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ORIGINAL RESEARCH

Translation and Validation of the Intermittent Catheterization Difficulty Questionnaire (ICDQ) into Greek

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Purpose: Clean intermittent self-catheterization (CISC) is a safe and effective alternative to managing incomplete bladder emptying in patients afflicted with neurogenic bladder conditions. The Intermittent Catheterisation Difficulty Questionnaire (ICDQ) is a validated questionnaire concerning the assessment of catheter use and patient difficulties during CISC. The present study aimed to translate and validate the ICDQ into the Greek language. A subsequent outcome was to substantiate the requirement of both urologist consultation with patients undergoing CISC and the detailed evaluation of various therapeutic options with the consultation of other specialist physicians.

Material and Methods: The study was undertaken between March 2022 and July 2022 and involved patients in an outpatient department of a Rehabilitation Centre. Sixty-two neurologic patients suffering from spinal cord injury (SCI), multiple sclerosis (MS), cauda equina (CE), and myelitis represented a convenience sample. To calculate test-retest reliability, patients filled out two consecutive questionnaires; an initial one and a second after one week. The socio and demographic circumstances of all participants were evaluated.

Results: The mean ICDQ total score at the test and retest was 5.96 ± 1.28 (mean total score \pm standard deviation) and 5.91 ± 1.29 , respectively. Evaluation of the data concerning alterations between men and women did not reveal statistically significant differences. Cronbach's alpha coefficient was 0.94, which proves the inter-correlation between the different topics. An ICC of 0.97 indicated very high intra-rater reliability.

Conclusion: ICDQ, a valid and reliable self-administered screening tool for CISC difficulties faced by patients using this procedure regularly, was successfully translated and validated into Greek. A more detailed evaluation and understanding of these difficulties would enhance the quality of CISC and allow for more suitable treatment and the selection of catheter types used. These improved treatment strategies are possible as repeated use and constant comparison of ICDQ scores determine treatment impact, facilitating treatment regimen modification, should it be required.

Keywords: ICDQ, clean intermittent self-catheterisation, urinary tract infection, urethral stricture, translation, validation, Greek

Introduction

Clean intermittent self-catheterization (CISC) is a safe and effective alternative to managing incomplete bladder emptying in patients with neurogenic bladder issues such as atoning detrusor or bladder neck dyssynergia.¹ Although health professionals consider it a simple and painless procedure and patients report improved quality of life, there are several complications.² Urinary tract infections and asymptomatic bacteriuria are the most common difficulties in patients utilising CISC. Catheter application or removal can sometimes cause local problems, including transitory striated urethral sphincter convulsions. The long-term practice of CISC sometimes results in urethral strictures, bleeding or urethrocele. Some patients complain of ephemeral limb spasticity characterised by spasms and stiffness. Others report pain or have difficulties accessing the meatus. Albeit rare, urethral perforation is another consequence.^{3–6}

The awareness of such complications and their objective assessment is essential to correctly deciding on the type of catheter and ensuring the patient's compliance and adherence to prescribed treatment. The Intermittent Catheterization Difficulty Questionnaire (ICDQ) was established in 2014 in the French language and developed to objectively assess and measure patient difficulties during CISC. In the literature, there is a detailed description of ICDQ content validity, internal consistency and test-retest reliability. ICDQ was originally presented in the French language, and three validated translations are available in English, Dutch and Tunisian Arabic.^{7–9}

The purpose of the current study was to create a Greek version of ICDQ and validate its relative reliability in neurologic patients. A subsequent consequence was to underline the requirement for office and outpatient urologists to consult their CISC patients and scrupulously assess different therapeutic options in collaboration with other specialist physicians.

Methods

The study was undertaken between March 2022 and July 2022 and involved patients in an outpatient department of a Rehabilitation Centre. During this period, Greece was not experiencing a surge in Covid-19 hospitalisation rates, so there were no specific lockdown measures. The study was endorsed by the ethics committee of the Physical Medicine and Rehabilitation Centre EU PRATTEIN, to which the Declaration of Helsinki binds. All participants gave informed consent to use their data before the study's commencement.

