

ORIGINAL REPORT

VALIDATION OF THE “ACTIVITY AND PARTICIPATION” COMPONENT OF ICF CORE SETS FOR STROKE PATIENTS IN JAPANESE REHABILITATION WARDS

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Objective: To validate the International Classification of Functioning, Disability and Health (ICF) Core Set for stroke in the assessment of functional status and disability in Japanese stroke patients.

Methods: The study included stroke patients admitted to the Kaifukuki (convalescent) rehabilitation wards. The comprehensive ICF Core Set for neurological conditions for post-acute care and the ICF rehabilitation set were evaluated with qualifiers assessed by the physiatrists at admission. The “activity and participation” (d) component was divided to sub-components (cognition-related activity, motor-related activity and participation). The correlations between numbers of problem categories in the entire “d” component and these sub-components in each ICF Core Set and the Functional Independence Measure (FIM) score were assessed using Spearman’s correlation coefficient.

Results: A total of 117 post-stroke patients (mean age 70.1±14.2 years, 53 women) were included. Correlation analysis identified significant and strong correlations between the values of the entire “d” component and sub-components (cognition-related activity and motor-related activity) of the 2 ICF Core Sets and FIM score. A significant, but weak, correlation between FIM and the participation sub-component was identified.

Conclusion: The “d” component of these 2 ICF Core Sets reflects functional status and disability and could be a valid measure in post-acute stroke patients in the rehabilitation setting.

Key words: ICF; rehabilitation; outcome assessment; stroke; activity; participation; cerebrovascular accident; FIM.

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INTRODUCTION

Assessment of functioning and disability using standardized tests is essential for examining the problems of stroke patients

who receive interdisciplinary rehabilitation (1). The International Classification of Functioning, Disability and Health (ICF) provides perspective on patients’ functional status, activities, participation, environmental and personal factors (2), and is a useful framework for goal setting in rehabilitation for stroke patients (3). However, the ICF is tremendously comprehensive, which limits its application in daily routine clinical practice. For this reason, the ICF research branch proposed and introduced the ICF Core Set for stroke in 2004 to facilitate the use of the ICF in clinical practice (4, 5). The ICF Core Set contents (which were developed for particular health conditions and settings) have been validated for several health conditions (6–8) including stroke (9–14). In addition, the inter-rater and intra-rater reliability of ICF categories with additional scoring guidelines, as well as the usefulness of ICF categories as outcome measures, have also been determined (15). To our knowledge, however, there are no studies that have analysed the concurrent validity of the ICF Core Set in stroke patients in the post-acute rehabilitation setting.

The most commonly used activity of daily living (ADL) measure in stroke rehabilitation is the Functional Independence Measure (FIM) (16). The FIM is useful in the prediction of prognosis (17), assessment of treatment outcome (18), comparison of clinical facilities (19), and making decisions on the allocation of social resources (20). In comparison with the FIM, the ICF Core Sets include more comprehensive categories in the activity and participation domains, and are therefore expected to provide evaluation of certain aspects that cannot be assessed by the FIM.

We hypothesized that certain ICF Core Sets can be a valid assessment tool for evaluating the functional status and disability of stroke patients in the post-acute rehabilitation setting. To test this hypothesis, the present study was designed to validate concurrently the activity and participation component of 2 ICF Core Sets; the comprehensive ICF Core Set for neurological conditions in post-acute care, and the ICF rehabilitation set in stroke inpatients in Japanese rehabilitation wards. Since it was difficult to distinguish between the activity domain and the participation domain in a single classification list, validation was accomplished by analysing the correlation between

the number of problem categories in the entire activity and participation component and respective activity and participation domains of ICF Core Sets and FIM score.

