Evaluation of the psychometric properties of the Barthel Index in an Italian ischemic stroke population in the acute phase: a cross-sectional study

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Summary

The objective of this study was to assess and validate the psychometric properties of the Italian culturally adapted Barthel Index (IcaBI) in a cohort of people with ischemic stroke. The validation process was conducted in an Italian cohort of 99 stroke inpatients to whom the IcaBI was administered in order to test its structural validity, and inter-and intra-rater reliability. The internal consistency (Cronbach's alpha) was 0.901. Factor analysis revealed a two-factor structure. The interclass correlation coefficient 3,1 (ICC) for intra-rater reliability was estimated at 0.987 (95% CI: 0.975-0.993), while the ICC for inter-rater reliability was 0.909 (95% CI: 0.852-0.948). This study demonstrates the psychometric properties of the IcaBI in an Italian stroke population, and therefore shows that the scale can be considered a valid and reliable assessment tool for measuring functional disability in Italian acute ischemic stroke survivors.

KEY WORDS: Barthel Index, functional disability, stroke, validation.

Introduction

Stroke is one of the most important cerebrovascular diseases in industrialized countries. Every year approximately 196,000 strokes occur in Italy, where it is the third leading cause of death. Twenty-five percent of stroke survivors completely recover their physical functioning, while 75% survive with disabilities: half of these have severe deficits and never fully recover (Quinn et al., 2011).
Many assessment tools have been developed for assessing post-stroke disability (Green and Young, 2001). Among them, the Barthel Index (BI) and the Rivermead Mobility Index have been shown to be the most reliable (Green and Young, 2001). Even though several limitations have been observed with regard to the sensitivity and responsiveness of the BI, with floor and ceiling effects affecting its potential utility (Quinn et al., 2011), it remains the tool most used by trialists for assessing disability outcomes (Duffy et al., 2013). The label "BI" is actually used to refer to a number of different instruments. First developed by Florence Mahoney and Dorothea Barthel (Mahoney and Barthel, 1965), the BI was subsequently amended by Collin et al. (1988) and Shah et al. (1989), although other versions presenting differences in the number of items or in the method of scoring have also been introduced (Quinn et al., 2011). A 10-item scale, where items are scored 0, 5 or 10, thus giving a maximum total score ranging from 0 to 100, has been used in several multicenter stroke trials and it seems reasonable to argue that this should become the uniform stroke trial BI (Quinn et al., 2011; Duffy et al., 2013). Even though the BI, used to assess disability in stroke patients and in chronic or orthopedic patients, has shown structural differences between these populations (Laake et al. 1995), in Italy it is widely used for determining whether the eligibility criteria for inpatient rehabilitation are satisfied, irrespective of the patient's illness, as well as for monitoring recovery. The Italian culturally adapted Barthel Index (IcaBI), which is based on the original instrument (Mahoney and Barthel, 1965), was recently validated (Galeoto et al., 2015), and its psychometric and clinimetric characteristics have since been evaluated in a population of patients affected by a variety of illnesses admitted to inpatient rehabilitation centers (Castiglia et al. 2017). The IcaBI showed optimal reliability and responsiveness, but, as with the original instrument, when used to measure disability in neurological and orthopedic patients, there emerged a discrepancy in its structural validity between these different populations. Indeed, factor analysis using principal component analysis revealed a mono-factorial structure for neurological patients, whereas for orthopedic patients this was found only after removal of item 1 "Feeding".

Substantial to optimal inter-rater reliability was found (intraclass correlation coefficient >0.74 <0.96). The IcaBI was found to be accurate (area under the curve =0.72) with a minimal clinically important change score of 35 points. A subgroup analysis of structural validity among neurological patients was not possible because of the small sample of people with stroke in that population (Castiglia et al., 2017).
Whereas Castiglia et al. (2017) evaluated the psychometric characteristics of the IcaBI in a population with neurological and orthopedic disability, the present paper describes this instrument's structural validity, intra-rater reliability and inter-rater reliability in a cohort of Italian people with ischemic stroke in the acute phase.

Materials and methods

This study was conducted by a research group composed of medical doctors and rehabilitation professionals from "Sapienza" University of Rome, "Tor Vergata" University of Rome, and the Rehabilitation & Outcome Measure Assessment (R.O.M.A.) association. In the last few years, the R.O.M.A. association has dealt with the validation of many outcome measures in Italy (Culicchia et al., 2016; Parente et al., 2017; De Mare et al., 2018; Galeoto et al., 2018 a, b, c, d; Covotta et al., 2018; Marquez et al., 2018; Berardi et al., 2018; Tofani et al., 2018; Dattoli et al., 2018; Attanasio et al., 2018; Migliorini et al., 2015; Murgia et al., 2018; Massai et al., 2018).

