortality, comorbidity, and increased health care costs.<sup>4</sup> Furthermore, studies report that dysphagia persists and perhaps worsens during the first month after stroke.<sup>5</sup> Available research has documented a high rate of spontaneous resolution of dysphagia symptoms after stroke; however, a substantial number of stroke survivors have dysphagia characteristics well beyond the rehabilitation period, and for some patients, dysphagia can be a permanent condition.<sup>2,4</sup> These persisting deficits affect physical and social functioning, quality of life for patients and their caregivers, community reentry opportunities, and health care resource utilization.

One persistent problem in studies of dysphagia poststroke is the variability in documenting dysphagia symptoms and their functional impact. Typically, to identify the presence of dysphagia symptoms, clinical investigators use subjective measures such as observations of coughing after liquid ingestion.<sup>6</sup> Although a standard clinical examination of dysphagia in stroke patients has recently been published,<sup>7</sup> few—if any—appropriate tools are available to document the functional impact of dysphagia symptoms on the oral intake of food and liquid in poststroke patients.

Functional level of oral intake of food and liquid in dysphagic patients is typically established after clinical or instrumental (fluoroscopic or endoscopic) examination. To document change in oral feeding function, clinical investigators often use global indicators such as time to return to oral feeding or feeding in the absence of complications. A variety of outcome scales are available that consider oral intake of food and liquid; however, these scales typically cover many aspects of impairment and often are disease specific.<sup>8,9</sup> Other scales may have a focus other than documenting change in eating abilities<sup>10,11</sup> or may suffer from poor psychometric characteristics (ie, no established reliability or validity characteristics).<sup>12,13</sup>

In this article, we describe the development of the Functional Oral Intake Scale (FOIS) for dysphagia in stroke patients. Subsequently, we evaluate the initial psychometric (reliability and validity) characteristics of this scale. Finally, we describe the sensitivity of the FOIS to document change in functional oral intake in a cohort of stroke patients.

## METHODS

### Development of the FOIS for Stroke Patients

Development of the FOIS for stroke patients has proceeded through 2 stages: (1) initial scale development and item selection, face validity, interrater reliability, and consensual validity and (2) criterion validity, cross-validation, and evaluation of sensitivity to expected change in functional performance.

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No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit on the author(s) or on any organization with which the author(s) is/are associated.

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0003-9993/05/8608-9278\$30.00/0  
doi:10.1016/j.apmr.2004.11.049

Table 1: Clinical Features of 302 Acute Stroke Patients

Clinical Features	Initial FOIS Ratings*				
	1	4	5	6	7
Mean age $\pm$ SD (y)	72.67 $\pm$ 11.40	69.16 $\pm$ 14.00	67.38 $\pm$ 14.80	55 $\pm$ 19.6	68.22 $\pm$ 8.30
Sex (%)					
Male	56	69	54	80	56
Female	44	31	46	20	44
Clinical syndrome					
Total anterior circulation	99	5	3	0	0
Partial anterior circulation syndrome	62	24	8	1	4
Lacunar syndrome	19	25	14	3	3
Posterior circulation syndrome	20	6	1	1	0
Unclear	1	1	0	0	2
Pathology					
Cerebral infarction	165	56	23	4	7
Cerebral hemorrhage	35	3	1	1	0
Unknown	2	3	1	0	2
Mean Modified Barthel Index score	6.3	11.1	12.3	13.8	15.4
Mean Modified Rankin Scale score	4.1	3.2	2.9	2.8	2.4
Mean MASA score	118.6	165.4	170.6	172.0	179.0

Abbreviations: MASA, Mann Assessment of Swallowing Ability; SD, standard deviation.

\*No patients received FOIS ratings of 2 or 3 on the initial scoring at admission.

We selected items for the initial scale based on a review of dysphagia literature and chose items with the intent of describing the type and amount of oral intake of food and liquid that a patient consumes on a daily basis. Limitations or modifications in oral intake may result from a person's self-perception of impaired swallowing ability or, in other instances, from management decisions made by health care professionals (physicians, speech pathologists, others) in response to their perceptions of a patient's impaired swallowing ability. The focus of the scale development was to describe the functional level of a patient's actual daily oral intake of food and liquid with consideration for modifications of either and the need for swallowing compensations.

