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Reliability and validity of the Slovenian Translation of the Functional Oral Intake Scale (FOIS-SI)

Zanesljivost in veljavnost lestvice funkcionalnega peroralnega vnosa (*angl.* Functional Oral Intake Scale, FOIS-SI) v slovenskem prevodu

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Abstract

Background: It is crucial that each and every stroke patient gets a systematic assessment of swallowing disorders, performed by a dysphagia specialist. Therefore, there is a need to use a standardized scale among professionals. The aim of this study was to translate, adapt, and obtain the statistical characteristics of the Functional Oral Intake Scale (FOIS), which is an observer-rated dysphagia severity scale primarily developed for stroke patients, into the Slovenian language.

Methods: We performed a 5-step translation and adaptation process. Six speech and language pathologists had evaluated 30 clinical records of patients with an acute ischemic stroke in the carotid artery territory with the Slovenian translation of the Functional Oral Intake Scale (FOIS-SI). Every clinical record included a speech and language clinical bedside assessment of dysphagia, the sex, age, National Institutes of Health Stroke Scale (NIHSS), comorbidities of patients and lesion location. We examined interrater and intrarater reliability and additionally convergent validity of FOIS-SI with the theoretically related IDDSI-Functional Diet Scale (IDDSI-FDS).

Results: The average measure Intraclass Correlation Coefficient (ICC) for the interrater reliability (ICC=0.959) and the intrarater reliability (ICC=0.979 and ICC=0.991) for both raters was excellent. The FOIS-SI scores correlated very high with the IDDSI-FDS (r_s=0.927).

Conclusion: The results of this study show that the Slovenian translation of the FOIS has an excellent interrater and intrarater reliability and very high validity, which implies the FOIS-SI can be used as a tool to quantitatively assess the severity of dysphagia in clinical practice and research in patients with stroke in carotid artery territory across the country in all medical and care settings.

Izvleček

Izhodišča: Pri bolnikih z disfagijo po ishemični možganski kapi v povirju karotidne arterije, ki jih obravnava specialist za disfagijo, je ključno sistematično vrednotenje stopnje disfagije. Zato strokovnjaki izražajo potrebo po uporabi standardizirane lestvice. Cilj raziskave je prevod in prilagoditev lestvice funkcionalnega peroralnega vnosa (*angl.* Functional Oral Intake Scale, FOIS), primarno sestavljene za bolnike po možganski kapi, ki je zdravnikom v pomoč pri vrednotenju izraženosti disfagije. Preverili smo tudi zanesljivost in veljavnost lestvice funkcionalnega peroralnega vnosa (FOIS-SI).

Metode: Izveden je bil 5-stopenjski proces prevoda in prilagoditve. Šest izkušenih logopedov, ki se ukvarjajo z disfagijo, je ovrednotilo 30 kliničnih poročil bolnikov po ishemični možganski kapi v povirju karotidne arterije. Poročila so vsebovala klinično logopedsko obposteljno oceno disfagije, spol in starost bolnika, ter lestvico Nacionalnega inštituta za zdravje za oceno nevrološke prizadetosti po možganski kapi (NIHSS), pridružene bolezni in mesto spremembe. Na podlagi podatkov smo izračunali zanesljivost. Študija veljavnosti je bila izvedena z iskanjem povezave med FOIS-SI in lestvico izraženosti disfagije IDDSI-FDS.

Rezultati: Zanesljivost med logopedi je bila odlična (ICC=0.959). Prav tako je bila odlična zanesljivost ob ponovnem vrednotenju (ICC=0.979 in ICC=0.991). V študiji smo zaznali zelo visoko korelacijo z IDDSI-FDS (r_s=0.927).

Zaključek: Rezultati študije so pokazali, da je slovenska različica FOIS izjemno zanesljiva ter zelo visoko veljavna, kar nakazuje, da se FOIS-SI kot kvalitativno orodje za oceno izraženosti disfagije lahko uporablja v klinične in raziskovalne namene.

