

Original Article

Reliability and Validity of a Tool to Measure the Severity of Dysphagia: The Food Intake LEVEL Scale

Kenjiro Kunieda, MD, Tomohisa Ohno, DDS, PhD, Ichiro Fujishima, MD, PhD, Kyoko Hojo, SLP, PhD, and Tatsuya Morita, MD

Department of Rehabilitation (K.K., I.F., K.H.), Hamamatsu City Rehabilitation Hospital, Shizuoka; Department of Neurology and Neurological Science (K.K.), Graduate School of Medicine, Tokyo Medical and Dental University, Tokyo; Department of Rehabilitation (T.O.) and Department of Palliative and Supportive Care, Palliative Care Team, and Seirei Hospice (T.M.), Seirei Mikatahara General Hospital, Shizuoka, Japan

Abstract

Context. Dysphagia is one of the most prevalent and distressing symptoms among palliative care patients, and a practical assessment tool is required.

Objectives. The aim of this study was to examine the reliability and validity of a tool to measure the severity of dysphagia: the Food Intake LEVEL Scale (FILS), a 10-point observer-rating scale.

Methods. The inter- and intrarater reliability was evaluated by three clinicians in 30 patients using weighted kappa statistics. The convergent validity was evaluated by examining correlations of FILS with the Functional Oral Intake Scale (FOIS) and patient-reported satisfaction levels with oral intake.

Results. Weighted kappa coefficients for interrater reliability ranged from 0.70 to 0.90 and those for intrarater reliability ranged from 0.83 to 0.90. The FILS score was highly associated with the FOIS ($\rho = 0.96\text{--}0.99$) and patient-reported satisfaction ($\rho = 0.89$).

Conclusion. The FILS seems to have fair reliability and validity as a practical tool for assessing the severity of dysphagia. Further study on the reliability, validity, and sensitivity of the FILS compared with the FOIS is needed. *J Pain Symptom Manage* 2013;46:201–206. © 2013 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.

Key Words

Dysphagia, food intake, measurement tool, validation

Address correspondence to: Kenjiro Kunieda, MD, Department of Rehabilitation Medicine, Hamamatsu City Rehabilitation Hospital, 1327-1 Wago-cho, Nakaku, Hamamatsu, Shizuoka 433-8511, Japan. E-mail: ken2rou@xk9.so-net.ne.jp

Accepted for publication: August 1, 2012.

© 2013 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.

Introduction

Dysphagia, defined as a dysfunction in the process of eating,¹ is one of the most prevalent and distressing symptoms among palliative care patients.^{2–4} To provide quality palliative care, reliable and valid assessment tools to

0885-3924/\$ - see front matter

<http://dx.doi.org/10.1016/j.jpainsymman.2012.07.020>

quantify the severity of dysphagia are necessary.

To date, a variety of assessment tools have been developed to measure the severity of dysphagia.^{1,4–14} These include patient-reported questionnaires, such as the Swallowing Quality of Life questionnaire,⁵ the M. D. Anderson Dysphagia Inventory,⁶ and the Sydney Swallow Questionnaire;⁷ objective evaluation using fluoroscopy or endoscopy, such as the Swallowing Performance Status Scale,⁸ Dysphagia Outcome and Severity Scale (DOSS),⁹ and National Outcomes Measurement System;¹⁰ and observer-rated severity scales, such as the Functional Outcome Swallowing Scale (FOSS) for staging oropharyngeal dysphagia,¹¹ Minimal-Eating Observation Form-Version II,¹² McGill Ingestive Skills Assessment,¹³ and the Functional Oral Intake Scale (FOIS).¹⁴ In many palliative care settings, the routine use of patient-reported questionnaires or measures requiring fluoroscopy or endoscopy for evaluation would be impractical because of patient burden. A simple observer-rated severity scale, therefore, would be most welcomed but few such scales have been psychometrically tested.

