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Validation of the UDI-6 and the ICIQ-UI SF – Croatian version

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ABSTRACT

Introduction and hypothesis: Despite the widespread use of UDI-6 and ICIQ-UI SF in Croatia, it remains unknown whether a realiable and valid measure for the population of interest is used. Thus, the aim of this study was to translate, adapt and validate the UDI-6 and the ICIQ-UI SF in Croatia.

Methods: The study included a total of 232 consecutive patients with urinary incontinence symptoms. The translation to Croatian followed standardized procedure. All participants underwent urodynamic assesment and completed UDI-6 and ICIQ-UI SF questionnaires at inclusion and 2 weeks after to assess test-retest reliability. Cronbach α coefficient was calculated in order to assess internal consistency.

Results: Both questionnaires had high internal consistency (Cronbach α for UDI-6 and ICIQ-UI SF was .83 and .85, respectively) and high test-retest reliability (intraclass correlation coefficient .99 for instruments). Strong correlation was found between urodynamic findings and total scores in UDI-6 and ICIQ-UI SF (ρ=0.88 and 0.89, respectively). Women with stress urinary incontinence (SUI) and detrusor overactivity (DOA) group had significantly higher scores on UDI-6 (Mdn=33.33 and Mdn=50, respectively) compared to women with no urodynamic abnormality (Mdn=0; $p<0.001$). Women with no urodynamic abnormality scored significantly lower on ICIQ-UI SF (Mdn=0; $p<0.001$) compared to women with SUI (Mdn=14) and DOA (Mdn=16). Women with DOA scored worse on Irritative and Obstructive symptoms when comparing with two other groups ($p<0.001$), while women with SUI had significantly worse score on Stress symptoms subscale ($p<0.001$).

Conclusions: The UDI-6 and ICIQ-UI SF have very good psychometric characteristics and can be used in Croatian urogynecology practice.

Keywords: ICIQ-UI SF; UDI-6; urinary incontinence; validation.

BRIEF SUMMARY

Translation, adaptation and validation through assessing psychometric properties of the UDI-6 and the ICIQ-UI SF in Croatia.

Introduction

According to The International Continence Society, urinary incontinence (UI) is defined as the complaint of any involuntary leakage of urine [1]. UI is common among women regardless of age with reported prevalence ranged from approximately 5% to 70% in different populations [2]. Multiple studies have demonstrated a link between UI and reduction in overall and health-related quality of life (QoL) [3-5]. Nowadays, QoL still remains a significant predictor of treatment-seeking for UI and is also important in assessing treatment effectiveness [6]. Concerning the failure of objective clinical parameters to evaluate the impact of the disease from the patient's perspective, various generic and specific questionnaires for measuring QoL have been created. In our everyday clinical practice, results obtained from those questionnaires are one of the main determination factors in decision whether to treat or not [1].

The Urogenital Distress Inventory (UDI-6) and the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) are the UI-specific questionnaires [7,8]. UDI-6 was developed in order to overcome impracticality of its previous validated version due to the length of time required **for its completion** [9]. ICIQ-UI SF was conceived as a simple, brief and robust questionnaire to assess the

symptoms and impact of UI that could be used comprehensively in clinical practice and research [8]. Regarding avalilable published reports, both questionnaires have shown to have high levels of validity, reliability and internal consistency [7,8,10-14].

Despite the widespread use of the UDI-6 and ICIQ-UI SF in Croatia, without the measurement properties tested, it remains unknown whether a realiable and valid measure for the population of interest is used. In the Croatian language, there is no validated questionnaire for evaluating the UI impact on QoL.

The present study was conducted with the aim to translate, adapt and validate the UDI-6 and the ICIQ-UI SF in Croatia.

