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Validation of the Chinese Version of the Functional Oral Intake Scale (FOIS) Score in the Assessment of Acute Stroke Patients with Dysphagia

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Abstract

This study aimed to validate the Chinese version of the Functional Oral Intake Scale (FOIS) score in acute stroke patients with dysphagia. A sample of 128 consecutive patients with acute stroke, admitted to Department of Neurology from April to October in 2016, completed the FOIS. The interrater reliability, criterion validity, discriminant validity, cross validation, and the sensitivity of FOIS scale were evaluated. Results showed that rater agreements were excellent for FOIS (Kw=0.881, p<0.001). A highly negative correlation between FOIS and WST (water swallow test) *was detected (r=−0.937, p<0.001). There was significant difference for FOIS level of patients with different evaluation outcomes (χ^2=126.551, p<0.001). The FOIS evaluation results were significantly correlated with two physiological measures of swallowing. The Chinese version of the FOIS score is a reliable scale for evaluating the level of oral feeding function in patients with acute stroke.*

Keywords:

Weights and measures; Deglutition disorders; Stroke

Introduction

Approximately 22-65% of the patients with stroke have dysphagia [1], and it has been estimated that 40-50% of these patients encountered aspiration problems [2], dysphagia, and related complications, which will lead to prolonged hospital stay, and are associated with increased mortality, comorbidity, and health care costs [3-4]. According to the American Heart Association and American Stroke Association guidelines for early stroke management, the primary step is to screen aspiration before the administration of food, liquid or medication in stroke patients [5]. There are many bedside screening tools for aspiration in stroke patients, and the WST (water swallow test) may be the most convenient screening tool among stroke patients in nursing practice [6]. A recent systematic review has suggested that the WST have sensitivities between 64-79% and specificities between 61-81% [6]. However, the assessment of aspiration risk does not constitute the only objective in the evaluation of dysphagic stroke patients, in whom potential feeding problems should also be addressed [7]. Eating without knowledge of the dysphagia can lead not only to pneumonia, but also to life-threatening conditions, such as dehydration, malnutrition, and suffocation [8, 9]. Therefore, evaluation of oral feeding function is especially important. These concerns strongly require a reliable scale that is easy to be used, to provide further swallowing function details in feeding and nutrient intake.

Concerning this problem, the Functional Oral Intake Scale (FOIS) for dysphagia in stroke patients, a novel oral feeding function rating system, was developed by the Florida Health Science Center in 2005 [10]. This is a 7-point ordinal scale that describes the typical functional oral intake of patients with stroke and dysphagia [11]. In the FOIS, all levels can calculate, such as what the patient consumes by mouth on a daily basis. Levels 1 through 3 are related to varying degrees of non-oral feeding, while levels 4 through 7 are varying degrees of oral feeding without non-oral supplementation, and it considers both diet modifications and patient compensations [10]. A score below 6, of a maximum of 7, indicates restrictions of oral intake of food and liquid [11]. A recent study shows that there is an association between the level of oral intake and the degree of oropharyngeal dysphagia in elderly post-stroke patients during chronic phase [12]. Another finding suggests a negative and moderate correlation between T-EAT-10 and FOIS [13]. However, this scale has been used in Japan [14] and Iran [15], but no Chinese version is available to date. The purpose of this investigation was to translate the English version of FOIS to Chinese, and to evaluate the interrater reliability, criterion validity, discriminant validity, cross-validation, and the sensitivity of the Chinese version of the FOIS in Chinese Han stroke patients with dysphagia.

Methods

This study was approved by the ethical committee of the Nanfang Hospital, Southern Medical University, Guangdong, China (No. NFEC-2016-145). Written and verbal informed consent was obtained from all patients or their caregivers, and all data were collected prospectively. A total of 128 patients with acute stroke, admitted to Department of Neurology (Nanfang Hospital, Southern Medical University) from April to October 2016 were included in this study. The inclusion criteria included willingness to participate in the study, being over the age of 18, normal cognitive function, admitted to Department of Neurology within three days of stroke onset, and having a clinical diagnosis of stroke confirmed by an attending stroke neurologist according to the World Health Organization's definition of stroke [16]. Exclusion criteria were: 1) History of other diseases that affect swallowing function, such as head and neck cancer, esophageal cancer, brain injury, myasthenia gravis or Guillain Barre Syndrome; and 2) patients with nasal feeding on admission. Demographic data, vital signs, diagnosis, day of evaluation, NIHSS, MBI, and the extent of dysphagia according to the WST were recorded.