For example, the Swallowing Quality of Life questionnaire is too time-consuming and complicated to be used in daily practice because of its many items (e.g., 44 items in the third version).⁵ The DOSS has a fair intra- and inter-rater reliability but has no validity testing and requires a videofluoroscopic swallowing study.⁹ The FOSS and National Outcomes Measurement System demonstrated no reliability or validity properties.^{10,11} Among the tools, the FOIS, a 7-point observer-rating tool, is the most promising for palliative care use because of its good reliability and validity, involving no patient burden.¹⁴

In Japan, however, the prototype of the Food Intake LEVEL Scale (FILS), a 10-point observer-rating scale to measure the severity of dysphagia, has been widely used since 1993 without any formal reliability and validity testing.¹⁵ The FILS is conceptually similar to the FOIS. Whereas the FOIS rates tube-dependent patients with markedly varying degrees of oral intake and alternative nutrition within a single level, the FILS divides those patients into three separate levels so that the severity may be classified more fully.

The primary aim of this study was to examine the reliability and validity of the widely used Japanese tool to measure the severity of dysphagia: the FILS.

Methods

This was a psychometric analysis of a measurement tool to assess the severity of dysphagia. The Institutional Review Board of Seirei Mikatahara General Hospital approved the scientific and ethical validity of this study.

Scale Development

The prototype of the FILS was originally developed in 1993 in Japan by a single specialist rehabilitation team for swallowing disorders. This scale measures the severity of dysphagia by examining to what degree patients take food orally on a daily basis. Levels 1–3 relate to the varying degrees of non-oral feeding. Levels 4–6 relate to the varying degrees of oral food intake and alternative nutrition. Levels 7–9 relate to the varying degrees of oral food intake alone, and Level 10 relates to normal oral food intake.

For this study, we initially reviewed and made minor changes in the wording of some items on the basis of discussions among the authors and a literature review.^{1,4–14} To facilitate the discussion and clarify the process of achieving a consensus, we adapted the Delphi method.¹⁶ We chose 24 panel members with at least three years of experience working as dysphagia management specialists to cover all the disciplines and different areas across Japan. The panel included 10 physicians, five dentists, eight speech-language pathologists, and one physical therapist. Each panel member was asked to rate the overall appropriateness of the FILS using a 9-point Likert type scale (1: inappropriate to 9: appropriate). In the first round, one panel member rated the appropriateness of the FILS as 6, and the remaining 23 members rated it as 7 or 8. After disseminating the results and after an e-mail discussion, we made minor revisions for clarification of the wording and performed the second Delphi round. In the second round, all members rated the appropriateness of the FILS as 7 or above: 7 points by five members,

8 points by 14 members, and 9 points by five members. We considered that the major discrepancies had been resolved and prepared the final version of the FILS (Table 1).

For potential international use, an English version of the FILS was created by using a formal double-back translation process.

Reliability and Validity Testing

This research included two studies for reliability and validity testing (Table 2). Study 1 examined interrater reliability, intrarater reliability, and convergent validity with the FOIS and involved 30 patients; Study 2 examined convergent validity for patient satisfaction involving another 25 patients with normal cognitive function.

Study 1

Patient Recruitment. Patients were consecutively recruited to this study from all inpatients of the rehabilitation department of a general hospital. As we expected kappa values of 0.8 with 95% confidence intervals ranging from 0.6 to 1.0, the estimated sample size was 26.

Interrater Reliability. To evaluate interrater reliability, three clinicians (one physician, one nurse, and one speech-language pathologist) independently evaluated the severity of patient dysphagia using the FILS. We chose these raters to explore the interrater reliability

across different disciplines, and these raters had more than three years of experience working as dysphagia management specialists. Score ratings were made by direct observation of each patient during meals and involved assessment of the type, amount, and method of oral food and liquid intake, with reference to the information from medical charts and a dietary journal. Each rater was blinded to the other raters' evaluations.

Intrarater Reliability. To evaluate intrarater reliability, the raters completed the FILS twice during two days (once per day, i.e., the second evaluation was performed 24 hours after the first evaluation). We determined that the interval of 24 hours was appropriate because longer periods could result in actual changes in patients' conditions, and we viewed a 24-hour interval as sufficient to avoid recall bias.

Convergent Validity With the FOIS. To evaluate convergent validity, we examined the association between the FILS and the FOIS. The FOIS is a 7-point ordinal scale that reflects the functional oral intake of patients with dysphagia. We chose the FOIS because it measures the severity of dysphagia, and we assumed that a strong association indicated the convergent validity of the FILS. The three clinicians rated the FILS and the FOIS at the same time.

Table 1
Food Intake LEVEL Scale

No oral intake

- Level 1: No swallowing training is performed except for oral care.
- Level 2: Swallowing training not using food is performed.
- Level 3: Swallowing training using a small quantity of food is performed.