1 Introduction

Swallowing is a complex physiological process, in which the activity of 50 pairs of muscles is orchestrated by an extensive neuronal network in the central nervous system to intake food into the mouth, prepare it and transport it from the oral cavity through the pharynx to the stomach (1,2). This process can be disturbed in many ways, which can lead to malnutrition, dehydration, and possibly death (3). Therefore, dysphagia is a common problem in all stages of swallowing. According to our clinical experience at the University Medical Centre (UMC) Ljubljana in the last years, dysphagia appears in 20% of stroke patients admitted for treatment to the Division of Neurology (unpublished clinical data). Globally the percentage is higher, around 50% (4). In the diagnostic process of dysphagia, a full bedside clinical examination is of utmost importance before objective methods, such as Videofluoroscopic Swallowing Study (VFSS) and Fiberoptic Endoscopic Evaluation of Swallowing (FEES), are eventually applied (5). Clinical swallowing bedside examination, VFSS, and FEES are mostly qualitative studies, which have limited options to precisely determine the severity of dysphagia. Yet, different follow-up methods for assessing dysphagia are also known to not be fully accurate. As a result, researchers developed quantitative scales based on both, VFSS and FEES techniques (6,7). However, not all patients have access to objective techniques, especially patients in general practices or nursing care facilities (8). Therefore, different self-evaluating questionnaires and scales which could help clinicians to determine the severity of dysphagia were developed. In Table 1 the characteristics of published and available swallowing scales are listed. Regarding dysphagia, only the questionnaire Quality of life in swallowing disorders (9) is translated and adapted to the Slovenian language. To compare the patient's level of dysphagia and outcome, a Slovenian translation of the severity scale is still needed. Since the Functional Oral Intake Scale (FOIS) has good psychometric characteristics (10), correlates significantly with the Food Intake Level scale, swallowing time of the Functional Assessment Measure, Mass Assessment of Swallowing Ability, Modified Barthel Index score, modified Rankin scale, VFSS (11), is easy to use, was translated to and validated in different languages (12-14), and was also used for different populations (11), and diseases (15-23), we decided to translate it and evaluate the initial psychometric characteristics of the Slovenian translation.

FOIS was developed based on reviewing dysphagia-related literature. The most describable items of a patient's oral or compensatory intake of food and liquids, and its potential modification, were selected for the final scale form. The initial scale had 10 levels, but this number was reduced to seven after the pilot study (10).

2 Methods

This paper is part of a larger research about dysphagia outcome of stroke survivors in acute care, which was approved by the National Medical Ethics Committee of the Republic of Slovenia (No. 0120-255/2029/3, 14.07.2020).

Table 1: Characteristics of different scales of the severity of dysphagia. The full name, levels, and directions of the severity of each scale are shown. Additionally, there is an explanation detailing whether or not the scale requires an objective assessment, such as the Videofluoroscopic Swallowing Study (VFSS) or the Fiberoptic Endoscopic Evaluation of Swallowing (FEES) and for which population the specific scale is most suitable. Furthermore, the most recent psychometric characteristics and recommendations of each scale are also mentioned.

Scale (reference)	Full name	Levels	Direction of severity	Requires an objective assessment	Population	Reliability and validity	Recommendations
DOSS (24)	Dysphagia Outcome and Severity Scale	7	From 1 (severe dysphagia - NPO) to 7 (full per-oral nutrition with normal diet)	Yes, mostly VFSS	Adults representing different diagnoses (neurological, general medical, pulmonary, cardiac and ear, nose, and throat diagnosis)	Interrater 90% and intrarater reliability 93%, no validity testing	Diet level, independence level, and type of nutrition.
DSRS (25)	Dysphagia severity rating scale	0-12	From 0 (best) to 12 (worst)	no	Adults with post stroke dysphagia.	Consensual validity – moderate, content validity – between 0.84 (good) to 0.96 (excellent), concurrent criterion validity - stronger with measures of swallowing and aspiration, lower with global measures of impairment, Intra and interrater reliability was >0. 90.	Modification of food and fluid, supervision requirements for feeding.
FILS (26)	Food Intake Level Scale	10	From level 1 (no oral intake – no swallowing training is performed except for oral care) to level 10 (oral intake alone – no dietary restriction, and the patients ingests three meals orally)	No	Different primary diseases (cerebrovascular, respiratory, neuromuscular, nephrological, cardiocirculatory, autonomic dysfunction cancer and cervical spine injury)	Interrater reliability ranged from 0.70 to 0.90 Interrater reliability ranged from 0.83 to 0.90. Convergent validity - highly associated with FOIS (p=0.96 -0.99)	Degree of patient's intake of food non-orally or orally.
FOSS (27)	Functional Outcome Swallowing Scale	6	From 0 (normal function and asymptomatic) to V (nonoral feeding for all nutrition)	yes	Full spectrum of oropharyngeal dysphagia in adults, especially aging patients and patients with head and neck cancer, neurologic disorders, gastroesophageal conditions, and psychiatric problems.	No formal study.	Physiological function, way of feeding, nutritional and respiratory status.

