Signa Vitae

ORIGINAL RESEARCH

Intermittent Catheterization Adherence Scale (ICAS): Italian translation, cultural adaptation and validation

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Abstract

The study aimed to translate, culturally adapt, and validate the Intermittent Catheterization Adherence Scale (ICAS) in Italian for people with Spina bifida and spinal cord injury. The population consisted of adults who practice self-catheterization, recruited through online questionnaire google docs. The ICAS was translated and culturally adapted following international guidelines. The test was administered together with the Italian version of Qualiveen-30 for quality of life related to practice self-catheterization, Spinal Cord Independence Measure self-report (SCIM-SR) for independence in activities of daily living, Moorong self-efficacy scale (MSES) for self-efficacy. The ICAS was administered two times within a week, in order to assess test-retest reliability. Its psychometric properties were evaluated according to international guidelines. After the translation and cultural adaptation processes, all items were either identical or similar to the 34 study participants. For internal consistency, Cronbach' alpha showed values of 0.845; has been obtained from the analysis of individual's answers for each item; interclass correlation coefficient showed values of 0.995; has been obtained from analysis of the answers individuals gave each subscale after a week. Pearson's correlation coefficient and Spearman's Correlation Coefficient showed statistically significant correlations; has been obtained for the comparison of ICAS with Qualiveen-30 and SCIM-SR. The validation of ICAS in Italian allows professionals to work with self-catheterization for people with neurological bladder to face psychological barriers before learning about the Clean Intermittent Self Catheterization (CISC), improving patients' adherence to it. Adherence is the basis of CISC since, if this is not carried out according to the prescription, various types of bladder problems may arise. At the same time, the ICAS can be used for the medical follow-up of people using intermittent self-catheterization techniques and finally for medical research.

Keywords

Tools; Psychometrics properties; Validity and reliability; Catheterizations techniques; Rehabilitation; Neurological bladder

1. Introduction

The use of intermittent catheterization should be considered the first choice in treating patients with neurological bladder, as it is to be considered a safe and effective treatment both in the short and long term. It should also be preferred in patients forced to catheterize for periods longer than 30 days, in a hospital or home setting.

The 30-day period represents the line between short-term and long-term catheterization. It is particularly significant considering that, after that time interval, all patients can be considered bacterial. For this reason, intermittent catheterization and self-catheterization have been proposed to replace permanent catheterization [1].

When patients have been familiarized with Intermittent Catheterization, they are likely to continue using it over the long term, although they may sometimes encounter difficulties [2].

Expert training intervention is essential in the rehabilitation process of people who will practice intermittent self-catheterization (ISC). It will be referred to caregivers, too, in case the person is not autonomous enough [3]. The therapist guides the individual until the practice is carried out correctly.

Patients need to continue performing ISC for as long as possible and for prescribers to ensure their patients' adherence to the procedure [2].

Very few studies have explored the factors responsible for nonadherence to Clean Intermittent Self-Catheterization

(CISC). Previous studies have shown that internal and external factors may be identified as barriers to successful CISC. Internal factors refer to patient-related factors that include physical or psychological barriers. Practical barriers consist of the physical factors that hinder catheterization, and psychological barriers refer to the psychosocial and cultural aspects that may restrict its use. External factors involve the quality of CISC teaching supervision, follow-up, and catheter availability in the community [4].

According to Crescenze *et al.* [5], prior studies in spinal cord populations showed that female sex predicted poor adherence with Clean Intermittent Catheterization (CIC), they demonstrated that women with mature, long-term spinal cord injuries continue to be dissatisfied with CIC. It is likely because access to the urethra is more challenging for women than men, and women may need to reposition to perform CIC successfully [5].

Adherence is the basis of CIC since, if this is not carried out according to the prescription, various types of bladder problems may arise.

Individuals can decide the catheterization timing, but they must respect the rules aimed at not increasing or reducing the water supply pathologically and avoiding over-distension of the bladder [6].

In the Italian scene of self-catheterization training, there is a need for a tool that allows knowing why people do not follow the prescribed therapy to improve patients' adherence to self-catheterization.

ICAS is a simple and easily reproducible test that can be an important resource in medical follow-up and could be useful in preventing complications from self-catheterization [2].

This study aimed to validate and culturally adapt in Italian an instrument that can allow Italian professionals working with self-catheterization for people with neurological bladder to face up with psychological barriers before learning about self-catheterization. In addition, the ICAS can be used for medical follow up of people using self-catheterization techniques.