METHODS

This multicentre cross-sectional study was conducted in 4 medical institutions in Japan, including Nishi-Hiroshima rehabilitation hospital (Hiroshima, Hiroshima, 4 board-certified physiatrists by Japanese Association of Rehabilitation Medicine for 139 beds), Kawakita Rehabilitation Hospital (Suginami-Ku, Tokyo, 1 board-certified physiatrist for 135 beds), Tokyo General Hospital (Nakano-Ku, Tokyo, 2 board-certified physiatrists for 343 beds) and Kyoto Ohara Memorial Hospital (Sakyo-Ku, Kyoto, 2 board-certified physiatrists for 203 beds). The study protocol was approved by the ethics committees of the respective participating hospitals. Post-acute stroke patients who were admitted to the Kaifukuki (convalescent) rehabilitation wards in the 4 medical institutions were recruited between 1 May and 30 October 2015. Inclusion criteria were: patients with a diagnosis of cerebral infarction, intracerebral haemorrhage or subarachnoid haemorrhage, and the duration of hospital stay more than 3 days in the convalescent rehabilitation wards.

The Kaifukuki (convalescent) rehabilitation ward, which is covered by the Japanese medical insurance system, provides interdisciplinary sub-acute rehabilitation therapy for patients requiring assistance in ADL after acute hospitalization (21, 22). Patients with disabling conditions, including stroke, traumatic brain injury, and other neurological diseases as well as orthopaedic diseases, such as hip fracture, are eligible for admission to the Kaifukuki rehabilitation ward. In Japan, rehabilitation therapy (physical, occupational and speech therapy) is limited to 3 h per day under the health insurance system. The upper limit of the stroke onset-to-admission interval in these rehabilitation wards is 60 days, and the maximum length of stay for stroke patients is limited to 150 days.

Data for ICF Core Sets were prospectively assessed at admission by physiatrists with ICF experience. Evaluation was based on the previously described methodology (23, 24). The information gathered from case histories, interviews, clinical examinations and various investigations, such as imaging studies and/or laboratory blood tests were translated to ICF categories. In this study, 2 ICF Core Sets were analysed; the comprehensive ICF Core Set for neurological conditions for post-acute care (5) and the ICF rehabilitation set (25). Each ICF Core Set comprised 4 different components: body function (b), body structures (s), activity and participation (d), and environmental factors (e). Each category was evaluated using ICF qualifiers that have 5 grade numeric levels, from 0=no difficulty, 1=mild, 2=moderate, 3=severe, to 4=complete difficulty. To increase reliability, 17 ICF categories that were linked to FIM items were assessed using the previously developed guideline for scoring (15), with the following qualifiers: 0= independent; 1= 1 person required for set up or supervision; 2= moderate assistance; 3= maximal assistance; and 4= total assistance. In this study, to assess the correlation between the values of ICF Core Sets and FIM that were based on the actual performance status, evaluation of activity and performance was based on the performance status. In addition, the qualifiers "8, not specified" and "9, not applicable" were used. The comprehensive ICF Core Set for neurological conditions for post-acute care consists of 116 categories. It includes 54, 11, 34 and 17 categories in the (b), (s), (d) and (e) components, respectively. On the other hand, the ICF rehabilitation set consists of 30 categories. It includes 9 and 21 categories in the (b) and (d) components, respectively.

The FIM is a standardized, widely used, tool for assessment of ADL. Its reliability and validity in the rehabilitation setting have been confirmed previously (26). The subtotal-summed scores of motor and cognitive subscales (motor FIM and cognitive FIM) are used to quantify functional independence. The training seminars for evaluating FIM items were conducted in the participating institutions. In this study,

enrolled patients were evaluated at admission by the interdisciplinary team, using the FIM.

Clinical characteristics (i.e. age at admission, gender, handedness, time to admission after stroke onset, stroke subtype, side of paresis, National Institute of Health Stroke Scale, modified Rankin scale, Barthel Index, and FIM at admission) of enrolled patients were analysed. The number of problem categories of total ICF Core Sets and every sub-component of the 2 ICF Core Sets were calculated. Problem categories were defined as categories with qualifier 1–4 (mild to total difficulty). In the present study, qualifier 9 and qualifier 8 were considered missing values. Since the aim of this study was to validate the ICF Core Set as an ADL measurement tool, by analysing the correlation between the ICF Core Set and FIM, we excluded the environment factors (e) from the analysis. The mean number of problem categories of total ICF Core Sets and every component of the 2 ICF Core Sets were calculated. In addition, the d component was classified into the following sub-components; cognition-related activity (chapter d1–3), motor-related activity (chapter d4–5), and participation (chapter d6–9). Similar analysis was applied to the sub-components.