Translation of the Chinese version of the FOIS

The items of the FOIS were first translated to Chinese by two bilingual neurology specialist, who had more than ten years of clinical experience (forward translation). A meeting, in which four dysphagia experts participated, was held to confirm a

single scale with a consensus (synthesis). Necessary adjustments in the translation were made after the consensus. Then, a native English speaker outside of the medical profession and a dysphagia expert with experience of studying abroad translated the instrument into English (backward translation). Finally, comparison by two bilingual experts derived English text and converted into a scale. The backward translation was finally sent to the original creator of the FOIS to double verified. Every item of FOIS was identical to the original version (Table 1).

Table 1 - The Chinese version of the Functional Oral Intake Scale (FOIS)

FOIS ITEMS **FOIS 条目**	**0 = Completely consistent 0 =完全一致** **4 = Completely inconsistent 4=完全不一致**				
Level 1: Nothing by mouth. 1级：完全不经口进食	0	1	2	3	4
Level 2: Tube dependent with minimal attempts of food or liquid. 2级：管饲依赖，极少尝试进食普通食物和液体食物	0	1	2	3	4
Level 3: Tube dependent with consistent oral intake of food or liquid. 3级：管饲依赖，经口进食同一质地的普通食物和液体食物	0	1	2	3	4
Level 4: Total oral diet of a single consistency 4级：完全经口进食单一粘稠度的食物	0	1	2	3	4
Level 5: Total oral diet with multiple consistencies, but requiring special preparation or compensations. 5级：完全经口进食多种粘稠度的食物，但需特殊制备或补给	0	1	2	3	4
Level 6: Total oral diet with multiple consistencies without special preparation, but with specific food limitations. 6级：完全经口进食多种粘稠度食物而无需特殊制备，但有特殊食物限制	0	1	2	3	4
Level 7: Total oral diet with no restrictions. 7级：完全经口进食，无任何限制	0	1	2	3	4

Interrater Reliability

Because of the characteristics of self-recovery of stroke dysphagia, this study did not assess the test-retest validity of the tool, but test interrater reliability to reflect the stability of FOIS. A one-page handout with written instructions describing the FOIS was provided to raters who were given opportunities to assess patients before study started. Through direct patient observation, or patient or caregiver statement, two stroke nurses, who were not involved with translation and have more than 5 years of clinical experience in neurology department, used FOIS to evaluate the amount, type and method of oral feeding or liquid to the newly admitted patients respectively. The WST was carried out according to the conventional method by 2 other stroke nurses at the time of admission. In addition, in order to minimize the possible changes in patient's level of swallowing function, all the assessments were completed within 48 hours when no substantial change of the swallowing ability was expected to be taken place [13].

Criterion Validity

The criterion validity of the FOIS was determined by assessing the correlation between FOIS and WST, NIHSS or MBI. WST, a useful screening tool for aspiration, was used to evaluate swallowing function and reflects the severity of dysphagia. The WST has 5 levels in which level 1 means normal swallowing function, while level 5 represents severe dysphagia. In addition, studies showed that there was a significant correlation between the swallowing function and the severity of stroke [17, 18]. The National Institutes of Health Stroke Scale (NIHSS) is a validate instrument that evaluate the severity of stroke [19]. The Modified Barthel Index (MBI) was used to evaluate the patient's performance in activities of daily living (ADLs). This scale is often regarded as a functional interpretation of disability or dependency in the ADLs. The potential associations between the FOIS ratings and the measures of stroke severity, ADLs, and swallowing ability were investigated by Chi-square, Cramer's V (dichotomized data) or ϕ (multiple category data). Only when this measure was dichotomized, the obtained scores could be included in the analysis. Although no cut point on NIHSS scale is universally accepted, this value was chosen because a score of more than 8 was used in the National Institute of Neurological Disorders and Stroke recombinant tissue plasminogen activator study to define a severe post-stroke neurologic deficit [19]. Dichotomized cut-off scores were 15 for the MBI. Finally, FOIS ratings were compared with the established criteria. The above measurements were collected when the patient was admitted to a stroke unit.