Scale (reference)	Full name	Levels	Direction of severity	Requires an objective assessment	Population	Reliability and validity	Recommendations
FOIS (10)	Functional Oral Intake Scale	7	From 0 (nothing by mouth) to 7 (total oral intake with no restrictions)	no	Initially for stroke patients, afterward studies in traumatic brain injury (TBI), head and neck cancer, vocal fold immobility, vagal schwannoma resection, cerebral palsy, postsurgical dysphagia, neurodegenerative diseases, post-extubation dysphagia in children, neurogenic dysphagia.	Stroke – high interrater reliability (85%), high criterion, and consensual validity.	Food restriction and way of feeding.
FOIS for infants (11)	Functional Oral Intake Scale	5	From 0 (nothing by mouth) to 5 (expansion of oral diet reached)	no	The general population of infants with dysphagia.	High inter-rater reliability (95.5%) and significantly correlated with aspiration severity in the VFSS.	Food restriction and way of feeding.
IDDS Functional Level Scale (28)	The International Dysphagia Diet Standardization Initiative Functional Diet Scale	9	0 (no food and no drinks) to 8 (no restrictions)	no	general	Initial consensual validity – 73% agreement, strong initial criterion validity with FOIS (R0.84, p<.001), initial interrater reliability - high interjudge reliability (Kendall concordance W=.819)	diet restriction
MEOF-II (29)	Minimal Eating Observation Form – Version II	9 yes-no items	Three dimensions (Ingestion, deglutition and energy) scored with 0 (problem) or 1 (without a problem).	no	elderly	Satisfying validity and reliability.	To identify meal-time problems.
MISA (30)	McGill Ingestive Skills Assessment	4 responses categories, max. 129 scores (higher score, less problems)	5 scales of 56 items	no	elderly	Preliminary high interrater agreement (0.90), and adequate preliminary validity.	functional ingestive skills
SPSS (31)	Swallowing Performance Status Scale	7	from 1 (normal) to 7 (severe impairment)	no	patients with neck and cancer	Reliable across the raters.	Diet modification, way of food intake.

This particular study was divided into two phases. Phase one was dedicated to the translation process, and phase two was focused on the study of reliability and validity of the Slovenian translation of FOIS (FOIS-SI) among clinicians.

2.1 Instrument description

2.1.1 Functional Oral Intake Scale

FOIS is a reliable scale to assess the functional severity of dysphagia. Observer-rated ordinal severity scale consists of seven levels, from nonoral feeding (Level 1) to oral feeding without any restrictions (Level 7). To quantify dysphagia severity, clinicians may obtain the level of dysphagia of a patient through medical charts, dietary diaries and/or verified patient reports (10).

2.1.2 Translation

Permission for translation was obtained from the author of the original FOIS scale (10). The translation was performed according to WHO guidelines of translation and adaptations of instruments (32). The phases were followed: (i) the initial translation from English to Slovenian was performed by two speech and language pathologists (SLPs); (ii) The synthesis of two translations was made to provide the initial version; (iii) Back-translation was performed by an independent translator, who did not know FOIS. Furthermore, discrepancies were discussed between SLPs and independent translators until the complete Slovenian version; (iv) The final Slovenian translation was obtained, and the complete version was pre-tested; (v) Finally, the complete version was finalized (see Table 2).

Table 2: Original Functional Oral Intake Scale (FOIS) and Slovenian translation of FOIS (FOIS-SI).