Criterion-concurrent validity was analysed using the Spearman's rank correlation coefficient to assess the correlation between the number of problem categories of the entire d component and the FIM total scale. In addition, the correlations between the number of problem categories of the subscales of d component and the subscales motor FIM and cognitive FIM were tested. Scales that measure similar concepts should have correlations, r , of more than 0.70 (27). Statistical analysis was performed using the SPSS 19.0 (IBM SPSS Inc., Armonk, NY, USA). The level of significance was set at $p < 0.05$.

RESULTS

Table I shows the clinical characteristics of the study patients. A total of 117 patients (53 women and 64 men) with a mean age of 70.1 years were included in the present study. The mean

Table I. Clinical characteristics of the 117 study patients

Clinical characteristics	
Age at admission, years, mean (SD)	70.1 (14.2)
Female, n (%)	53 (45.3)
Right-handedness, n (%)	112 (95.7)
Sources of patients, n (%)	
NHRH	52 (44.4)
KRH	26 (22.2)
TGH	25 (21.4)
KOMH	14 (12.0)
Time to admission after stroke onset, days, mean (SD)	34.2 (19.6)
Disease characteristics	
Stroke subtype, n (%)	
Cerebral infarction	67 (57.2)
Intracerebral haemorrhage	39 (33.3)
Subarachnoid haemorrhage	11 (9.4)
Left side paresis, n (%)	46 (39.3)
NIHSS at admission, n (%)	6.1 (5.3)
mRS at admission, n (%)	3.44 (1.16)
BI at admission, n (%)	45.3 (32.2)
FIM score at admission, n (%)	
Total score	68.7 (32.0)
Motor score	46.9 (24.4)
Cognitive score	21.8 (9.9)

NHRH: Nishi-Hiroshima Rehabilitation Hospital; KRH: Kawakita Rehabilitation Hospital; TGH: Tokyo General Hospital; KOMH: Kyoto Ohara Memorial Hospital; NIHSS: National Institutes of Health Stroke Scale; mRS: modified Rankin Scale score; BI: Barthel Index; FIM: Functional Independence Measure.

Table II. Number of problem categories in the 2 International Classification of Functioning, Disability and Health (ICF) Core Sets

	Comprehensive ICF Core Set for neurological conditions for post-acute care		ICF rehabilitation set	
	Categories <i>n</i>	Problem categories Mean (SD)	Categories <i>n</i>	Problem categories Mean (SD)
Body functions (Component b)	54	24.0 (11.1)	9	5.32 (2.40)
Body structures (Component s)	11	2.27 (1.52)	0	–
Activities and participation (Component d)				
Total component (d–9)	34	21.3 (10.1)	21	12.7 (5.5)
Cognition-related activity (d1–3)	17	9.31 (6.87)	2	1.18 (0.88)
Motor-related activity (d4–5)	15	11.4 (4.58)	13	9.44 (3.83)
Participation (d6–9)	2	0.56 (0.73)	6	2.09 (2.16)
Total (Components b + s + d)	99	47.5 (21.0)	30	18.0 (7.5)

SD: standard deviation.

time to admission after stroke onset was 34.2 days. Clinically, 67 patients (57.2%) had cerebral infarction, 39 patients (33.3%) had intracerebral haemorrhage, and 11 patients (9.4%) had subarachnoid haemorrhage. The mean FIM score at admission was 68.7. The mean motor and cognitive FIM points were 46.9 and 21.8, respectively.

Table II shows the mean numbers of problem categories in the 2 ICF Core Sets. The mean and standard deviation (SD) numbers of problems categories were 47.5 (21.0) in the comprehensive ICF Core Set for neurological conditions for post-acute care and 18.0±7.5 in the ICF rehabilitation set.