Materials and methods

Participants and study design

A prospective observational study was conducted between August 2019 and January 2020 in the urogynecology outpatient clinic, Department of Obstetrics and Gynecology, University Hospital Center Zagreb, Croatia. The study was approved by the Institutional Review Board (No. 021-1/149-19) as a part of randomized controlled trial with objective to evaluate accessible conservative treatment modalities of stress urinary incontinence (SUI) in our Department. Study protocol is available at clinicaltrials.gov (Identifier: NCT04307680). Before randomization and final enrolling into trial, all participants will be provided with detailed nutritional consuelling in order to achieve necessary weight reduction and to achieve appropriate daily fluid intake and caffeine reduction. By randomization, the subjects will be assigned either to a group that will perform home-based intensive Kegel exercise regimen for 8 weeks or to a group that will receive

extracorporeal magnetic innervation also for 8 weeks. Shortly after last treatment session, the respondents would again complete all the questionnaires they had filled out before starting the survey. Thereafter, all subjects will be recalled at three different time points (8, 12 and 16 weeks after the end of treatment) to check the short-term effects of these two treatment modalities. Short-term effects will be evaluated and compared with subjective (UDI-6, ICIQ-UI SF) and objective assessment tools (perineometer).

All enrolled participants gave written informed consent before their inclusion. To be eligible for participation, subjects are required to fulfill the following conditions: 1) females 18 years or older; 2) symptoms of UI for at least 6 months; 3) fluent and literate in Croatian language; and 4) ability to independently understand the questions in the questionnaires.

The following are the exclusion criteria: 1) urinary tract infection (UTI) and hematuria; 2) neurologic conditions (e.g., stroke, epilepsy, Parkinson disease, multiple sclerosis); 3) pregnancy; 4) intellectual disability and 5) missing data in any of the responses of the questionnaires.

All respondents who agreed to participate had completed questionnaires at two predetermined time points: shortly after signed informed consent and two weeks after on a control visit. After completing questionnaires at the baseline**,** urodynamic studies were performed in accordance to the standard evaluation protocol of our clinic as recommended by International Continence Society [1]. Urodynamic assessment was performed by the investigator who was blinded to the patient's questionnaire scores.

Questionnaires

The UDI-6 is a six-item inventory assessing symptoms associated with lower urinary tract dysfunction and genital prolapse. Item responses range from 0 „ not at all“ to 3 „greatly“. The total score on the questionnaire is obtained by averaging the results of all items multiplied by 33 and 1/3 to put scores on a scale of 0 to 100. Higher score indicates more symptom distress. In addition to the total score, three subscales can be calculated: irritative symptom subscale (1st and 2nd item), stress symptom subscale (3rd and 4th item) and obstructive/discomfort symptom subscale (5th and 6th item) [7,10].

The ICIQ-UI SF consists of three scored items about frequency of urination, amount of leakage and impact on everyday life. Additional fourth item is not included in total score, although aims to determine the type of UI. The total score is the sum of first three items, ranging from 0 to 21, with higher score indicating greater severity of symptoms [8].

Translation

The initial forward translation was made by the two bilingual researchers in urogynaecology who independently translated UDI-6 and ICIQ-UI SF questionnaires to Croatian. After that, they met to discuss discrepancies in translation and to create a new unified version of questionnaires. The new version of UDI-6 and ICIQ-UI SF was sent to a bilingual native English speaker who back-translated questionnaires to English without having access to the original version of the questionnaires. An expert group (urogynaecologist, methodologist and bilingual native English speaker) then reviewed all versions of the translations and found no major differences. After that, preliminary pilot testing was conducted on a small sample (n=20) to check out if there is confusion about any item and/or whether the respondents have any suggestions for improvement.

The Croatian versions of the UDI-6 and ICIQ-UI SF were then established (Appendices).