Functional Oral Intake Scale (FOIS)	
Tube dependent (Levels 1-3)	
1	No oral intake
2	Tube dependent with minimal/inconsistence oral intake
3	Tube dependent with consistent oral intake of food or liquid
Total oral intake (Levels 4-7)	
4	Total oral intake of a single consistency
5	Total oral intake of multiple consistency requiring special preparation.
6	Total oral intake with no special preparation, but must avoid specific foods or liquid items
7	Total oral intake with no restrictions
Lestvica funkcionalnega peroralnega vnosa (FOIS-SI)	
Odvisnost od hranilne cevke (raven 1-3)	
1	Brez peroralnega vnosa.
2	Odvisnost od hranilne cevke z minimalnim/občasnim peroralnim vnosom.
3	Odvisnost od hranilne cevke z rednim peroralnim vnosom.
Popoln peroralni vnos (raven 4-7)	
4	Popoln peroralni vnos z eno konsistenco.
5	Popoln peroralni vnos z več konsistencami, ki zahtevajo poseben način priprave.
6	Popoln peroralni vnos brez posebne priprave, a z izogibanjem določenih izdelkov hrane/pijače.
7	Popoln peroralni vnos brez omejitev.

2.1.3 Subjects

The clinical records of 30 patients with an acute ischemic stroke in the carotid artery territory, who were hospitalized at the Division of Neurology of the UMC Ljubljana, Slovenia, were reviewed and sent to six SLPs. Included with the clinical records was a report of speech and language clinical bedside assessments of dysphagia (CBAD), sex, age, National Institutes of Health Stroke Scale (NIHSS) (33), and comorbidities of patients. The CBAD was performed within the first two weeks after the acute ischaemic stroke in the area of carotid artery, and covered the following details: (1) anatomy and functionality of oral structures, (2) feeding method, (3) description of oral and pharyngeal phases of swallowing, possible symptoms of impaired safety and/or efficacy of swallowing, and (4) detailed IDDSI diet level of food and liquid (34).

2.1.4 Raters

All raters were SLPs with more than 2 years of working experience in treating patients with dysphagia (2 to 17 years of working experience, M=7.33 years). Their results were used to calculate interrater reliability. One skilled clinical SLP with 23 years of experience in treating dysphagia patients was evaluating the same 30 clinical cases using both scales, IDDSI-FDS, and FOIS-SI. Those results were used to calculate convergent validity.

2.1.5 Interrater and intrarater reliability

The interrater reliability of FOIS-SI was obtained as a result of comparing the scores of six SLPs from different facilities across the country. Regardless of their familiarity with the FOIS-SI scale, all raters received written instructions on how to evaluate the severity of dysphagia using the translated scale. They were asked to assign each speech and language pathology report a FOIS rating between Level 1 and Level 7. Each rater was blinded to other raters' evaluations.

To evaluate intrarater reliability, two SLPs evaluated the same 30 clinical cases on two occasions within an interval of 10-14 days. The cases were shuffled to ensure as objective assessment as possible.

2.1.6 Convergent validity

To evaluate convergent validity, we examined the association between FOIS-SI and IDDSI-Functional Diet Scale (IDDSI-FDS). The IDDSI-FDS was chosen according to CBAD recommendations on IDDSI diets (34), aiming to classify dysphagia severity based on suggested diet modifications.

The IDDSI-FDS is a scale that can objectively capture oral dysphagia and texture restriction. Authors recommend its use for paediatric and adult populations, especially where the IDDSI framework and its 8 levels of food and liquids consistency are used (28). One skilled clinical SLP evaluated 30 clinical cases separately, once with IDDSI-FDS and once with FOIS-SI.

2.1.7 Data gathering and statistical analysis

For gathering data, we used Microsoft® Excel®, 2016. All statistical analyses were performed using SPSS Statistics, version 25, IBM® SPSS®.

To calculate reliability the Intraclass Correlation Coefficient (ICC) was used. A two-way random-effect model based on single ratings and absolute agreement assessed the interrater reliability, and a two-way mixed effect model based on single rating and absolute agreement assessed the intrarater reliability for either rater. Interpretation was as follows: between 0.5 and 0.75, moderate; between 0.75 and 0.9, good; above 0.90, excellent agreement (35). Mean estimations along with a 95% confidence interval (CI) were reported for the ICC.