2. Materials and methods

A group of researchers made up of the University of Rome "La Sapienza" rehabilitation professionals and the Association of "Rehabilitation and Outcome Measure Assessment" R.O.M.A. carried out several systematic reviews and validated a lot of outcome measures in Italy over the past year [7–17].

After receiving consent from Intermittent Catheterization Adherence Scale (ICAS)'s authors, the tool was translated and culturally adapted following international guidelines [18].

2.1 Translation and cultural adaptation process

The original English version of the ICAS was translated into Italian by three translators (one native speaker and two Italians familiar with English and Italian).

These individuals produced three independent translations. The translations' results were synthesized by a fourth person who had not been involved in any of the previous translations. The literally translated version of the questionnaire was translated back into the original language by three Italian translators who had not seen the original version. The back-translated version of the tool was compared with the original. The developers have approved this version of the tool.

An Italian physiotherapist, an Italian occupational therapist, and one clinical psychologist, who were familiar with both languages, reviewed the translated version and then revised and reformulated some items to reduce differences from the original version. The final Italian version can be seen as Supplementary Material.

2.2 Subjects

To be enrolled in this study, individuals had to be adults with spina bifida or spinal cord injury who practice self-catheterization. Individuals with cognitive or psychiatric problems (as determined by clinical screening) were excluded from the study.

Individuals who met the inclusion criteria were informed about purposes and methods of the study, and they were asked to sign the informed consent. The interested eligible participants were included in the present study.

2.3 Instruments

The ICAS is a tool validated in France in 2018 to evaluate patients' adherence to the practice.

The scale consists of 8 items, including factors such as:
• the reasons why the individual does not carry out self-catheterization according to prescription;
• difficulties related to practice in everyday situations.

The answers to the questions are "yes" or "no" for the first seven questions. The eighth question has the most chance of answering "never", "sometimes", "often", "regularly", "always", which is given a score ranging from 0 to 1.

The ICAS was administered together with the whole following questionnaires: Intermittent Catheterization Acceptance Test (I-CAT), the Qualiveen-30 questionnaire, and the Moorong self-efficacy scale (MSES).

The Qualiveen-30 questionnaire covers bladder problems an individual may experience, and it consists of 30 items required to express opinion by making an X on the box considered most appropriate.

The MSES consists of 16 items about self-efficacy. The questions referred to individuals with spinal cord injury and their performance in activities of daily living.

To answer the questions, they have to make an "X" in the appropriate box: "very unconfident", "moderately unconfident", "lightly unconfident", "not confident, not unconfident", "a little confident", "moderately confident", "confident".

2.4 Statistical analysis

In order to evaluate the interrelation of the items and the scale's homogeneity, the internal consistency was calculated by analyzing each item's answer and calculating the 'Cronbach's alpha' coefficient,

The time interval for test–retest was 7–8 days; this timeframe represented a period enough long to prevent recall and sufficiently short to support the assumption that the patients

T A B L E 1. Demographic characteristics of 34 participants.

	Frequency	Percent
Gender		
Male	20	58.8
Female	14	41.2
Lesion level		
C6–C7	2	5.9
L–S	7	20.6
L1– L2	3	8.8
Spina bifida	1	2.9
T10–T12	7	20.6
T7–T9	7	20.6
T1–T4	1	2.9
T3–T6	5	14.7
Education		
Missing answers	14	41.2
Graduation	13	38.2
Elementary School	1	2.9
Middle School	6	17.6
Marital status		
Missing answers	10	29.4
Maiden/Celibate	7	20.6
Divorced	3	8.8
Married	12	35.3
Widow/Widower	2	5.9
Current job		
Missing answers	10	29.4
Unemployed	3	8.8
Employee	10	29.4
Retired	11	32.4
Number of self-catheterizations per day		
0–3	3	8.8
4	7	20.6
5	17	50.0
6	2	5.9
8	1	2.9
Place for self-cathetherization		
Missing answers	4	11.8
Bathroom	7	20.6
Wheelchair	13	38.3
Bed	8	23.5
Car	1	2.9
No self-catheterization	1	2.9
Need assistance when practice self.cathetherization		
Missing answers	5	14.7
Sometimes	4	11.8
No	23	67.7
Yes	2	5.9
Need assistive devices when practice self-cathteterization		
Missing answers	4	11.8
No	25	73.5
Yes	5	14.7

remain stable. The intraclass correlation coefficient (ICC) was calculated to measure test–retest reliability.

An optimal ICC value to establish the grade to which repeated measurements are free from measurement error is 0.70. The questionnaire's test-retest is considered stable because the ICC value is >0.70.