Statistical analysis

Continuous data is presented as mean ± standard deviation (SD), median and interquartile range (IQR), while discrete data is presented as frequencies and percentage. Reliability of UDI-6 and ICIQ-UI SF were assessed by Cronbach's Alpha coefficient. The test-retest reliability was calculated using intraclass correlation coefficient (ICC). Analysis of variance (ANOVA) was used to test differences for continuous data. The construct validity of both questionnaires was verified using the Kruskal-Wallis nonparametric test to detect differences between three groups (no urodynamic abnormality, SUI, DOA) and Spearman's rho coefficient to calculate the correlation between urodynamic values and results of the questionnaires. Significance values from post-hoc pairwise comparisons were adjusted by the Bonferroni correction for multiple tests. Chi-square test was used for comparisons between groups for categorical variables. Significance level was set as $p<0.05$. Data analysis was perfomed using SPSS 23.0 (IBM Corp., Armonk, NY). We analyzed only participants who had complete data in all the questionnaires.

Results

Sample characteristics

During the study period, 291 consecutive patients with UI symptoms were enrolled. Among them, 33 women fulfilled at least one exclusion criteria, hence were excluded from final analysis. Additional 26 women were lost to follow-up. Therefore, a total of 232 women were analysed and constituted the study population. The mean age ± sd of the

participants is shown in the Table 1. As seen, there was no significant difference in the mean age between three groups ($p>0.05$). No significant difference between the groups was found in average BMI scores ($p>0.05$) nor in education level ($p>0.05$). Statistically significant difference was obtained in parity ($p<0.05$), where women with SUI had significantly higher number of deliveries compared to group with no urodynamic abnormality and detrusor overactivity (DOA).

Reliability

Internal consistency assessed by the Cronbach's Alpha coefficient and test-retest reliability computed by the Intraclass Correlation Coefficient (ICC) are shown in Table 2. Values of Cronbach's Alpha indicate good internal consistency for UDI-6 as well as for ICIQ-UI SF, 0.83 and 0.85 respectively. Test-retest assessment was completed 2 weeks after baseline assessment, and obtained results indicate good reliability ranging from 0.97 to 0.99.

Construct validity

None of the items in UDI-6 failed either the convergent or the discriminant validity (Table 2). Post-hoc pairwise comparisons found that women with no urodynamic abnormality scored significantly lower on UDI-6 and ICIQ-UI SF compared with DOA and SUI group ($p<0.001$) (Table 3). Women with DOA scored significantly worse on Irritative and Obstructive symptoms when comparing with two other groups ($p<0.001$), while women with SUI had significantly worse score on subscale Stress symptoms when comparing with two other groups ($p<0.001$) (Table 3). Strong linear relationship was found between urodynamic findings and results on UDI-6 and ICIQ-UI SF ($\rho=0.880$

and ρ=0.888 respectively), as well as on all subscales of UDI-6 (Table 4). Futhermore, the correlation between total scores of UDI-6 and ICIQ-UI SF was high and significant (ρ=0.907; p<0.01).

Discussion

The present study provides validity and reliability evidence to support the use of the Croatian version of the UDI-6 and ICIQ-UI SF in everyday clinical practice and research. Both questionnaires present a simple tool with adequate consistency, reliability and validity as diagnostic instruments. Furthermore, this study shows a high correlation between the Croatian version of the UDI-6 and ICIQ-UI SF, addressing importance of standardized translation protocol.

Both questionnaires are used worldwide and our results are comparable to most other countries who also found good psychometric properties [7,8,10-16]. Specifically, internal consistency is considered adequate when the Cronbach's Alpha coefficient is at least 0.7 [17]. On the contrary, if the Cronbach's Alpha value is higher than 0.9, some questionnaire items are essentially asking the same thing in multiple ways, and therefore have to be removed [17]. In our study, Cronbach's Alpha coefficient for UDI-6 and ICIQ-UI SF was 0.83 and 0.85, respectively, indicating good internal consistency. Other studies found Cronbach's Alpha for UDI-6 ranging from 0.6 to 0.9, with the exception of Arabic validation who found α=0.32 (despite other very good psychometric characteristics) and Dutch validation α=0.49 for control group [10-13,18-21]. Our Cronbach's Alpha for ICIQ-UI SF is also consistent with other validation studies, who have found it to be in a range from 0.7 to 0.97 [15,16,22-24]. The validity was supported

by the high positive correlation between the both questionnaires and urodynamic findings.