ICDQ comprises 13 statements considering both the frequency and the intensity domain. The instrument explicitly describes the ease of catheter insertion and withdrawal, the presence of pain, limb spasticity, urethral sphincter spasms, and local urethral bleeding during catheterisation.⁷ ICDQ uses a four-point Likert type scale for the answer presentation, with 0 corresponding to "None" (Intensity) or "Never" (Frequency). Answer 3 corresponds to "Considerable" for intensity and "Always" for frequency, respectively. A mean score for each patient corresponds to the overall score for both the frequency and intensity domains.⁷

Translation and Cross-Cultural Adaptation

Sperber's translation method was employed to render a Greek language version of ICDQ from the original French.¹⁰ Two continence nurses, two functional urology specialists and one physiotherapist, all native speakers of Greek and proficient in French, undertook the translation. Only easily understood words which comply with the original intention were used. The resultant Greek version was then retranslated back into French by a native French speaker fluent in Greek. It was subsequently reviewed by comparison with the French original.

In adherence to Sperber's method, we also evaluated the Greek ICDQ version using a group of bilingual laypeople fluent in the source language. This group excluded translators and back-translators. Speech comparability and interpretability similarity were two criteria used to ascertain translation accuracy. Low scores denote a high level of compatibility and similarity, meaning that the translation is suitable for clinical practice settings, whereas high scores indicate the converse. Our ICDQ translation achieved a mean comparability score of 1.88 and a mean similarity of interpretability score of 1.87, thereby indicating a high degree of accuracy. To ascertain suitability in terms of understandability, interpretation and cultural relevance, the translation was tested on five native Greek people. Subsequent feedback and amendments meant that our Greek version of the ICDQ was now ready for statistical validation (The English and the Greek Translation - Supplementary File 1).

Study Participants

Sixty-two neurologic patients suffering from spinal cord injury (SCI), multiple sclerosis (MS), cauda equina (CE), and myelitis represented a convenience sample. These patients are representative individuals at both ends of the severity scale regarding bladder issues, making them suitable for validity determination.

The criteria for inclusion were: a) being at least 18 years of age, b) independently performing CISC for at least six months, and c) being able to provide informed consent. The SCI patients were limited to the C6 injury level because C6 represents the highest International American Spinal Injury Association (ASIA) level able to perform catheterisation, with an acceptable success rate.¹¹ The physical and cognitive abilities of all patients were sufficient to allow them to perform CISC and achieve a Pencil and Paper Test (PP-Test) score greater than 60% (10/15).¹² One inclusion criterion was the patients' ability to catheterise independently. Thus, patients who generally received assistance with catheterisation were excluded from participation. Candidates with any impediment to ICDQ comprehension, such as those with dementia, cognitive impairment or an insufficient command of the Greek language, were excluded. Socioeconomic and demographic circumstances (such as age, gender, etc.) were reported, as were a type of affliction, period using CISC, and number of CISCs per day.

A continence nurse outlined the details of the ICDQ questionnaire to all participants. Each patient received two ICDQs (test and retest), along with prepaid envelopes for submission. To eliminate any possible effect a clinical setting might have on responses, the questionnaires were entirely self-administered in the privacy of the home. All partakers were prompted by a phone call to undertake and submit the retest one week after the first test. The number of test and retest submissions was large enough to allow statistical analysis.

Psychometric Validation

The study group evaluated the patient's attitude to the questionnaire concerning comprehension, relevance, and acceptance in terms of time consumption. The patients responded to three questions with a "Yes/No/Do not know" response: "Did you understand the questions easily?" "Did you find the questions relevant?" "Do you think you need much time to answer the questionnaire?" The answer "Do not know" was accepted as being negative. The number of missing responses in the questionnaire was acknowledged as a criterion for the comprehension of ICDQ. The patients' attitude about the time spent on the questionnaire was one of the acceptance criteria. Internal consistency was measured by Cronbach's alpha and its confidence interval. A result of ≥ 0.70 was considered satisfactory.¹³

As previously delineated, patients filled out two consecutive questionnaires; an initial one and a second after one week. This was to calculate test-retest reliability. A questionnaire is reproducible if these two measurements produce similar outcomes. The Intraclass Correlation Coefficient (ICC) measures the correlation between the two replies given to the same question over both tests. An ICC result of >0.60 indicates that results are unchanged.¹⁴

Our statistical analysis included the determination of quantitative data (mean and standard deviation of age, total ICDQ score, number of CISCs per day, and period of CISC used). A p-value <0.05 was considered to be statistically significant.