Oral intake and alternative nutrition

- Level 4: Easy-to-swallow food less than the quantity of a meal (enjoyment level) is ingested orally.
- Level 5: Easy-to-swallow food is orally ingested in one to two meals, but alternative nutrition is also given.
- Level 6: The patient is supported primarily by ingestion of easy-to-swallow food in three meals, but alternative nutrition is used as a complement.

Oral intake alone

- Level 7: Easy-to-swallow food is orally ingested in three meals. No alternative nutrition is given.
- Level 8: The patient eats three meals by excluding food that is particularly difficult to swallow.
- Level 9: There is no dietary restriction, and the patient ingests three meals orally, but medical considerations are given.
- Level 10: There is no dietary restriction, and the patient ingests three meals orally (normal).

Swallowing training: Training conducted by an expert, well-instructed caregiver, or the patient himself/herself to improve the swallowing function.

Easy-to-swallow food: Food that is prepared so that it is easy to swallow even without mastication, for example, meat and vegetables are gelatinized or homogenized in a mixer.

Alternative nutrition: Non-oral nutrition such as tube feeding and drip infusion.

Food that is particularly difficult to eat: dry and brittle food, hard food, water, and so on.

Medical considerations: guidance, tests, examinations, and so on, for symptoms suggestive of swallowing disorders such as choking and the feeling of food remaining in the pharynx.

Table 2
Measurement Schedule

Study 1	First (First Day)	Second (Next Day)
A physician	FILS, FOIS	FILS
A nurse	FILS, FOIS	FILS
A speech-language pathologist	FILS, FOIS	FILS
Study 2	Examination	
Speech-language pathologists	FILS	
Patients	VAS of satisfaction with oral intake	

FILS = Food Intake LEVEL Scale; FOIS = Functional Oral Intake Scale for Dysphagia; VAS = visual analogue scale.

Study 2

Patient Recruitment. Another sample of 25 patients was consecutively recruited to Study 2 from inpatients of the rehabilitation department of a general hospital, if they met the following inclusion criteria: 1) referred to the rehabilitation department with dysphagia problems, 2) cognitively intact and capable of replying to a questionnaire (clinically diagnosed), and 3) consented to this study.

Convergent Validity With Patient Satisfaction. To evaluate the convergent validity, we examined the association between the FILS and patient-reported satisfaction with oral intake using a 100 mm visual analogue scale (VAS) ranging from 0 (completely dissatisfied with oral intake) to 100 (completely satisfied).¹⁷ We decided to use a VAS because subjective improvement is an important aspect in palliative care settings. The clinicians rated the FILS while blinded to the patient-reported satisfaction score.

Statistical Analyses

For inter- and intrarater reliability, weighted kappa coefficients were calculated. We assumed that a kappa statistic of 0.6 or more indicated good reliability and 0.8 or more indicated excellent reliability. For convergent validity, we calculated the Spearman rank correlation coefficient, and we assumed that a ρ of 0.6 or more indicated adequate convergent validity.

All statistical analyses were performed using SPSS statistics 18.0 (IBM SPSS Inc., Tokyo, Japan).

Results

The patients' background characteristics are summarized in Table 3. Among the 90 assessments in Study 1, the number of each FILS score was 1 ($n = 10$), 2 ($n = 7$), 3 ($n = 11$), 4 ($n = 8$), 5 ($n = 6$), 6 ($n = 8$), 7 ($n = 11$), 8 ($n = 11$), 9 ($n = 8$), and 10 ($n = 10$).

Reliability

Interrater reliability was good (Table 4), with weighted kappa coefficients of 0.73 between the physician and nurse, 0.90 between the physician and speech-language pathologist, and 0.70 between the nurse and speech-language pathologist. Intrarater reliability was excellent (Table 5), with weighted kappa coefficients of 0.83 (physician), 0.90 (nurse), and 0.97 (speech-language pathologist).

Validity

In Study 1, the FILS score was highly associated with the FOIS score, with a ρ of 0.96 (physician: $P < 0.001$), 0.96 (nurse: $P < 0.001$), and 0.99 (speech-language pathologist: $P < 0.001$).

In Study 2, the FILS score was highly associated with the patient-reported satisfaction score ($\rho = 0.89$; $P < 0.001$).