One of the main UDI-6 strength is the separation of symptoms into three subscales, covering a whole spectrum of urogenital symptoms. Our study confirmed that the differences in subscales could discriminate different urodynamic findings. Specifically, higher irritative and obstructive symptoms were found in women with DOA, while higher stress symptoms subscale was found in women with SUI, which is largely consistent with other studies [10-12]. Based on current Croatian medical practice, UDI-6 is used at some primary heathcare providers and centers as a screening tool for women with UI. On the other hand, ICIQ-UI SF is more used in specialised urogynecological centers, as a standard method in preoperative and postoperative evaluation.

The limitation of the study is that we recruited patients from a tertiary refferal urogynecological centre. In such setting, we assume to have more patients with worse UI symptomatology, and therefore result generalization is limited.

In conclusion, the Croatian version of the UDI-6 and ICIQ-UI SF was successfully translated, adapted and validated so the questionnaires are now ready for use as a reliable tool for assessing women with UI in everyday clinical practice.

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Conflict of interest

The authors declare that they have no conflict of interest.

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Table 1. Characteristics and urodynamic diagnosis of the participants (n=232)

	No urodynamic abnormality (n=113)	SUI (n=63)	DOA (n=56)	p-value

Age	56.87 ± 7.598	54.32 ± 8.048	56.73 ± 7.914	0.095
BMI	29.14 ± 3.879	29.69 ± 4.01	28.01 ± 3.753	0.057
Education level				
Elementary	17 (15%)	6 (9%)	8 (14%)	
High school	55 (49%)	39 (62%)	21 (38%)	0.178
BsC	18 (16%)	11 (17%)	13 (23%)	
MA	23 (20%)	7 (11%)	14 (25%)	
Parity	1.93 ± .831	2.43 ± 1.132	1.77 ± 1.027	0.042

Table 2. Internal consistency, test-retest ICC and item convergent and discriminant validity

	Cronbach's Alpha	Test-retest reliability ICC	Item convergent validity [a] (success rate %)	Item discriminant validity [b] (success rate %)
UDI-6 baseline	0.83	0.99	N/A	N/A
Irritative symptoms	0.80	0.99	100%	100%
Stress symptoms	0.78	0.99	100%	100%
Obstructive symptoms	0.71	0.97	100%	100%
ICIQ-UI SF baseline	0.85	0.99	N/A	N/A

a Percentage of correlation coefficients calculated between one item and its score higher than 0.4
b Every time an item is correlated higher to a scale other than the one it belongs to is calculated as a failure.
N/A not available

Table 3. UDI-6 and ICIQ-UI SF total scores and subscale scores, baseline and retest (n=232)