Results

Of the 62 CISC-utilising patients participating in the study, 58 agreed to fill in the ICDQ questionnaire (response rate of 93.5%). Three people did not submit the retest and were therefore excluded. This left 55 patients eligible for the statistical analysis (total response rate of 84.6%). Table 1 describes the patients' demographics (age, gender) and their clinical characteristics (neurological disease, months of CISQ and number of CISQ per day).

All patients used hydrophilic-coated or pre-lubricated-coated catheters. Twenty-three individuals had spontaneous micturition but underwent intermittent catheterisation due to excessive residual urine. Thirty-two patients depended on

Nature of Disease	Number (%)	No Females/ Males	Age (Years), Mean ± SD	Months of CISQ, Mean ± SD	Number of CISQ, Mean n/Day ± SD
Spinal cord injury	28 (50.9%)	8/20	37.2 ± 5.71	54.9 ± 24.9	5.68 ± 0.71
Multiple sclerosis	21 (38.2%)	10/11	50.1 ± 3.95	47.4 ± 16.1	4.19 ± 0.96
Cauda equina	3 (5.5%)	2/1	52.0 ± 2.0	42.0 ± 6.66	3.66 ± 0.44
Myelitis	3 (5.5%)	1/2	55.3 ± 3.11	40.5 ± 7.85	3.66 ± 0.44

Table I Patient's Demographic and Clinical Characteristics

CISC because they were unable to urinate. There was no change in the urinary catheter type during the study. No missing data was found after the questionnaire examination. All patients found questions relevant and easy to understand. Two patients, one suffering from MS and one from SCI, suggested an additional question about the type of catheter: "Do you think changing the kind of catheter (Nelaton to Tiemann or vice-versa) could alleviate the problems?" Finally, all patients, except two, found that answering ICDQ is not time-consuming.

The Kaiser-Meyer Olkin (KMO) value and Barlett' test results were examined to determine that the data were suitable for factor analysis (Table 2). Cronbach's alpha coefficient was 0.94, indicating a high degree of inter-correlation between the different topics.

The mean ICDQ total score at test and retest (one week later) was 5.96 ± 1.28 (mean total score \pm standard deviation) and 5.91 ± 1.29 , respectively. The ICC was 0.97, indicating excellent intra-rater reliability. Table 3 presents the ICC values for each item of the ICDQ questionnaire.

Measure of Factor Analysis Applicability	Measured Values			
Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy	0.808			
Bartlett's Test of Sphericity				
Approx. chi-square	63.512			
df	4			
Significance	0.001			

Table	2	Kaiser-Meyer-Olkin	(KMO)	Measure	of	Sampling	Adequacy	and
Bartlet	ťs	Test of Sphericity						

ltem	ICC Value
ltem l	0.98
ltem 2	0.96
ltem 3	0.97
ltem 4	I
ltem 5	0.98
ltem 6	I
ltem 7	0.95
ltem 8	0.98
ltem 9	0.98
ltem 10	0.97
ltem I I	0.96
Item 12	0.97
Item 13	I

Table 3The ICC Values for EachItem of the ICDQ Questionnaire

Further evaluation of the data concerning alterations between men and women did not reveal statistically significant differences between these two groups (p>0.05).

Discussion

Health professionals accept CISC as the most appropriate management of chronic urinary retention in individuals with a risk of function deterioration of the upper urinary tract.¹⁵ On the other hand, in the literature, there are reports about difficulties that make patients unwilling to follow the suggested catheterisations. These urological complications are urinary infections, urethral trauma and strictures, pain, and sometimes convulsions of the striated urethral sphincter.³ The study's primary objective was to establish a validated Greek translation of the ICDQ, the questionnaire designed to evaluate CISC difficulties in patients who routinely use this method to alleviate their condition.