Discussion

The present article describes the development process and psychometric properties of

Table 3
Baseline Characteristics of Patients

	Study 1	Study 2
	($n = 30$)	($n = 25$)
	<i>n</i>	<i>n</i>
Mean \pm SD age (years)	76 \pm 7.9	74 \pm 7.7
Sex		
Male	23	15
Female	7	10
Primary disease		
Cerebrovascular disease	15	17
Respiratory disease	4	0
Neuromuscular disease	3	3
Nephrological disease	2	0
Cardiocirculatory disease	2	2
Cancer	2	3
Cervical spine injury	1	0
Autonomic dysfunction diseases	1	0

Table 4
Interrater Reliability

	Weighted Kappa Coefficients	95% CI
Physician and nurse	0.73	0.55–0.91
Physician and speech-language pathologist	0.90	0.78–1.00
Nurse and speech-language pathologist	0.70	0.52–0.88

a simple scale for measuring the severity of dysphagia. One of the most important findings of this study is that the FILS has fair reliability and validity. The second important finding is that the FILS is highly and significantly associated with the degree of patient satisfaction.

The interrater reliability was good for the FILS. Weighted kappa coefficients for interrater reliability ranged from 0.70 to 0.90. Although there are several tools for assessing the severity of dysphagia, the FOSS has not shown reliability.¹¹ The DOSS and the FOIS have good interrater reliability:^{9,14} the DOSS has been reported to show an interrater reliability of 90%, and the FOIS reportedly has an average kappa value that ranges from 0.86 to 0.91. The FILS has a slightly lower interrater reliability than the DOSS and FOIS. One possible reason is that, whereas the DOSS and FOIS include seven items, the FILS includes 10 items; therefore, the interrater reliability is lower compared with the other scales. Nonetheless, the kappa statistic for the FILS was high enough, and the tool seems to show adequate interrater reliability.

The intrarater reliability was excellent for the FILS, ranging from 0.83 to 0.97. The FOSS and FOIS have not shown intrarater reliability, whereas the DOSS has been reported to show intrarater reliability of 93%. The fact that the FILS shows an excellent intrarater reliability under statistical adjustment of by-chance agreement is one of the psychometric merits of this scale.

The FILS shows strong associations with the VAS scores of the patients themselves. The palliation of symptoms and maintenance

Table 5
Intrarater Reliability

	Weighted Kappa Coefficients	95% CI
Physician	0.83	0.68–0.98
Nurse	0.90	0.78–1.00
Speech-language pathologist	0.97	0.90–1.00

of quality of life are important goals of clinical care for dysphagic patients in palliative care settings. We correlated the FILS with the subjects' satisfaction with eating and drinking. For the DOSS and FOIS, there are no reports showing a relationship between these tools and patient-reported levels of satisfaction with eating and drinking.^{9,14} The strong association with patients' subjective satisfaction could make interpretations more meaningful in intervention studies involving palliative care settings, where patients' subjective improvement is important.

One of the strengths of the FILS is its convenience. The DOSS requires a videofluoroscopic swallowing study for scoring,⁹ and these examinations can only be done in a limited number of facilities. The FILS does not need this type of examination and can be used anywhere because score ratings are made by direct observation during each patient's meal. This suggests that simple observation of the patient's level of oral intake in daily practice may be sufficient to determine the severity of dysphagia.

Another potential strength is that the FILS may be theoretically more sensitive to changes in the oral intake of food and liquid over time because the FILS includes 10 items and the FOIS includes seven items.¹⁴ Although the FOIS includes Level 3 as tube-dependent with consistent oral intake of food or liquid, there are markedly varying degrees of oral intake and alternative nutrition within this single level. Therefore, we divided Level 3 of the FOIS into three parts in the FILS, that is, Levels 4–6 of the FILS relate to varying degrees of oral intake and alternative nutrition. Thus, the FILS might document changes more accurately than the FOIS with regard to understanding the changes in swallowing performance. Further studies on the sensitivity profile of the FILS and FOIS are needed.

The study had some limitations. First, the patient sample was relatively small and the study was done at a single center; a multicenter validation study is required. Second, because the same clinician rated the two observer-rated tools for convergent validity, the lack of blinding might lead to a close correlation between the FILS and FOIS.