The Intermittent Catheterization Adherence Scale (ICAS), the Italian version of the SCIM, the Moorong self-efficacy scale (MSES), and the Qualiveen-30 questionnaire were administered together and using the Pearson's correlation co-

efficient and Spearman's Correlation Coefficient concurrent validity was analyzed.

All statistical analyses were performed using IBM-SPSS version 23.00 (IBM Corp., Chicago, IL, USA). and COSMIN checklist guidelines to validate the scale.

In our case, the construct validity, is calculated by analyzing the total scores obtained by the individuals in the different questionnaires and calculating the Pearson correlation coefficient.

The following values were considered in the interpretation of the results: –0.1 to 0.1 no linear relationship; +1/–1 perfect positive/negative linear relationship; a value between 0.1 and 0.3 (or between –0.1 and –0.3) is a weak positive (negative) linear relationship; values between 0.3 and 0.7 (or –0.3 to –0.7) are a moderate positive (negative) linear relationship; values between 0.7 and 1.0 (or –0.7 and –1.0) are a strong positive (negative) linear relationship.

3. Results

3.1 Subjects

Thirty-four subjects who met the inclusion criteria were enrolled in the study, 58.8% were male, 50% of the whole population use to do 5 self-catheterization per day, and the higher percentage of population perform it in the wheelchair. In Table 1 are reported the demographic characteristics of the participants. All patients gave their consent before inclusion.

3.2 Reliability

The Intermittent Catheterization Adherence Scale (ICAS) has a very good degree of internal consistency: a total Cronbach's alpha of 0.845. The internal consistency was evaluated in order to confirm the interrelation of the items and the scale's homogeneity, it was calculated by analyzing individual's answers for each item and calculating the Cronbach's alpha, as reported in Table 2.

The scale's stability was calculated by analyzing the answers individuals gave each subscale after a week and calculating the intraclass correlation coefficient (ICC), as shown in Table 3.

3.3 Validity

Construct validity has been performed, an analysis that allows determining if the ICAS subscales correlate with other instruments that measure constructs theoretically expected to be related. In this case, the construct validity is calculated by analyzing the total scores obtained by individuals in the different questionnaires and calculating the Pearson's correlation coefficient, as reported in Table 4, and Spearman's Correlation Coefficient, as reported in Table 5.

Both Pearson's correlation coefficients and Spearman's Correlation Coefficient of the ICAS with the Italian version of QUALIVEEN-30, SCIM SR, and the Moorong Scale were included between 0.3 and 0.7, indicating a good concurrent validity of the ICAS. Specifically, ICAS's total score showed a statistically significant correlation with "discomfort with limits" and "sensation" subscale of the QUALIVEEN-30, and all subscale of the SCIM-SR.

4. Discussion

The study aimed to validate an Italian version of the Intermittent Catheterization Adherence Scale (ICAS).

In this paper, authors reported the translation, the cultural adaptation of ICAS for use among Italian people who need intermittent catheterization, and the following evaluation of its validity evidence.

The original English version was translated into Italian following the international guidelines.

Participants in the present study were adults between 17 to 76 years old, diagnosed with spina bifida or spinal cord injury.

An important index to evaluate a test's reliability is the Cronbach's alpha that showed similar values to the original version of the scale: a good internal consistency.

The Pearson's coefficient of the ICAS with the other questionnaires indicates a good current validity.

According to Girotti *et al*. [19], patients who adhere to CISC had significantly better scores in psychological and social relations domains. It may be associated with better support and motivation from relatives and friends, which help patients accept and understand their condition better. The adherence rate evaluation is a very important issue [19]. The strong correlation between the ICAS and the subscale of QUALIVEEN-30 confirms that adherence to CISC is related to quality of life. Specifically, ICAS's total score showed a statistically significant correlation with "discomfort with limits" and "sensation" subscale of the QUALIVEEN-30, this suggest that people with higher levels of adherence fell less discomfort related to CISC and have lower sensation of embarrassment.

The relationship between ICAS and SCIM SR was expected because the SCIM SR included a section about "respiration and sphincter management" related to the type of catheterization and the autonomous management of bladder functions. This study has certain limitations, in fact the sample was not large enough to allow subgroup analysis or to detect differences between groups (gender, age etc.).

5. Conclusions

In conclusion, validation of ICAS in Italian allows professionals working with self-catheterization for people with neurological bladder to face up with psychological barriers before the learning of Clean Intermittent Self Catheterization (CISC), improving patients' adherence to it.

The culturally adapted ICAS is a valid and reliable questionnaire, at the same time, the ICAS can be used for the medical follow-up of people using intermittent self-catheterization techniques and finally for medical research.