The original French version of ICDQ is simple, suitable, easy to understand, and validated by a neurological population performing CISC. Our translation in the Greek language, like the other available validations, exhibits a high Cronbach's alpha coefficient. The Greek translation demonstrates accuracy, homogeneity, and excellent internal consistency in this validation study. It also indicates high patient acceptance as recognized by the minimal amount of absent information. We should mention that all available translations of ICDQ, except the Dutch translation, report a high percentage of patient participation. In the Dutch translation, only 50 out of 111 patients were eligible for the study. Our translation, compared with other similar scales, exhibits analogue results. The available validations of the ICSQ questionnaire have similarly high internal consistency and reliability.

The secondary outcome of our paper is that Greek urologists can use ICDQ to evaluate treatment acceptance by patients and the difficulties of modified treatments. New treatment modalities with ISC may produce novel challenges that can be easily recognized and quantified simultaneously. Health professionals can offer alternative solutions like suitable body position, another type of catheter, or a specific pharmacological treatment such as α -adrenoreceptor antagonists or intra-sphincter botulinum toxin injection.¹⁶ Finally, frequent ICDQ usage informs health professionals of the effectiveness of therapeutic strategies by comparing the most recent results with those of the initial questionnaire.

Urinary tract infections (UTIs) are among the most commonly studied CISC complications. UTIs are more common in patients with indwelling catheters than in those performing CISC.¹⁷ In the literature, few studies report no significant difference in adjusted incidence rates of UTIs among patients managed with CISC versus indwelling urethral catheters.⁶

Urethral strictures are one of the challenging side-effects of CISC caused by a complex relationship. The act of repetitive catheterisation may result in inflammation, repeated microtrauma and the formation of secondary urethral strictures.¹⁸ According to the literature, the incidence of developing secondary urethral strictures in patients using CISC ranges from 4.2–40%.^{4,19,20} There are few studies which compare stricture rates in patients using intermittent catheter-isation versus other bladder emptying methods, and their findings are inconsistent.^{18,20} In the same way, studies examining hematuria in patients utilising CISC produce mixed results.^{19,21–23} Hydrophilic catheters reduce urethral trauma and complications.²⁴ However, the current evidence is limited, especially regarding the optimal catheter type for decreasing urethral complications and urinary tract infections.²⁵ As a result, adopting an international questionnaire like ICDQ that will permit additional research examining these complications and potential interventions to prevent them is essential.

Many studies describe the pain as one of the common difficulties in performing CISC. It is usually related to urethra trauma and bleeding, also known as complications.²⁶ These difficulties in the process cause distress and negatively impact the quality of a patient's life. Pain is a sensory and unpleasant emotional experience and, generally, is a limiting factor of activities, whatever their type.²⁷ Regarding the prevalence of pain according to gender, one would expect the majority of men, but that is not the case. Women also report pain because they find it difficult to immediately identify the urethral meatus and to advance the catheter in an anatomically oriented manner during the catheterisation.²⁷

This study showed no difference between men and women in mean total ICDQ scores. Our results are supported by other studies, although we could assume that men present more problems with CISC than women due to anatomical differences.²⁸ In the same way, in multiple sclerosis, males do not present differences in the frequency of striated urethral sphincter spasms.²⁸

Conclusion

ICDQ, a valid and reliable self-administered screening tool for patients who experience difficulties with regular CISC use, was successfully translated and validated into Greek. Evaluating and understanding more about the challenges encountered, better CISC utilisations, improved treatment strategies, and more appropriate choice of catheter types are all rendered possible. The improvement of treatment strategies is the result of frequent ICDQ use, with the comparison of results being a measure of treatment effectiveness from which treatment regimens can be modified for suitability.

Abbreviations

CISC, clean intermittent self-catheterization; ICDQ, Intermittent Catheterization Difficulty Questionnaire; SCI, spinal cord injury; MS, multiple sclerosis; CE, cauda equina; ICC, Intraclass Correlation Coefficient; ASIA, American Spinal Injury Association; PP-Test, Pencil and Paper Test; UTI, Urinary tract infections.

Disclosure

The authors report no conflicts of interest in this work.

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