In conclusion, the FILS seems to have fair reliability and validity as a practical tool for assessing the severity of dysphagia. Further study

on the reliability, validity, and sensitivity of the FILS compared with the FOIS is needed.

Disclosures and Acknowledgments

No funding was provided for this study, and the authors declare no conflicts of interest.

The authors thank Akio Tsubahara, Fumiko Ohshima, Gentaro Mizojiri, Tomoyuki Honda, Sonoko Nozaki, Hiroshi Abe, Junko Fujitani, Haruo Inada, Naoko Shindo, Yasutomo Motohashi, Yasuyuki Iwasa, Haruka Tohara, Koichiro Ueda, Yuji Ishikawa, Sumiko Okada, Mitsuko Shimizu, Chieko Kojima, Isami Kumakura, Yuri Fujiwara, Kenichi Hasegawa, Motoki Moriwaki, Ryo Kozu, and Mariko Fujimori for the development of the scale. They also thank Mitsunori Miyashita, RN, PhD, for statistical advice.

References

1. Hansen T, Kjaersgaard A, Faber J. Measuring elderly dysphagic patients' performance in eating—a review. *Disabil Rehabil* 2011;33:1931–1940.
2. Teunissen SC, Wesker W, Kruitwagen C, et al. Symptom prevalence in patients with incurable cancer: a systematic review. *J Pain Symptom Manage* 2007;34:94–104.
3. Sykes NP, Baines M, Carter RL. Clinical and pathological study of dysphagia conservatively managed in patients with advanced malignant disease. *Lancet* 1988;2:726–728.
4. Durlacher JE, Brennan MT, Verdonck-de, et al. Swallowing dysfunction in cancer patients. *Support Care Cancer* 2012;20:433–443.
5. McHorney CA, Robbins J, Lomax K, et al. The SWAL-QOL and SWAL-CARE outcome tool for oropharyngeal dysphagia in adults: III. Documentation of reliability and validity. *Dysphagia* 2002;17:97–114.
6. Chen AY, Frankowski R, Bishop-Leone J, et al. The development and validation of a dysphagia-specific quality-of-life questionnaire for patients with head and neck cancer. The M. D. Anderson dysphagia inventory. *Arch Otolaryngol Head Neck Surg* 2001;127:870–876.
7. Dwivedi RC, St Rose S, Roe JW, et al. Validation of the Sydney Swallow Questionnaire (SSQ) in a cohort of head and neck cancer patients. *Oral Oncol* 2010;46:e10–e14.
8. Karnell MP, McCracken E. A data base information storage and reporting system for videofluorographic oropharyngeal motility (OPM) swallowing evaluations. *Am J Speech Lang Pathol* 1994;3:54–60.
9. O'Neil KH, Purdy M, Falk J, Gallo L. The Dysphagia Outcome and Severity Scale. *Dysphagia* 1999;14:139–145.
10. American Speech-Language-Hearing Association. National Outcomes Measurements System: Annual report. Rockville, MD: ASHA, 1998.
11. Salassa JR. A functional outcome swallowing scale for staging oropharyngeal dysphagia. *Dig Dis* 1999;17:230–234.
12. Westergren A, Unosson M, Ohlsson O, Lorefält B, Hallberg IR. Eating difficulties, assisted eating and nutritional status in elderly (> or = 65 years) patients in hospital rehabilitation. *Int J Nurs Stud* 2002;39:341–351.
13. Lambert HC, Gisel EG, Groher ME, Abrahamowicz M, Wood-Dauphinee S. Psychometric testing of the McGill Ingestive Skills Assessment. *Am J Occup Ther* 2006;60:409–419.
14. Crary MA, Mann GD, Groher ME. Initial psychometric assessment of a functional oral intake scale for dysphagia in stroke patients. *Arch Phys Med Rehabil* 2005;86:1516–1520.
15. Fujishima I. Textbook of rehabilitation for swallowing disorders associated with stroke, 1st ed. [in Japanese]. Tokyo: Ishiyaku Publishers, 1993.
16. Fitch K, Bernstein SJ, Aguilar MD, et al. The Rand/UCLA appropriateness method user's manual. Santa Monica, CA: RAND, 2001.
17. Wewers ME, Lowe NK. A critical review of visual analogue scales in the measurement of clinical phenomena. *Res Nurs Health* 1990;13:227–236.