Initially, the scale included 10 items. After pilot application in a tertiary care teaching hospital, unused items were omitted, and the remaining 7 items were retained for subsequent psychometric analysis (appendix 1). Levels 1 through 3 relate to varying degrees of nonoral feeding; levels 4 through 7 relate to varying degrees of oral feeding without nonoral supplementation. These latter scale levels consider both diet modifications and patient compensations, but all levels focus on what the patient consumes by mouth on a daily basis.

To score functional oral intake with this scale, clinicians may obtain information from a variety of sources including medical charts, dietary journals, and/or verified patient reports. Verification of patient reports may be obtained from a spouse or family members or from a variety of sources for institutionalized patients. Finally, maintaining a 3-day dietary journal is strongly encouraged for home-based patients.

### Interrater Reliability

To evaluate interrater reliability, 6 speech-language pathologists with more than 3 years of clinical experience in dysphagia management applied the FOIS to dietary excerpts taken from the medical charts of 84 consecutive patients who had been seen for dysphagia management at a tertiary care academic medical center. No training was provided to these raters beyond a description of the scale. Interrater reliability was evaluated with Spearman correlations and the Cohen  $\kappa$  statistic.

In addition, percentage agreement was calculated among the 6 judges.

### Validity

Consensual validity was estimated by evaluating agreement with predefined scale rankings by 63 dysphagia clinicians (speech-language pathologists). Clinicians were recruited from a specialized dysphagia listserv on the Internet. A posting on the listserv requested that interested clinicians respond to a survey about a scale that rates the severity of dysphagia. Those who responded by e-mail were sent the scale and asked to provide the appropriate ratings. Each clinician was provided with basal (level 1) and ceiling (level 7) scores and asked to rank the intervening scale items. Agreement with predefined FOIS ratings by the authors was calculated, and Kendall's concordance was computed.

Criterion validity was evaluated from data gathered on a sample of 302 consecutive stroke patients who were admitted to an acute tertiary care hospital and followed up for 6 months (table 1). Inclusion criterion for this study mandated that patients were seen within 7 days of symptom onset. All patients had a clinical diagnosis of stroke confirmed by an attending stroke neurologist according to the World Health Organization's definition of stroke,<sup>14</sup> and all patients had clinical indications for the presence of dysphagia as judged by a qualified speech-language pathologist. Initially, patients underwent a baseline assessment that included demographic characteristics, comorbidities, premorbid functioning, clinical stroke syndrome, stroke pathology, and computed tomography and magnetic resonance imaging brain scan results. The Modified Rankin Scale (MRS) was used to measure stroke severity and handicap.<sup>15</sup> This scale includes reference to symptoms, dependency, and lifestyle limitations subsequent to stroke. The Modified Barthel Index (MBI) was used to evaluate activities of daily living (ADLs).<sup>16</sup> This commonly used scale is often considered as a functional interpretation of disability or dependency in the ADLs. Finally, the Mann Assessment of Swallowing Ability (MASA)<sup>6</sup> was used to evaluate swallowing function clinically. This procedure is a psychometrically vali-

dated clinical evaluation of dysphagia characteristics. Independent of these clinical protocols, the type, amount, and method of oral food and liquid intake were assessed from direct patient observation or patient or caregiver report. These oral intake assessments were prospectively entered in the study database for later analysis. Finally, videofluoroscopic swallowing assessment was completed. All assessments were completed within 72 hours of admission into a dedicated stroke unit.

An assessor who was blinded to the clinical and instrumental swallowing examinations reviewed the database and applied FOIS ratings to the oral intake assessments obtained from this sample of stroke patients at different time points. Chi-square and Cramer's V (dichotomized data) or  $\phi$  (multiple category data) correlation analyses were completed to study the potential associations between the FOIS scores and the measures of stroke severity, functional daily activities, and swallowing ability. Data from these protocols were dichotomized, and FOIS scores were compared with established criteria (ie, MRS score  $\leq 3$ , MBI score  $\leq 15$ , MASA score  $\leq 170$ ). These analyses were completed for data obtained on admission to a stroke unit and again 1 month later.

Cross-validation was estimated by comparing FOIS scores to dichotomized dysphagia and aspiration ratings and categoric dysphagia and aspiration severity ratings derived from videofluoroscopic studies of swallowing function.<sup>1</sup> These comparisons were completed only for data obtained on initial admission to the stroke unit.