Table III shows the Spearman correlation coefficients for the correlation between FIM score and the values derived from the 2 ICF Core Sets. A strong correlation was found between the FIM score and the values of (d) component in the comprehensive ICF Core Set for neurological conditions for post-acute care ($r=-0.86$), and in the ICF rehabilitation set ($r=-0.76$). Furthermore, a strong correlation was found between the motor-related activity (d4–5) and motor FIM in the comprehensive ICF Core Set for neurological conditions for post-acute care ($r=-0.85$), and in the ICF rehabilitation set ($r=-0.79$). In addition, there was a significant correlation between the cognition-related activity (d1–3) and cognitive FIM in the comprehensive ICF Core Set for neurological conditions for post-acute care ($r=-0.85$), and in the ICF rehabilitation set ($r=-0.74$). Finally, there were weak correlations between

participation (d6–9) and FIM total and sub-total score in these 2 ICF Core Sets. All p -values for r were <0.001 .

DISCUSSION

The present study was designed to concurrently validate 2 ICF Core Sets; the comprehensive ICF Core Set for neurological conditions for post-acute care and the ICF rehabilitation set. Our results emphasize the validity of the 2 ICF Core Sets based on analysis of the correlation between the number of problem categories of the ICF Core Sets and the FIM score. Furthermore, the results confirmed the strong correlation between motor-related activity (d4–5) and motor FIM and between cognition-related activity (d1–3) and cognitive FIM score. Our results also showed a significant correlation between the values of participation-related categories (d6–9) and FIM score, although the correlation had a weak correlation coefficient.

The ICF Core Set has not been widely used as a clinical assessment tool in clinical and research practice due to the lack of data on reliability and validity. Goljar et al. (28) published a study that identified the correlation between changes in problem ICF categories and that of FIM score for stroke patients in the post-acute rehabilitation setting. However, the described methodology could not be replicated in cross-sectional studies. Furthermore, Kohler et al. (15) reported the inter-rater and intra-rater reliability and agreement of the ADL categories

Table III. Correlations between Functional Independence Measure (FIM) score and number of problem categories of activity and participation component in 2 International Classification of Functioning, Disability and Health (ICF) Core Sets (Spearman's r)

		FIM		
		Total score	Motor score	Cognitive score
Comprehensive ICF Core Set for neurological conditions for post-acute care	Total component (d1–9)	–0.86	–0.80	–0.85
	Cognition-related activity (d1–3)	–0.74	–0.64	–0.85
	Motor-related activity (d4–5)	–0.85	–0.85	–0.68
	Participation (d6–9)	–0.33	–0.27	–0.42
ICF rehabilitation set	Total component (d1–9)	–0.76	–0.76	–0.71
	Cognition-related activity (d1–3)	–0.68	–0.61	–0.74
	Motor-related activity (d4–5)	–0.81	–0.79	–0.66
	Participation (d6–9)	–0.35	–0.28	–0.44

$p < 0.001$ for all values.

FIM: Functional Independence Measure.

that were assessed using ICF qualifiers with additional scoring guidelines. For this reason, we used their guidelines for ICF qualifiers to increase reliability. Summing up qualifiers is not recommended for theoretical and statistical problems. To deal with the problem, the construct validity and dimensionality of the ICF Core Set for low back pain, osteoarthritis, breast cancer and stroke had been evaluated previously by Rasch analysis, which indicated the need for modification of each ICF Core Set (29–33). However, these complex methods; evaluation of the ICF Core Set with Rasch transformed score and modification of ICF Core Sets, do not enhance the clinical use of ICF Core Sets in the immediate future. To handle the statistical problem of ICF qualifiers, we concurrently validated the ICF Core Set by using the numbers of problem categories. To our knowledge, such study design and analysis have not been published previously. Thus, our study demonstrated a strong correlation between the numbers of problem categories in the ICF Core Set and FIM and confirmed the validity of the ICF Core Set for stroke in the post-acute rehabilitation setting.