	No urodynamic abnormality (n=113)		SUI (n=63)		Detrusor overactivity (n=56)		p-value
	mean ± sd	median (IQR)	mean ± sd	median (IQR)	mean ± sd	median (IQR)	
UDI-6 baseline	2.61 ± 4.138	0 (0-5.56)	40.74 ± 13.086	33.33 (33.33-50)	52.98 ± 15.056	50 (44.44-66.67)	.000
Irritative symptoms	1.33 ± 2.995	0 (0-0)	9.26 ± 5.556	11.11 (5.56-11.11)	24.21 ± 6.982	25 (16.67-27.78)	.000
Stress symptoms	.00 ± .000	0 (0-0)	23.99 ± 6.453	22.22 (16.67-27.78)	11.51 ± 6.073	11.11 (5.56-16.67)	.000
Obstructive symptoms	1.28 ± 2.349	0 (0-0)	7.50 ± 9.624	5.56 (0-11.11)	17.26 ± 8.252	16.67 (11.11-22.22)	.000
ICIQ-UI SF baseline	.05 ± .225	0 (0-0)	13.62 ± 3.123	14 (12-16)	15.07 ± 3.196	16 (13-17.75)	.000
UDI-6 retest	2.26 ± 3.902	0 (0-5.56)	41.71 ± 13.086	38.89 (33.33-50)	54.86 ± 15.171	55.56 (44.44-66.67)	.000
Irritative symptoms	1.23 ± 2.543	0 (0-0)	9.61 ± 5.574	11.11 (5.56-11.11)	24.50 ± 6.929	22.22 (18.06-31.94)	.000
Stress symptoms	.00 ± .000	0 (0-0)	24.34 ± 6.185	22.22 (22.22-27.78)	12.10 ± 6.366	11.11 (5.56-16.67)	.000
Obstructive symptoms	1.03 ± 2.294	0 (0-0)	7.76 ± 7.094	5.56 (0-11.11)	18.25 ± 8.522	16.67 (11.11-26.39)	.000
ICIQ-UI SF retest	.05 ± .225	0 (0-0)	13.75 ± 2.984	14 (12-16)	15.23 ± 3.139	16 (13-17)	.000

*p-values were calculated using Kruskal-Wallis test

Table 4. Correlation between urodynamic findings, UDI-6 total score and subscales and ICIQ-UI SF

	Urodynamic	UDI-6	Irritative	Stress	Obstructive	ICIQ-UI SF
Urodynamic finding	1	0.880**	0.896**	0.763**	0.745**	0.888**
UDI-6		1	0.899**	0.830**	0.836**	0.907**
Irritative symptoms			1	0.643**	0.699**	0.795**
Stress symptoms				1	0.538**	0.861**
Obstructive symptoms					1	0.730**
ICIQ-UI SF						1

** $p<0.01$

Appendices

A1: Upitnik urinarnih tegoba, kratka verzija (UDI-6)

Za svako pitanje, zaokružite broj koji najbolje opisuje taj problem za Vas u posljednjih mjesec dana.

Jeste li doživjeli i, ako jeste, koliko Vas muči:

1. Učestalo mokrenje
2. Nevoljni gubitak urina zbog hitnoće?
3. Gubljenje mokraće prilikom (fizičke) aktivnosti? (hodanje, trčanje, smijanje, kihanje, kašljanje)
4. Male količine gubitka urina? (kapi)
5. Poteškoće sa pražnjenjem mjehura ili mokrenjem?
6. Bol ili nelagoda u donjem dijelu trbuha, zdjelici ili genitalnom području?

0 = ne uopće; 1 = malo; 2 = umjereno; 3 = prilično

A2: ICIQ-UI kratka verzija

Velik broj osoba ima povremeno nevoljno bježanje mokraće. Ovim upitnikom želimo otkriti koliki broj osoba ima nevoljno bježanje mokraće i koliku smetnju im to predstavlja. Bili bismo zahvalni ako biste mogli odgovoriti na niže navedena pitanja razmišljajući o tome kakve ste tegobe imali UNAZAD ČETIRI TJEDNA:

1. Koliko često vam bježi mokraća?

0 = nikada; 1 = otprilike jednom tjedno ili rjeđe; 2 = dvaput ili triput tjedno; 3 = otprilike jednom dnevno; 4 = više puta dnevno; 5 = stalno

2. Ovim pitanjem želimo utvrditi koliko prema *Vašem mišljenju* urina Vam pobjegne. Koliko urina prema Vašem mišljenju Vam *uobičajeno* pobjegne?

0 = ništa; 2 = mala količina; 4 = umjerena količina; 6 = velika količina

3. Ukupno gledano, koliko značajno bježanje mokraće (urinska inkontinencija) utječe na Vaš svakodnevni život?

rang od 0 = nimalo do 10 = značajno