**Sensitivity to Change**

To evaluate whether the FOIS was clinically sensitive to change in oral intake, the scale was applied to dietary information of 302 acute stroke patients at 3 time points: on admission to the stroke unit, at 1 month postonset, and at 6 months postonset. A blinded assessor completed FOIS ratings. Subsequently, the distribution of FOIS ratings was plotted to evaluate change over time in functional oral intake in this cohort of stroke patients.

**RESULTS**

**Interrater Reliability**

Agreement between paired judges ranged from 85% to 95%. Perfect agreement was observed across all judges on 85% of all patient records. Rank correlations ranged between .98 and .99. Average  $\kappa$  values ranged from .86 to .91.

**Consensual Validity**

Agreement with the predefined scale scores ranged from 81% to 98%. The Kendall concordance was .90.

**Table 2: Chi-Square and Cramer's V Correlations Between the FOIS Scale and the MRS, MBI, and MASA Scores Taken Within 72 Hours of Admission to Stroke Unit and at 1 Month Poststroke**

Test	$\chi^2$	P	Cramer's V Correlation
<b>Admission</b>			
MRS	28.6	<.001	.31
MBI	30.9	<.001	.32
MASA	33.8	<.001	.53
<b>One month poststroke</b>			
MRS	64.9	<.001	.49
MBI	64.6	<.001	.49
MASA	60.7	<.001	.76

**Table 3: Chi-Square and Cramer's V (dichotomous) Correlations (Continuous Data) Between the FOIS and Dysphagia or Aspiration Presence or Severity**

Test: Admission	$\chi^2$	P	Correlation
Dysphagia presence (+/-)	12.97	.011	.26
Aspiration presence (+/-)	30.17	<.001	.40
Dysphagia severity	56.48	<.001	.54
Aspiration severity	17.07	NS	.30

NOTE. Dysphagia and aspiration ratings were obtained from videofluoroscopic swallowing studies obtained within 72 hours of admission to the stroke unit.

Abbreviation: NS, not significant.

**Criterion Validity**

All stroke measures (MRS, MBI, MASA) were significantly associated with the FOIS score on admission to a stroke unit and at 1 month poststroke (table 2). The strongest association at both time points was between the FOIS and the MASA, a tool reflecting swallowing ability based on clinical examination. Strength of association increased for all measures between admission and 1 month.

**Cross Validation**

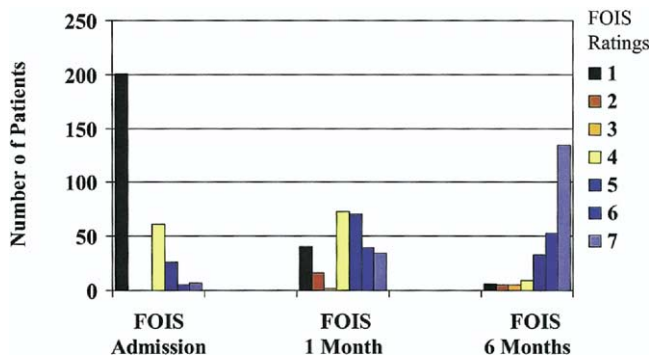
The FOIS was significantly associated with presence of both dysphagia and aspiration identified from videofluoroscopic examination of swallowing function. FOIS ratings were significantly associated with dysphagia severity but not aspiration severity (table 3).

**Sensitivity to Change**

Figure 1 shows the change in FOIS score distributions on admission to a stroke unit and at 1 month and 6 months poststroke. This figure shows the sensitivity to change in a group of acute stroke patients who would be expected to show substantial change in oral intake of food and liquid.

**DISCUSSION**

Collectively, these data indicate adequate interrater reliability in addition to adequate consensual and criterion validity and cross-validation with other swallowing measures. The FOIS has been shown to reflect change in oral intake of food and liquid over time in a cohort of acute stroke patients who were expected to have improved oral intake. These preliminary studies indicate that the FOIS may be an appropriate tool to clinically document change in functional oral intake of food



**Fig 1. Change in the distribution of FOIS ratings obtained from 302 acute stroke patients at initial assessment (within 72h of admission to stroke unit), 1 month postonset, and 6 months postonset.**

and liquid in stroke patients. In addition, this tool may serve to document change in functional oral intake of food and liquid in prospective studies of stroke-related dysphagia and to evaluate potential associations between this functional outcome measure and other indices of stroke recovery.