Patients and procedures

The IcaBI was administered to a cohort of hospital inpatients with ischemic stroke. All subjects were recruited from the Stroke Unit of the Department of Neuroscience, Policlinico Tor Vergata, Rome, Italy, between May 2016 and September 2016. All patients were informed about the study and their interest in taking part in it was recorded; those who eventually took part in the study gave their informed consent prior to their inclusion (Galeoto et al., 2015, 2016).
All applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research. Post-comatose patients were excluded, as were individuals aged <18 years, those affected by spinal cord injuries, cognitive impairment or psychiatric illnesses, and those who did not consent to enter the study. Three physical therapists participated voluntarily in this prospective reliability study. Assessments were made by observing patients' performances directly at the bedside, since the subjects included in this research were in the acute disease phase.
The therapists were trained in administration of the IcaBI by the first Author of this paper. As each of the participating therapists had his/her own clinical load, the matching of patients with raters was done by a convenience method, but the raters nevertheless all performed the same number of assessments. Structural validity and intra-rater and inter-rater reliability were calculated according to the COSMIN criteria (Mokkink et al., 2010). The IBM Statistical Package for the Social Sciences (SPSS) version 18.0 for Windows OS was used to perform the statistical analyses, which consisted of descriptive analysis, factor analysis and calculation of intraclass correlation coefficient 3,1 (ICC) values (Koo and Li, 2016). The variables were described using frequency tables, means and standard deviations.

Structural validity

The structural validity of the instrument was assessed by means of an exploratory factor analysis (EFA) with principal axis factoring extraction and promax rotation with Kaiser normalization.
Sampling adequacy was investigated using the Kaiser-Meyer Olkin test (KMO) and the suitability of data for factor analysis by means of Bartlett's test of sphericity. A confirmatory factor analysis (CFA) was also conducted to confirm the structure obtained from the EFA: $\chi 2$ test and the root mean squared error of approximation (RMSEA) were evaluated as indices of goodness of fit. An RMSEA value of about 0.05 or less and a non-significant $\chi 2$ test were taken to indicate a close fit of the model (Mulaik et al., 1989). In order to evaluate internal consistency, Cronbach's α coefficient was calculated, with a value of >0.70 being considered acceptable for the test (Mokkink et al., 2010). In order to assess the acceptability, comprehensibility and practicality of the scale, the time of administration was measured and the number of missing items was taken into account.

Intra-rater reliability

A minimum sample size of 30 participants was considered (Shoukri et al., 2004; Hallgren, 2012; McMillan and Hanson, 2014) in order to avoid distortions when measuring the ability of the IcaBI to remain stable over time for repeated measures performed by the same rater on different occasions.
The patients were assessed twice, each time by the same physical therapist, with an interval of 24 hours between assessments. This served to rule out changes in their clinical conditions. Indeed, the subjects included in this study were in the acute disease phase, where rapid changes in the clinical features could represent a source of bias in assessing the stability of the IcaBI over time. Intra-rater reliability was estimated using two-way random ICC for absolute agreement ($p<0.05$) (Cerny and Kaiser, 1977; Koo and Li, 2016). The ICC value ranges from 0.00 to 1.00, with higher values reflecting higher reliability. An ICC value >0.70 reflects good agreement, and a value >0.75 excellent agreement. In this study, good to excellent reliability for IcaBI was hypothesized. As the BI is characterized by ordinal scores, Cohen's Kappa was also calculated; in this case, values >0.61 were considered to reflect substantial agreement, and values >0.81 to reflect optimal agreement (Hallgren 2012).

Inter-rater reliability

In order to establish its inter-rater reliability, IcaBI was administered, independently, by three physical therapists during the same day. The sample size was calculated according to McMillan and Hanson (2014) and Lam et al. (2014). To determine whether the test was reliable, the ICC was calculated, considering an ICC >70 as reliable.
Light's Kappa for multiple raters was calculated too, with values >0.61 taken to reflect substantial agreement, and values >0.81 to reflect optimal agreement (McMillan and Hanson, 2014).