Discrimination validity

Clinical comprehensive evaluation, as evaluation standard, was applied to this study [20]. On the basis of the patient's swallowing disorder and the severity of symptoms, the patients were divided into three groups: normal oral feeding group, oral feeding disorders without tube-feeding group, and tube-feeding group. The FOIS evaluation results of the three groups of patients were judged. The specific content of clinical comprehensive evaluation include the evaluation grade of WST, eating pattern and food form (exclude tooth or oral disorders), cough, whether nasal feeding, fiber optic bronchoscopy and so on. According to the actual situation of the patients and the analysis of the results of the patients' caregivers, clinical doctors and nurses, it is judged to be the existence of swallowing disorders when the patient's eating patterns and food patterns changed. In addition, cough during eating and drinking was also judged to be dysphagia.

Cross validation

Cross-validation was evaluated via comparing FOIS scores with the incidence of dysphagia and aspiration, and with the severity of dysphagia and aspiration according to video fluoroscopy swallowing study (VFSS), a golden standard for the diagnosis of dysphagia, impaired swallowing function, and aspiration [21]. All the above comparisons were completed within 72 hours of admission to the stroke unit.

Sensitivity to Change

In order to explore the sensitivity of the FOIS scale and to evaluate the changes of oral feeding function, the FOIS scale was used to evaluate the swallowing function in patients at 3 time points, at admission to the stroke unit, at 1 month post-onset, and at 3 months post-onset. Subsequently, the rating

distribution bar chart of FOIS was plotted to evaluate the changes of functional oral intake over time.

Statistical Analysis

Statistical analysis was carried out using Windows-based SPSS 20.0. Arithmetical means and standard deviations (mean ± SD) for quantitative variables were calculated, and categorical variables were presented as frequencies. All statistical tests were conducted at a 5 % significance level.

For both the FOIS score and the WST, pairwise weighted K values were calculated. Interrater reliability was evaluated with the Cohen K statistic. A K statistic of 0.4 or less is considered poor, values between 0.4 and 0.6 are considered fair to moderate, those between 0.6 and 0.8 suggest good inter-observer agreement, and values higher than 0.8 suggest excellent agreement [22]. This approach is conservative for our reliability comparisons, in that the agreement among raters will be inflated by these automatically perfect agreements [23]. Chi-square and Cramer's V correlation analyses were calculated to assess criterion validity and cross-validation. Discriminant validity was tested by non-parametric rank sum test. And the sensitivity of the FOIS scale for clinical assessment was investigated by plotting rating distribution bar chart.

Results

Patient Characteristics

From April 2016 to October, 128 patients were enrolled. Detailed patients' characteristics are summarized in Table 2. The average age of patients was 59.16 years (median = 59 years, range = 22–80 years), and 70% were men. The diagnoses of the patients selected for the study were ischemic stroke (103 patients, 81%), hemorrhagic stroke (12 patients. 9%), unknown (13 patients, 10%). Twenty-nine patients (22%) were indwelled gastric tube.

Table 2 - Clinical Features of 128 Acute Stroke Patients

	Initial FOIS Ratings*				
Clinical Features	**1**	**4**	**5**	**6**	**7**
Patients	29	2	2	20	75
Mean age±SD (y)	59.76± 13.64	74.00 ±7.07	69.50 ±7.78	60.40 ±8.54	57.85± 10.90
Sex (%)					
Male	65.5	50	100	90	66.7
Female	34.5	50	0	10	33.3
Smoking(%)					
Yes	17.2	0	0	50	30.7
No	75.9	50	100	50	62.7
Quit smoking	6.9	50	0	0	6.7
Pathology					
Cerebral infarction	25	2	2	20	55
Cerebral hemorrhage	3	0	0	0	9
Unknown	1	0	0	0	11
Inhospital Day	12.65	12	17.5	10.95	9.08
Mean MBI score	14.66	20	37.5	60	70.80
Mean NIHSS score	10.62	6.5	8	5.15	2.59

Abbreviations: SD, standard deviation; rTPA, Recombinant Tissue Plasminogen Activator; MBI, Modified Barthel Index; NIHSS, National Institutes of Health Stroke Scale.