Interrater reliability was high for the FOIS in the absence of specific training for raters. Raters did, however, have clinical experience in the management of dysphagia in adult patients. Collectively, these observations suggest that the FOIS is a robust tool that may be used without training by clinicians with a background in adult dysphagia management.

Consensual validity was high for the FOIS. Raters typically agreed with the scale ratings predefined by the authors. This result reflects a high degree of agreement with the progression of items across the 7 levels of the FOIS.

Associations between the FOIS and the MRS, MBI, and MASA were significant on admission to the stroke unit, with moderate to low correlations that reflect the strength of these associations. At 1 month postonset, these associations were stronger in all cases. These stronger associations may have resulted from adjusted diet levels based on further evaluation or therapy; from reduction in stroke morbidity as reflected in the MRS, MBI, and MASA; or from a change in combined factors. Dysphagia characteristics tend to show significant improvement by 1-month poststroke.<sup>4</sup> These changes may be related to overall improvement in health and functional status and thus all outcome tools show change in the same direction. Associations between the FOIS and the MASA were the strongest at both assessment points. These associations were expected, because the MASA measures swallow function and the FOIS measures the functional outcome of swallow function—oral intake.

The FOIS appears to be sensitive to change in oral intake of food and liquid over time in acute stroke patients. This attribute is essential when documenting functional oral intake of food or liquid in any patient group that is expected to change over time. Accurate documentation of change is important in understanding spontaneous resolution of deficits in the context of overall stroke recovery or for detailing improvement associated with rehabilitation efforts. Change in swallowing performance has been documented by the MASA procedure.<sup>7</sup> Combined with FOIS information on functional oral intake as a consequence of swallowing performance, these 2 scales offer clinicians and researchers a standard approach to document swallowing ability and subsequent changes in functional oral intake.

We recognize that oral intake patterns may be affected by various sources. Dysphagic patients will self-select foods and liquids depending on a range of factors. Such factors could include—but are not necessarily limited to—taste, flavor, aesthetics, personal likes and dislikes, and ease of swallowing. Alternatively, clinicians (physicians, speech pathologists, others) may determine specific diet levels based on perceptions of safety and/or efficiency of eating. In this study, FOIS scores were determined independently of swallowing evaluations, and we did not consider whether the diet level was selected by the patient or by the clinician. The key factor in assigning FOIS scores was the patient's daily level of functional oral intake.

Most existing outcome scales that reference swallowing and eating activities have very poor psychometric characteristics. For example, the Functional Outcome Swallowing Scale for Staging Oropharyngeal Dysphagia<sup>13</sup> has not shown reliability, validity, or sensitivity to change over time. The score for this protocol is based on identification of clinical symptoms. Another scale, the Dysphagia Outcome and Severity Scale,<sup>12</sup> reports interrater and intrarater reliability for 4 raters but no

validity data or any information on sensitivity to change over time. This scale also requires that a videofluoroscopic swallowing study be completed for scoring purposes.

From a different perspective, general outcome scales like the National Outcomes Measurement System<sup>11</sup> or the Therapy Outcome Measures<sup>10</sup> reference swallowing ability or functional oral intake as part of a more comprehensive outcome scale for communication, cognition, or swallow performances. These scales have been shown to be sensitive to change over time in various populations, but neither has demonstrated reliability or validity. Finally, disease-specific outcome scales seem to present the best psychometric data. Examples include the Performance Status Scale for Head and Neck Cancer Patients<sup>8</sup> and the Amyotrophic Lateral Sclerosis Severity Scale.<sup>9</sup> Both have demonstrated reliability and sensitivity to change.

Conversely, the FOIS had reliability among raters and strong validity characteristics. Additionally, this tool showed sensitivity to change in functional oral intake in a group of stroke patients who were expected to improve over time. These strengths support the FOIS as an appropriate tool to document current functional oral intake and change in oral intake over time in stroke patients.