Results

Structural validity

In total, 141 patients were initially screened for inclusion. Twenty-nine of them did not agree to participate, and 13 did not meet the inclusion criteria. The IcaBi was thus administered to a total of 99 people with ischemic stroke. The mean age of the sample was 73.82 ± 11.93 years (range 45-97); 48 subjects (48.5%) were males, and 51 were females (51.5%). The mean time from ischemic event to the first administration of the BI was 3 ± 1 days.

The sample was adequate (KMO=0.813) and the data were suitable (Bartlett's test of sphericity= 816.26; p=0.000) for factor analysis. EFA with principal axis factoring extraction revealed a two correlated factors structure which explains 62.44 of the total variance, with the first factor explaining 53.88% and the second 8.56%. After promax rotation with Kaiser normalization the first factor was found to affect the first five items, the second factor the last five items. The factor loadings for each item are described in Table I. The fit indices of the CFA confirmed a two-factor structure, with a non-significant $\chi 2$ test ($\chi 2 = 25.831$; p= 0.309) and RMSEA < 0.05 (RMSEA = 0.035). Compared with EFA, a model with both the first and the second factor loading on the first (feeding), the fourth (dressing) and the eighth (transfers) items better fits with the two-factor structure. Cronbach's alpha was 0.901 (p < 0.001). The mean administration time between all the raters was 5 ± 2.5 minutes. No missing values were found. Figure 1 shows a path diagram of the CFA, reporting regression weights of each latent factor on each variable and covariance values.

Table I - Exploratory factor analysis with promax rotation.

	Component	
	1	2
Feeding	0.407	
Bathing	0.971	
Grooming	0.944	
Dressing	0.759	
Bowels	0.606	
Bladder		0.780
Toilet use		0.997
Transfers		0.555
Mobility		0.747
Stairs		0.551