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

Interrater Reliability of the FOIS Score

The overall reliability was excellent for both the FOIS score (Kw= 0.881, Spearman, r=0.972) and the WST (Kw= 0.844, Spearman, r=0.965) (Table 3). The rater agreement was good to excellent for stroke nurses. For the FOIS score, 29 of 128 (23%) observations had the lowest level (1). The distribution of the FOIS was comparable with the distribution with the WST. One level of the WST was recorded on 81 occasions. However, 75 were scored at the highest FOIS level (7). In the remaining 9 instances, food with multiple viscosity could be taken without the help of special preparation or compensation, but some specified food could not.

Table 3 - The Kappa values and Spearman's correlation of the FOIS and The WST for the correlation between the two assessments

Rater Pair	No. of patients	FOIS			WST		
		K	**SR**	***P***	**K**	**SR**	***P***
N/N	128	.881	.972	.000*	.844	.965	.000

FOIS, Functional Oral Intake Scale; WST, Water Swallow Test; N, nurse. **P*<0.001

Criterion Validity

The WST is a clinical screening instrument to assess the status of swallowing function in patients. As shown in the table, there is a strongest negative correlation between the FOIS and the WST (r = -.937, p < 0.001). The NIHSS and MBI were also significantly associated with the FOIS ratings on admission to a stroke unit (Table 4).

Table 4 - Chi-Square, Spearman's correlation and Cramer's V Correlations between the FOIS Scale and the NIHSS, MBI, and WST Scale within 48 Hours of Admission to Stroke Unit

Test	X^2	P	SR	Cramer's V Correlations/ϕ
NIHSS	57.84	.000*	-.480	.84
MBI	61.71	.000*	-.553	.81
WST	6.18	.000*	-.937	1.73

**P*<0.001

Discrimination validity

Clinical comprehensive evaluation was performed in all patients who met the inclusion criteria. According to the evaluation results of swallowing function, the patients were divided into three groups: normal oral feeding group, oral feeding disorders without tube-feeding group, and tube-feeding group. Non-parametric rank sum test was completed to evaluate the FOIS level among the three groups of patients. The evaluation results of the 3 groups were statistically significant difference (χ^2=126.551, *P*<0.001) (Table 5), indicating the FOIS scale can be used to determine whether or not the patients had oral feeding disorder as well as the severity of the symptoms.

Table 5 - The FOIS level among the three groups of patients

Group	Patients	FOIS level	X^2	P
Normal oral feeding group	75	Level1		

Oral feeding disorders without tube-feeding group	24	Level4-6	126.55	.000*
Tube-feeding group	29	Level7		

*P<0.001

Cross-validation

The cross-validation analysis data showed that the FOIS was significantly associated with presence of both dysphagia and aspiration derived from VFSS. Dysphagia severity was significantly correlated with FOIS ratings (χ^2=65.32; P<0.001), but the aspiration severity was not (Table 6).

Table 6 - Chi-Square, Spearman's correlation and Cramer's V Correlations between the FOIS Scale and Dysphagia or Aspiration Presence or Severity

Item	X^2	*P*	Cramer's V Correlations/ϕ
Dysphagia (+)	55.96	.000*	.93
Aspiration (+)	65.48	.000*	.93
Dysphagia Severity	65.32	.000*	.52
Aspiration Severity	19.02	NS	.31

*P<0.001. NS, not significant.

Sensitivity to Change

Data of oral feeding function of stroke patients at admission to a stroke unit, at 1 month and 3 months post-stroke were shown by FOIS level distribution map (Figure 1). The oral feeding function of the patients showed a gradual improvement within three months after stroke, which is consistent with the results of a previous study [24]. Therefore, the FOIS scale can sensitively reflect substantial changes of oral intake of food and liquid for stroke patients.