Convergent validity was calculated with the Spearman's rank correlation coefficient, assuming that a κ of 0.7 or more indicates a high positive correlation between two scales and more than 0.9 indicates a very high positive correlation (36).

3 Results

Of the 30 patients (age 72.23±1.73 years, ranging from 48 to 94 years), 7 were women and 23 were men (female to male ratio 1:3.29). The acute ischaemic stroke was located in the left carotid artery territory in 20 patients and in the right carotid artery territory in 10 patients. The most common pathologies found in the group of patients in the study were arterial hypertension (90%), hyperlipidaemia (70%), right-sided haemiparesis (56.67%), atrial fibrillation (40%), carotid artery stenosis (26.67%), and left-sided haemiparesis (20%). Regarding the NIHSS, the prevalent scores were severe (>13) in 15 patients (50%), moderate (6-13) in 11 patients (36.67%), and mild (1-5) in 4 patients (13.33%). The severity of dysphagia was assessed with FOIS-SI (see Table 3).

The ICC was used to determine if there was an agreement between the SLPs' judgements of clinical cases on FOIS-SI. The results showed that the ICC for interrater

Table 3: The severity of dysphagia among 30 patients with acute stroke in the carotid artery territory as assessed by 6 raters using FOIS-SI. Additionally, 2nd ratings of two raters and one highly skilled SLP, who evaluated dysphagia using FOIS-SI and IDDSI-FDS.

SLP	1 FOIS-SI	2 FOIS-SI		3 FOIS-SI	4 FOIS-SI	5 FOIS-SI	6 FOIS-SI		Highly skilled SLP	
Case		1st rating	2nd rating				1st rating	2nd rating	FOIS-SI	IDDSI-FDS
1	1	1	1	1	1	1	1	1	1	0
2	5	5	5	5	6	6	5	5	5	5
3	5	5	5	5	5	5	6	6	5	6
4	5	5	5	5	4	4	5	5	5	5
5	1	2	1	1	1	1	1	1	1	0
6	5	5	5	5	5	5	5	5	5	6
7	2	2	2	2	3	3	2	2	2	0
8	5	5	5	5	4	4	4	4	5	5
9	5	5	5	5	4	4	5	5	5	5
10	5	5	5	5	5	5	6	5	5	6
11	5	5	5	5	4	4	5	6	5	5
12	5	5	5	5	4	4	5	5	5	5
13	5	5	5	5	5	5	5	5	5	6
14	6	6	6	6	6	6	6	6	6	7
15	2	1	2	2	2	2	1	1	2	0
16	4	4	4	4	4	4	4	4	4	1
17	1	1	1	1	1	1	1	1	1	0
18	5	5	5	5	5	5	5	5	5	6
19	1	1	1	1	1	1	1	1	1	0
20	6	6	6	6	6	6	5	5	6	7
21	4	4	4	4	4	4	4	4	4	1
22	5	5	6	5	6	6	6	6	5	7
23	5	5	5	5	5	5	5	5	5	6
24	7	7	7	7	7	7	7	7	7	8
25	5	5	4	5	5	5	5	5	5	3
26	1	1	1	1	1	1	1	1	1	0
27	2	2	2	2	1	1	2	2	2	0
28	4	4	4	4	4	4	4	4	4	1
29	4	4	4	4	4	4	4	4	4	1
30	6	6	6	5	6	6	6	6	5	7

Legend: SLP – speech and language pathologists; FOIS – Functional Oral Intake Scales; FOIS-SI – Slovenian translation of FOIS; IDDSI-FDS – Functional Diet Scale.

reliability was excellent being 0.959 (0.934-0.978).

Two SLPs (SLP 2 and SLP 6, see Table 3) evaluated 30 clinical cases on two occasions. The second evaluation was performed two weeks after the first one. The ICC for intrarater reliability was excellent being 0.979 (0.957-0.990) and 0.991 (0.980-0.995) for rater 2 and 6, respectively.

One highly experienced SLP evaluated the same 30 cases with the FOIS and the IDDSI-FDS in parallel (see Table 3). Spearman's rank correlation coefficient was used to evaluate convergent validity. There was a very high positive correlation between FOIS-SI and IDDSI-FDS, which was statistically significant, r_s=0.927, p=.0001.