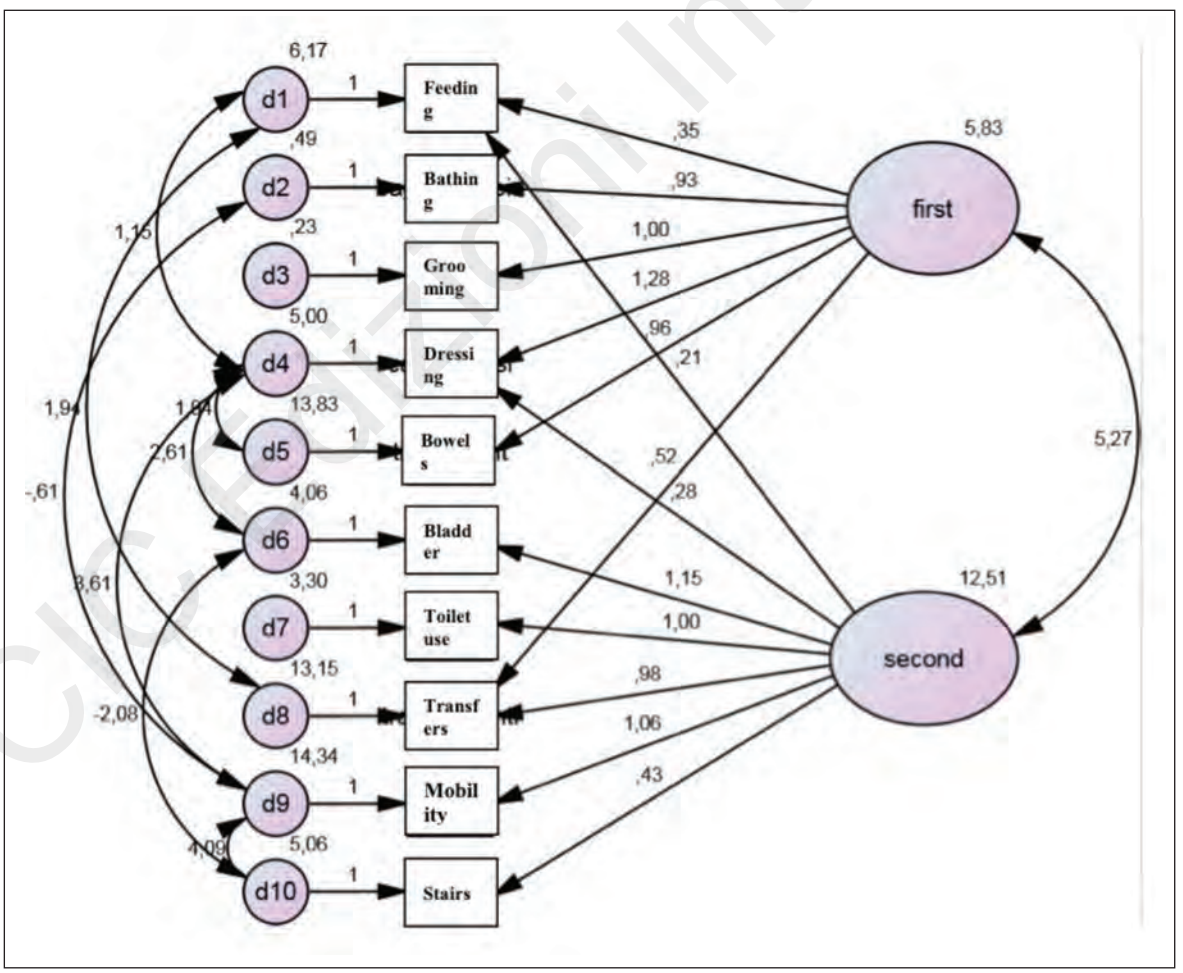

Figure 1 - Path Diagram of Confirmatory Factor Analysis (CFA).

Intra-rater reliability
In order to assess its intra-rater reliability, the IcaBI was administered to 39 patients by the same physical therapist twice. No missing values were found. ICC was 0.987 (95% CI: 0.975-0.993), revealing optimal intra-rater reliability. Cohen's Kappa was 0.69, revealing substantial agreement. Table II shows the reliability values for each item.

Inter-rater reliability
To assess its inter-rater reliability, the IcaBI was administered to each of the 39 subjects by three physical therapists on the same day. No missing values were found. ICC values revealed optimal inter-rater reliability (ICC = 0.909; 95% CI: .852-0.948). Light's Kappa values revealed substantial agreement (K = 0.79). Table III shows the reliability values of each item.

Discussion

Several studies have found the BI to be a valid and reliable tool for assessing both disability and responsiveness following an acute event, such as stroke (McMillan and Hanson, 2014; Lam et al., 2014; Wade, 1993; Post et al., 1995). The BI has been translated and validated in many languages worldwide, such as Turkish, Persian, Chinese, Brazilian, Dutch and Japanese (Post et al., 1995; Küçükdeveci et al., 2000; Oveisgharan et al., 2006; Leung et al., 2007; Cincura et al., 2009; Ohura et al., 2014). In Italy, the original version of the BI (Mahoney and Barthel, 1965) is used to determine eligibility criteria for inpatient rehabilitation and to monitor patients' recovery. However, before this study, there was only one Italian study on the reliability and validity of the BI in a cohort of patients with different pathologies. The present study. which used the 10-item version translated into Italian and culturally adapted (IcaBI) (Galeoto et al., 2015), is the first conducted to verify its reliability and consistency in an Italian population made up solely of stroke survivors. It has been suggested that a measurement tool should be selected on the basis of empirical evidence and not clinical significance (Hobart et al., 2001). An assessment tool should certainly be scientifically sound in terms of three basic psychometric properties: reliability, validity and responsiveness (Sharrack et al., 1999).
The findings of this study may provide useful information to both clinicians and researchers needing to choose between competing measures (Hsueh et al., 2002). In this study, the BI was found to be a valid and reliable tool for assessing ischemic stroke-related disability in the early stages following the cerebrovascular accident (Hsueh et al., 2002). Most previous studies on the original BI have been conducted in stroke populations and revealed an optimal internal consistency (Cronbach's alpha > 0.85) (Hsueh et al., 2002; Quinn et al., 2017). The internal consistency value obtained in the present study (Cronbach's alpha = 0.90) is in line with these previous studies. The IcaBI was previously found to show significant intra-rater and inter-rater reliability when administered to a cohort of general inpatient rehabilitation subjects (Galeoto et al., 2015; Castiglia et al., 2017). In this study, substantial to optimal reliability was also found in a population of acute stroke survivors, with total values for intra-rater analysis and inter-rater analysis of 0.99 and 0.91 respectively.
With regard to the assessment of reliability, the highest value recorded was 0.95, for the item Feeding in the intra-rater test-retest analysis. Instead, the lowest ICC value (0.55) was recorded for the item Transfers. Although it was less than 0.70, it did not adversely affect the internal consistency of the scale. This low ICC value detected in relation to the evaluation of transfers in these acute patients may indicate a certain difficulty, for evaluators, with the evaluation process.
The structural validity of the BI has often been debated. Some Authors described a unidimensional structure (Moura Minosso et al., 2010), while other researchers identified two different factors depending on the category of patients (Laake et al., 1995; Galeoto et al., 2015; Castiglia et al., 2017). The results of the EFA and the CFA in this study support the hypothesis of a two correlated factors structure of the IcaBI when it is administered to a cohort of people with ischemic stroke. One factor is probably due to basic and visceral functions and their relationship with the upper limb mobility, which is impaired in acute stroke. The second factor, involving transfer and general mobility items, is probably linked more to lower limb impairment.
In conclusion, the IcaBI was found to be a valid, reliable and useful tool for assessing disability in early stroke. Its accuracy and concurrent validity with other instruments, such as the National Institutes of Health Stroke Scale, the Modified Rankin Scale and the Fugl Meyer Assessment, should be assessed, in order to better define its characteristics.