The reason for the strong correlation between the values of the ICF Core Sets and FIM was probably related to the structural similarity between the ICF Core Sets and FIM. Kohler et al. (15) linked 18 FIM items to appropriate ICF categories. For example, “toileting” in the motor FIM items was linked to “d530 toileting”, and “expression” in the cognitive FIM items was linked to “d330 speaking”. Based on the linking rules between FIM items and ICF categories, the comprehensive ICF Core Set for neurological conditions for post-acute care contains 16 FIM items, with the exception of “stairs” and “social interactions”. In addition, the ICF rehabilitation set contains 13 FIM items, excluding “bowel management”, “comprehension”, “expression”, “problem solving”, and “memory”.

What is the reason for the weaker correlation between total component, cognition-related activity and motor-related activity in the ICF rehabilitation set and FIM score, compared with the correlation between these in the comprehensive ICF Core Set for neurological conditions for post-acute and FIM score? While no direct analysis was performed regarding this question, we speculate that the reason for the weak correlation can be the inclusion of lower number of categories in the ICF rehabilitation set. In particular, only 2 categories (“d230 carrying out daily routine” and “d240 handling stress and other psychological demands”) on cognition in the ICF rehabilitation set and that these 2 categories are not linked to FIM items. Thus, the cognitive aspect in ICF rehabilitation set would be supplemented with additional ICF categories that were previously linked to cognitive FIM items. The strong correlation between the ADL domain in the ICF Core Sets and FIM indicated the validity of the ICF Core Sets as an ADL measurement tool. The weak correlation between participation (d6–9) and FIM in the present study indicated that the ICF Core Sets can evaluate participation, which cannot be assessed by FIM.

The clinical use of the ICF Core Sets set is limited to patients with particular health conditions and setting. This feature does not allow healthcare professionals to assess patients with various diseases with a single assessment tool, and then

compare the severity of functioning and disability without taking into consideration the overall health condition or setting. Comparison of the degree of functioning and disability in one patient group with those with other health conditions or settings is, however, important in the appropriate allocation of social and medical resources. The ICF rehabilitation set that was also evaluated in the present study was recently developed for diverse health conditions and settings by the ICF research branch (25). The ICF rehabilitation set contains 7 categories of ICF generic set (34) and 23 categories that were found to be relevant solely in the clinical population. To our knowledge, the ICF rehabilitation set has not yet be assessed in the clinical setting. Hence, the present study is the first to demonstrate the clinical validation of the ICF rehabilitation set and its potential application for diverse health conditions and settings.

Our study has certain limitations. First, the number of problem categories in the ICF Core Set in the present study did not reflect the grade of every category, which did not have sufficient sensitivity for the assessment of functioning and disability. Thus, the clinical use of the sum of the ICF qualifiers, which is considered to be a more sensitive assessment than the number of problem categories, is not recommended for a variety of reasons. Therefore, the use of the number of problem categories is a convenient and feasible option in clinical practice. Secondly, the present study enrolled only patients admitted to the Kaifukuki (convalescent) rehabilitation wards, where severely or mildly ill patients are not usually admitted. Our sample does not represent the stroke patient population in Japan. Thirdly, there was a possibility of centre-effect and clustering of observations within the institutions. Future study with developed standardized measurement and evaluation of its inter-rater reliability would be needed. Fourthly, the assessment of ICF Core Set required approximately 30 min for the comprehensive ICF Core Set for neurological conditions for post-acute care and its routine clinical uses would be a burden for clinicians. Fifthly, some categories in ICF Core Sets were assessed as qualifier 8 or 9 and considered missing value because of its difficulty of evaluating these categories in post-acute stroke patients. Development of additional guideline for evaluating these categories would be necessary.

In conclusion, this study validated the “activity and participation” component of the 2 ICF Core Sets; the comprehensive ICF Core Set for neurological conditions for post-acute care and the ICF rehabilitation set. The results indicate that the ICF Core Sets reflect the degree of functioning and disability and are valid clinical measures of ADL in post-acute stroke in the rehabilitation setting.

The authors declare no conflicts of interest.

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