4 Discussion

FOIS was initially developed for adult stroke patients (10). It has also been justified for the pediatric population (11), and patients with other diseases (15-23). The FOIS was translated into different languages (German, Italian, Chinese), where psychometric studies showed FOIS to be a valid instrument for the evaluation of dysphagia (12-14). However, solely the German and the Chinese studies were comparable to ours since the Italian study had a different research perspective.

The purpose of the present paper was to translate and adapt the FOIS scale of functional severity of dysphagia in stroke patients and make this scale available to Slovenian clinicians and researchers across the country in all clinical and care settings. The study was not intended to determine the reliability of clinical bedside examination itself.

Enrolled SLPs evaluated 30 clinical records of stroke survivors. The patients had an ischemic stroke in the carotid artery territory. CBAD was performed by the time of patients' acute phase after the stroke event. As far as reliability of the FOIS-SI is concerned, both intra- and interrater reliability were analyzed. The ICC for interrater and intrarater reliability were both excellent, the first being 0.959 and the second being 0.979 and 0.991. Intrarater reliability value was similar (or greater) to those reported in the German study, where Fleiss kappa (κ=0.83) showed high agreement; Chinese study, where Cohen kappa showed excellent agreement (κ=0.881); and original English study, where an average kappa value ranged from 0.86 to 0.91. High reliability in these studies could be because raters received prior FOIS training (12), the study taking place at just a single facility (14), or the group of patients being more homogenous (10). There was no report about intrarater reliability in the aforementioned studies. Raters in our study were familiar with the FOIS-SI scale and received written instructions beforehand, which can potentially contribute to the excellent interrater and intrarater reliability. However, some discrepancies were found. The disagreements were mostly detected between FOIS Level 4 and 5 and between FOIS Level 2 and 3, where the insecurities were mostly about the different types of tubes and with the term single consistency (see Table 3).

In our study, the validity of the FOIS-SI was evaluated with the IDDSI-FDS theoretically related scale. The IDDSI-FDS scale was chosen since the IDDSI framework is slowly spreading both internationally and nationally. One highly skilled SLP evaluated the severity of dysphagia with both, FOIS-SI and IDDSI-FDS. Results have shown a very high positive correlation between these two scales. To our knowledge, a study of the correlation between these two scales has not been performed yet. The German and Chinese studies, on the other hand, tested the validity of the translated FOIS scales with the stroke scales NIHSS and MRS and showed significant correlation. Additionally, the German and Chinese studies correlated FOIS with the golden standards of diagnosis of swallowing disorders (FEES and VFSS) and found a significant association between the severity of dysphagia as assessed by these two methods. However, the Chinese study did not show a significant correlation of FOIS with aspiration (14), which was the case as well in the original FOIS study (10).

There is one major limitation in this study that could be addressed in future research. For convergent validation, we used IDDSI-FDS, which was, up to this point, only initially validated. For this reason, further validation studies using other scales or one of the golden standards for diagnosing swallowing problems, such as FEES or VFSS, should be used. However, the Chinese, German, and original study validated their FOIS scale not only with different dysphagia and stroke scales but also with the golden standards, which definitely confirmed FOIS to be a valid scale to evaluate the severity of dysphagia in stroke survivors.

Future studies should investigate, whether FOIS-SI can provide an accurate level of dysphagia severity in other groups of patients with dysphagia, and the responsiveness of the scale to SLP treatment.

5 Conclusion

This study was intended to determine the interrater reliability across clinicians from different clinical institutes across the entire country, evaluate intrarater

reliability, and determine the convergent validity of FOIS-SI.

The initial psychometric characteristics study implies that FOIS-SI could be a useful tool for various clinical and scientific purposes for quantifying the severity of dysphagia across the country and different facilities. Since stroke patients often get transferred to different hospitals or clinics due to change in the amount of care they require as their treatment progresses, utilizing a standardized model between hospitals, clinics, and care settings can contribute to better dysphagia outcomes as well as to a higher quality of life in dysphagia patients.

Conflict of interest
None declared.

Acknowledgments

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