Limitations of the study
This study has a number of limitations. A major one is the sample size; some may consider a sample of 99 to be small, given that established guidelines indicate that

Table II - Intra-rater reliability.

	TEST Mean ± SD	RE-TEST Mean ± SD	ICC [CI 95%]	Cohen's Kappa
Feeding	7.28 ± 2.76	7.69 ± 2.77	0.96 [0.92-0.98]	0.95
Bathing	1.92 ± 2.46	1.79 ± 2.43	0.95 [0.90-0.97]	0.95
Grooming	2.05 ± 2.74	1.79 ± 2.43	0.91 [0.83-0.95]	0.89
Dressing	3.59 ± 4.43	3.85 ± 4.51	0.94 [0,88-0.97]	0.96
Bowels	6.03 ± 4.47	6.28 ± 4.55	0.87 [0.77-0.93]	0.78
Bladder	3.08 ± 4.53	2.95 ± 4.55	0.92 [0.85-0.96]	0.89
Toilet use	2.44 ± 4.11	3.21 ± 4.21	0.87 [0.76-0.93]	0.75
Transfers	6.92 ± 5.92	7.18 ± 5.71	0.98 [0.96-0.99]	0.93

Table III - Inter-rater reliability.

	Operator 1 Mean ± SD	Operator 2 Mean ± SD	Operator 3 Mean± SD	ICC [IC 95%]	Light's kappa
Feeding	7.56±2.78	7.82±2.76	7.56±2.78	0.95 [0.91-0.97]	0.97
Bathing	1.67±2.39	1.92±2.46	1.67±2.39	0.93 [0.88-0.96]	0.96
Grooming	1.92±2.46	2.05±2.74	1.79±2.43	0.80 [0.69-0.88]	0.89
Dressing	3.97±4.47	3.59±4.43	3.85±4.65	0.93 [0.88-0.96]	0.91
Bowels	6.28±4.40	6.03±4.47	6.15±4.51	0.83 [0.72-0.90]	0.77
Bladder	2.82±4.41	3.08±4.53	2.69±4.42	0.90 [0.82-0.94]	0.93
Toilet use	3.08±4.07	2.44±4.11	3.08±4.07	0.82 [0.72-0.90]	0.91
Transfers	6.92±5.69	6.92±5.92	6.79±5.44	0.55 [0.37-0.71]	0.89
Mobility	3.85±6.12	3.85±6.01	3.85±6.12	0.88 [0.81-0.93]	0.97
Stairs	1.41±3.43	1.41±3.43	1.41±3.43	0.85 [0.76-0.93]	1.00
SCALE TOT	39.23±28.09	38.72±30.36	38.72±29.24	0.91 [0.85-0.95]	0.79

10 to 20 participants per estimated parameter are needed to analyze psychometric properties (Kline, 2011).

Even though the sample was smaller than the size required, the precision of our confidence interval was equal to that of previous studies. In addition, as suggested by others (Quinn et al., 2011; Kline, 2011), the BI is not sensitive to change at extremes of ability. These "floor" and "ceiling" effects limit the utility of this scale and, in particular, make it less discriminating in patients with severe or minor stroke events. For longer-term assessment, the BI on its own is unlikely to be sufficiently sensitive and should be replaced by, or used together with, other scales.

The Nottingham Extended ADL Scale compares favorably to the BI and is less susceptible to the ceiling effects described.

In conclusion, the Italian translated and culturally adapted version of the BI seems to be valid and reliable as a tool for assessing stroke patients. The scale is easy to understand and can be administered quickly. Thus, it can be considered a useful tool for healthcare professionals needing to measure functional disability in health and social environments along the continuum of care.

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