TABLE 2. Internal consistency: scale's homogeneity, calculated by analyzing individual's answers for each item. Cronbach's alpha values and Cronbach's alpha if item for the Italian version of the I Intermittent Catheterization Adherence Scale (ICAS).

	Mean	Std. deviation	Median	Minimum	Maximum	25 percentil	50 percentil	75 percentil	Cronbach's alpha if item deleted
Do you sometimes forget to selfcatheterize?	0.50	0.51	0.5	0	1	0	0.5	1	0.85
Sometimes people do not self-catheterize for reasons other than simply forgetting. Over the past 2 weeks, have there been days when you have not self-catheterized?	0.30	0.47	0	0	1	0	0	1	0.81
Have you ever reduced the frequency of your self-catheterization, or have you ever stopped self-catheterizing altogether without informing your doctor, because you felt uncomfortable with the procedure?	0.27	0.45	0	0	1	0	0	0.25	0.81
When traveling or when leaving home, do you ever forget to bring your selfcatheterization kit with you?	0.20	0.41	0	0	1	0	0	0	0.81
Referring to yesterday, did you selfcatheterize according to your prescribed routine?	0.13	0.35	0	0	1	0	0	0	0.83
When symptom perception is diminished or absent, do you sometimes stop or decrease your self-catheterization routine?	0.20	0.41	0	0	1	0	0	0	0.81
Having to self-catheterize daily can be experienced as a real burden by some people. Is your self-catheterization routine and practice at times upsetting for you?	0.43	0.50	0	0	1	0	0	1	0.84
Do you sometimes have difficulty remembering when to perform your selfcatheterization, even though you may respect the prescribed frequency?	0.35	0.32	0.25	0	1	0.25	0.25	0.313	0.84
							Total alpha = 0.845		

T A B L E 3. Stability: Intraclass correlation coefficient between test-retest after one week of Italian version of the Italian version of the Intermittent Catheterization Adherence Scale (ICAS). Analyzing the answers individuals gave each subscale after a week.

	Mean test	St.dev test	Mean retest	St. dev retest	Intraclass Correlation	95% Confidence interval	
						Lower bound	Upper bound
ICAS Total score	1.07	0.78	1.07	0.75	0.995	0.98	1.00

T A B L E 4. Criterion validity: Pearson's correlation coefficient between the Italian version of the I Intermittent Catheterization Adherence Scale (ICAS) Qualiveen. Spinal Cord Injury Measure Self.

	Qualiveen-30				SCIM-SR				Moorong	
	discomfort with limits	frequency of limits	Fears	sensation	selfcare-SCIM-SR	respiration & sphincter management-SCIM-SR	mobility-SCIM-SR	score	daily activities instrumental self efficacy	social functioning interpersonal self efficacy
ICAS total	0.495**	−0.139	0.209	0.540**	0.712**	−0.680**	−0.490**	0.437*	−0.006	0.07

*. Correlation is significant at the 0.05 level (2-tailed). **. Correlation is significant at the 0.01 level (2-tailed).
ICAS, Intermittent Catheterization Adherence Scale; SCIM-SR, Spinal Cord Independence Measure III-Self Report; MSES, Moorong self-efficacy scale.

T A B L E 5. Criterion validity: Spearman's Correlation Coefficient between the Italian version of the I Intermittent Catheterization Adherence Scale (ICAS) Qualiveen. Spinal Cord Injury Measure Self and Moorong self-efficacy scale.

	Qualiveen-30					SCIM SR				Moorong	
	discomfort with limits	frequency of limits Qualiveen	Fears qualiveen	sensation qualiveen	totale	Selfcare-SCIM-SR	respiration & sphincter management-SCIM-SR	mobility-SCIM-SR	score	daily activities instrumental self efficacy	social functioning interpersonal self efficacy
ICAS total	0.415*	−0.025	0.175	0.546**	0.374*	0.624**	−0.349*	−0.323	0.386	−0.244	−0.101

*. Correlation is significant at the 0.05 level (2-tailed). **. Correlation is significant at the 0.01 level (2-tailed).
ICAS, Intermittent Catheterization Adherence Scale; SCIM-SR, Spinal Cord Independence Measure III-Self Report; MSES, Moorong self-efficacy scale.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. Ethics committee approval is not required for this study, this research involved secondary use of clinical data which is provided without any identifier or group of identifiers which would allow attribution of private information to an individual. Informed consent was obtained from all participants for being included in the study.

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CONFLICT OF INTEREST

The authors declare no conflict of interest. Giovanni Galeoto is the Guest Editor of the journal.

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