Although the FOIS shows strong associations to stroke severity, handicap, and swallowing performance scales, additional information on the consequences of reduced functional oral intake should be obtained. Specifically, it seems appropriate to evaluate FOIS ratings against factors such as nutritional status and quality of life. Future assessment of the FOIS should include these aspects of functional impairment after stroke. Such comparisons will help clinicians and investigators to understand better the consequences of reduced oral intake of food and liquids and the effect of change in functional oral intake on other aspects of patient wellness.

## CONCLUSIONS

The FOIS is an ordinal scale that reflects the functional oral intake of patients with dysphagia. Results of this study indicate that the FOIS is robust in terms of interrater reliability and consensual validity. Compared with standard clinical measures of stroke outcome, the FOIS shows strong criterion validity and cross-validation. Finally, in a cohort of acute stroke patients, the FOIS showed an expected increase in functional oral intake over a 6-month recovery period. Collectively, the results of our study suggest that the FOIS may be a useful tool with which to document clinical change and may be appropriate as an independent measure of functional oral intake in prospective studies of stroke-related dysphagia.

**Acknowledgment:** We acknowledge the contributions to data analysis of Julia Pizzi, MA, Research Associate at the Royal Perth Hospital, Perth, Western Australia.

## APPENDIX 1: FOIS ITEMS

- Level 1: Nothing by mouth.
- Level 2: Tube dependent with minimal attempts of food or liquid.
- Level 3: Tube dependent with consistent oral intake of food or liquid.
- Level 4: Total oral diet of a single consistency.
- Level 5: Total oral diet with multiple consistencies, but requiring special preparation 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.

**References**

1. Mann G, Hankey GJ, Cameron D. Swallowing disorders following acute stroke: prevalence and diagnostic accuracy. *Cerebrovasc Dis* 2000;10:380-6.
2. Mann G, Hankey GJ, Cameron D. Swallowing function after stroke: prognosis and prognostic factors at 6 months. *Stroke* 1999;30:744-8.
3. Finestone HM, Foley NC, Woodbury MG, Greene-Finestone L. Quantifying fluid intake in dysphagic stroke patients: a preliminary comparison of oral and nonoral strategies. *Arch Phys Med Rehabil* 2001;82:1744-6.
4. Smithard DG, O'Neill PA, England RE, et al. The natural history of dysphagia following a stroke. *Dysphagia* 1997;12:188-93.
5. Sala R, Munto MJ, de la Calle J, et al. Swallowing changes in cerebrovascular accidents: incidence, natural history, and repercussions on the nutritional status, morbidity, and mortality. *Rev Neurol* 1998;27:759-66.
6. DePippo KL, Holas MA, Reding MJ. Validation of the 3-oz water swallow test for aspiration following stroke. *Arch Neurol* 1992; 49:1259-61.
7. Mann GD. *The Mann Assessment of Swallowing Ability*. Clifton Park: Singular Thomas Learning; 2001.
8. List MA, Ritter-Sterr C, Lansky SB. A performance status scale for head and neck cancer patients. *Cancer* 1990;66:564-9.
9. Hillel AD, Miller RM, Yorkston K, McDonald E, Norris FH, Konikow N. Amyotrophic lateral sclerosis severity scale. *Neuro-epidemiology* 1989;8:142-50.
10. Enderby P. *Therapy outcome measures: speech-language pathology*. San Diego: Singular Publishing Group; 1997.
11. American Speech-Language and Hearing Association. *National Outcomes Measurement System: annual report*. Rockville: AHSA; 1998.
12. O'Neil KH, Purdy M, Falk J, Gallo L. The dysphagia outcome and severity scale. *Dysphagia* 1999;14:139-45.
13. Salassa JR. A functional outcome swallowing scale for staging oropharyngeal dysphagia. *Dig Dis* 1999;17:230-4.
14. Stroke—1989. Recommendations on stroke prevention, diagnosis, and therapy. Report of the WHO Task Force on Stroke and other Cerebrovascular Disorders. *Stroke* 1989;20:1407-31.
15. Burn JP. Reliability of the modified Rankin Scale. *Stroke* 1992; 23:438. Comment on: *Stroke* 1991;22:1242-4.
16. Collin C, Wade DT, Davis S, Horne V. The Barthel ADL index: a reliability study. *Int Disabil Stud* 1988;10:61-3.