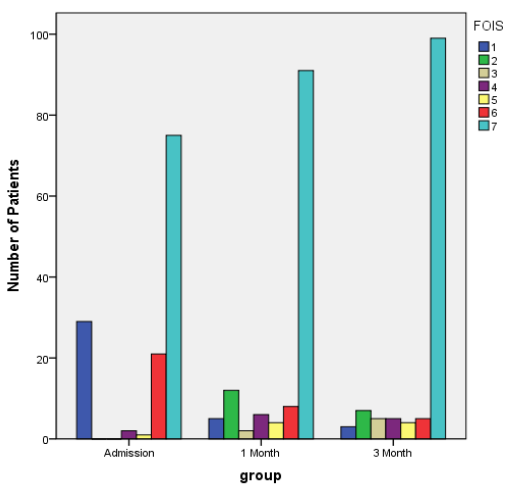

Figure 1. Changes of swallowing function in patients on admission to a stroke unit and at 1 month and 3 months post-stroke.

Discussion

As an oral feeding function evaluation tool, the FOIS scale is easily mastered and used in a diverse range of patients. It is a clinically useful instrument to record the severity of symptoms, and to monitor the progression of the disease and the effect of treatment. It has been shown to be strongly associated with swallowing dysfunction [13, 14, 25]. What is more, it has important clinical significance to accurately record the symptoms of dysphagia and the changes of oral feeding function in patients during the whole treatment period. Therefore, it is necessary to use the FOIS scale in clinical practice.

The interrater reliability of FOIS was high, which is consistent with the results of the original authors [10], suggesting the FOIS had a high reliability and stability. In terms of validity, the results demonstrated that there was a strong negative correlation between the FOIS and WST. However, we found that participants, even in WST level 1, had a certain degree of difficulty in feeding through the mouth. For example, Level 6 refers to the patients who can eat most foods by mouth, but avoid foods that are difficult, such as meat, salad, or dry foods. The food avoidance is specifically due to swallowing difficulty. Associations between the FOIS and the NIHSS or MBI were moderate at admission to the stroke unit. The moderate correlation may be explained by the uneven distribution of patients according to the FOIS. The number of patients at the extreme ends of the FOIS was too concentrated, and there were fewer participants in middle ranges of the FOIS. Once the patients took food by detaining nasogastric tube, they would be informed that eat any food by mouth or injection of food through tubes are not allowed. This is why no patients in FOIS level 2 or 3 were included.

In addition, this study evaluated the distinguish performance of the FOIS scale by the clinical comprehensive evaluation index. The clinical comprehensive evaluation index was revised according to the literature and on opinions of neurology experts. The FOIS evaluation results of three groups patients were compared, and the difference was statistically significant (P<0.001). Verified by VFSS, the FOIS shows an excellent cross-validation. Therefore, the discrimination performance of FOIS scale is excellent, and the FOIS scale can be used to determine whether or not the patients had oral feeding disorder, as well as the severity of the symptoms.

From the FOIS level distribution map, it seems sensitive to the changes in the oral feeding function of the patients. It is very important to accurately record the oral feeding function of the stroke patients throughout the whole time of their illness. We use the WST scale to evaluate the swallowing function of patients again, and combined use the FOIS scale to record the oral feeding status of the patients. In this way, doctors can have a better grasp of the patient's overall rehabilitation.

Although there was a strong correlation between FOIS and WST scale, overall, there are some subtle differences that do exist. In the study, we found that the FOIS provides more details of swallowing function than WST, and therefore, it is superior to WST due to the availability of nutritional status, and has higher ability to recognize different stages of swallowing function. Thus, we suggest that the combination of WST and FOIS scale should be employed to evaluate the swallowing functions of patients with acute stroke.

Conclusion

The Chinese version of the FOIS scale can be used to reliably assess oral feeding function in adult Chinese patients with acute stroke and is worthy of recommendation and application in clinical practice.

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