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## DEVELOPMENT AND VALIDATION OF THE ITALIAN VERSION OF THE INTERMITTENT SELF-CATHETERIZATION QUESTIONNAIRE (ISC-Q)

### Hypothesis / aims of study

Intermittent catheterization is an effective and practical method for individuals with chronic urinary retention and is a procedure recommended over indwelling catheterization. Despite several well known advantages, the use of intermittent catheters has also been negatively associated with psychological well-being, such as embarrassment and low self-esteem. Therefore, there is a need to evaluate catheter-related quality of life. Until a few years ago researchers could rely only on generic QoL instruments (Qualiveen and Cather-related Quality of Life instrument). However, recently, a new instrument, the Intermittent Self-Catheterization Questionnaire (ISC-Q) has been presented and validated. The aim of the present study is to develop and validate the Italian version of the ISC-Q.

### Study design, materials and methods

**Questionnaires:** The ISC-Q is a 24 items Patient Related Outcome that explore four issues related to self intermittent catheterization: ease of use (8 items), convenience (4 items), discreteness (6 items) and psychological well-being (6 items). Each item is score with a 5 point Likert scale (from strongly disagree to strongly agree). The questionnaire has been developed and validated in the United Kingdom, France and Germany and demonstrated to have good psychometric features.

**Translation procedure:** The translation process was performed according to standard guidelines including both language translation and cultural adaptation. Two independent translations were performed and compared by a broader expert committee. A back translation from Italian to English has been made by a linguistic expert with expertise in medical English, who was blinded to the original English version of questionnaire.

**Subjects:** Patients were recruited from 19 centers in Italy. Inclusion criteria were that participants were at least 18 years old, and performing clean intermittent catheterization because of neurogenic bladder either due to spinal cord injury, myelomeningocele, multiple sclerosis or other pathologies.

**Procedure:** Questionnaires were sent to each patient who also signed an informed consent. The questionnaires were returned to a single center and examined in an anonymous way. Beside the ISC-Q, the patients were asked to answer six questions on the understandability and clarity of the Italian ISC-Q. Each question was scored with a 5 point Likert scale (from strongly disagree to strongly agree). A subgroup of subject was asked to repeat the test at 2 weeks distance for test-retest reliability and to complete also the Qualiveen to assess the convergent validity of ISC-Q.

**Statistic:** *Descriptive analyses* were applied to calculate means and standard deviations of the demographic variables. The *internal consistency* was determined from Cronbach's  $\alpha$  coefficient [28]. *Criterion validity* was determined through the concurrent use of Qualiveen; the Pearson's  $r$  correlation coefficient used the criteria of poor ( $r < 0.49$ ), fair ( $r = 0.50-0.74$ ) and strong ( $r > 0.75$ ). *Reliability* was performed using the Intraclass Correlation Coefficient and test-retest methodology in a sub-sample at baseline and two weeks (14 days). Known groups validity was assessed through the comparisons of the ISC-Q scores across participants with differing age, gender and pathology, with different levels of education, coming from different parts of Italy and with different duration of intermittent self-catheterization. Individuals with different characteristics may experience difficulties when performing ISC. Aim of this analyses was to assess if subjects with different characteristics showed different ISC-Q scores. The *sensitivity* was determined by two different methods. The effect size-based estimate for a small change was calculated according to Cohen's methodology as  $0.2 \times s$ , where  $s$  = standard deviation. The Minimal Detectable Change 90 (MDC95) was calculated as follows [25]. The standard error of the measurement (SEM) was calculated using the formula:  $SEM = s \sqrt{1-r}$ , where  $s$  = standard deviation,  $r$  = the reliability coefficient for the test and Pearson's correlation coefficient between test and retest values. Thereafter the MDC90 was calculated using the formula:  $MDC90 = SEM \times \sqrt{2} \times 1.65$ .

### Results

We enrolled in the study 217 subjects (65.6% males and 34.4% females) using self intermittent catheterization to void their bladder. Most of the patients had a spinal cord injury, followed by myelomeningocele and multiple sclerosis. Mean age was 43 years. Mean duration of ISC was 3.3 years. The questionnaire concerning the understandability and clarity of the questionnaire showed in general that all the questions were understandable and clear. However, based on the comments of the patients it was decided to move the second question ("it is difficult to prepare the catheter to insert it") of the ease of use part of the questionnaire to the last place because some patients commented it was in contrast with the first question. There was a high degree of *internal consistency* for the total score and for the 4 parts of the questionnaire with an individual item  $\alpha$  range of 0.79 to 0.81. Pearson correlation between the different parts of the questionnaire and the total score showed values ranging from 0.24 to 0.78 ( $p < 0.05$ ). The *test-retest reliability* was high with ICC values higher than 0.9 for the 4 parts of the questionnaire and the total score. The correlation with the Qualiveen showed faint to null *convergent validity*. With regard to known groups validity individuals with different ages reported significant different total ISC-Q scores, with older subjects showing lower scores ( $p < 0.05$ ). Males and females reported different scores in the convenience domain, with females reporting higher scores ( $p < 0.001$ ). The effect size-based estimate for a small change ranged from 3.8 to 6 points. The MDC95 ranged from 4.1 to 12.1.

### Interpretation of results

The questionnaire was translated without difficulty and minimal culturally-specific adaptation were required. The internal consistency ( $\alpha$  ranging from 0.79 to 0.81) confirmed no item redundancy. The same characteristic was confirmed by Pearson

correlations that showed fair to good values according to our methodology. This demonstrates that the four domains, although exploring the same concept (ISC), do not overlap and therefore are not redundant. In the same time, the higher Pearson values found between the four domains scores and the total score demonstrates that this latter could be a useful indicator of all aspects related to ISC. The high values of test-retest reliability demonstrated the stability of the questionnaire along time. The known groups validity study demonstrated both the generalizability and the capacity to discriminate of the Italian ISC-Q. The comparison between groups with different characteristics showed no effect of pathology, level of education, region of provenience and duration of ISC. This means that the questionnaire could be reliably used along a variety of conditions. The statistically significant differences between age classes and demonstrate that the questionnaire is able to discriminate in those conditions where we expect that a difference does exist. The effect of age on bladder management is already well known at least in spinal cord injury subjects: older individuals may have more difficulties in performing ISC due to pre-existing conditions such as prostatic hypertrophy, balance control difficulties and visual loss. The difference between males and females with regard to the convenience domain is also somehow expected. This domain assess aspects of ISC (storage and disposal of catheters) that are strictly related to the dimension and shape of the catheter. As these characteristics are clearly in favor of females, this difference is easily explainable.

#### Concluding message

The Italian ISC-Q has the same robust psychometric characteristics of the original questionnaire. This study provides researches with a valid, reliable and sensitive patient related outcome, specifically focused on ISC. ISC-Q could provide a focus on both functional and psychological issues, and optimize ISC care and guide professionals and individuals using ISC to select appropriate catheters. Another possible field of application of the questionnaire is the education of patients to ISC, in particular for assessing the efficacy of educational programs.

#### References

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