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Comparison of Two Questionnaires for Assessing the Severity of Urinary Incontinence: The ICIQ-UI SF Versus the Incontinence Severity Index

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Aims: To compare the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) with the Incontinence Severity Index (ISI), and to propose intervals for four severity levels of ICIQ-UI SF. **Methods:** Cross-sectional, Internet-based study of 1,812 women responding to a general health questionnaire. Four severity levels for the ICIQ-UI SF scores were constructed by iteratively adjusting the ranges for these levels until maximum Kappa scores were obtained when cross-tabulated with the ISI in a random sample of half of the women with urinary incontinence. Using these intervals, weighted Kappa was calculated for the remaining women as a validation process. **Results:** Three hundred forty-three women had urinary incontinence, and completed the ISI and the ICIQ-UI SF. A high correlation between the ISI and ICIQ-UI SF scores with versus without the QoL item was found (Spearman's rho = 0.62, $P < 0.01$ vs. rho = 0.71, $P < 0.01$, respectively). Maximum Kappa with quadratic weighting was obtained for the following scale for the ICIQ-UI SF: slight (1–5), moderate (6–12), severe (13–18) and very severe (19–21) (Kappa = 0.61), and without the QoL item: slight (1–3), moderate (4–5), severe (6–9) and very severe (10–11) (Kappa = 0.71) in the development sample. Correspondingly, for the validating sample, maximum Kappa with quadratic weighting was 0.61 and 0.74. **Conclusions:** A high correlation between the ICIQ-UI SF and the ISI was found. The ICIQ-UI SF may be divided into the following four severity categories: slight (1–5), moderate (6–12), severe (13–18) and very severe (19–21). *Neurourol. Urodynam. 28:411–415, 2009.*
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Key words: female; Internet; questionnaires; urinary incontinence; validation studies

INTRODUCTION

There is a need for valid instruments for between-study comparisons of patients' characteristics and outcomes in studies of urinary incontinence (UI) performed in different settings. Especially, robust methods for assessing the severity of UI in both epidemiological and clinical settings are welcome. Two of the validated questionnaires for assessing the severity of UI in women are the Incontinence Severity Index (ISI),[1] validated in several studies,[2–4] and the International Consultation on Incontinence Questionnaire—Urinary Incontinence Short Form (ICIQ-UI SF),[5] also validated in several studies.[6–15] Both questionnaires were highly recommended by the 2004 International Consultation on Incontinence, and were awarded Grade A status based on standard validation criteria.[16] Both questionnaires assess frequency and volume. The ICIQ-UI SF also assesses impact on quality of life (QoL), while the ISI purposely does not. Responsiveness to change has been shown for the ISI.[3] Randomized controlled trials of conservative and surgical treatments of UI have been published for both the ICIQ-UI SF[17,18] and the ISI.[19,20]

The present study is a comparative analysis of these two instruments. We also wanted to determine if the severity categories of the ISI could be used to develop similar or corresponding severity categories for the ICIQ-UI SF, using questionnaire data collected by a survey on the Internet.

MATERIALS AND METHODS

The WEB-EPI Study

We used web-banners to invite a convenience sample of women to join a women's health study on the Internet, focusing on women's general health; not just on urinary incontinence. The banners or links led to a short introductory page presenting the logo of the University of Bergen and our department. The introductory page presented the title "Women's Health Study 2002," followed by a paragraph about the general purpose of the study, including information stating that entries would be anonymous, and the data collected would be used only for research purposes. No specific

Conflicts of Interest: none.
Abbreviations used: UI, urinary incontinence; ICIQ-UI SF, the international consultation on incontinence questionnaire—urinary incontinence short form; ISI, the incontinence severity index; GP, general practitioner.
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information about our intention to compare two similar indexes was given. Those not willing to participate were advised to click their way out.

Web page 2 requested information about six items (age, gender, menarche, menopause, pregnancy, and number of children). Web page 3 presented six more items (number of voidings per 24 hr, nocturia, urinary tract infections, completeness of bladder emptying, urgency, and urinary leakage). Urinary leakage was the only branching item in the entry form. It was formulated "Do you have urinary leakage?" ("Yes" or "No"), and clicking here was the only mandatory item to be entered. "No" directed the respondent to the exit page, where the respondent could choose between "Finish" and "Clear" in English language. "Yes" defined the respondent as having urinary incontinence in accordance with the definitions set by the International Continence Society.[21] The respondent was then led to an incontinence questionnaire with 10 items, including the ISI, and then led to the next web page with the four-item ICIQ-UI SF. "Next Page" or "Clear" lead to the exit page, with the choice between "Finish" and "Clear" in English language. After the exit page, the users were hyperlinked to a web page with general information about UI at www.NettDoktor.no.[22]

Type of UI was determined by two questions. If the respondent answered "Yes" to loss of urine when coughing, sneezing, laughing or lifting heavy weights, a stress component was defined. If she answered, "Yes" to leaking urine when experiencing a sudden and strong urge to urinate, an urgency component was defined. When answering "Yes" to both of these two questions, the respondents were defined as having mixed incontinence. "No" to both questions, or "No" to one and "Missing" to the other were grouped as "Other." This diagnostic classification has previously been used in many studies, including the EPINCONT study.[23]

The respondents were not promised any score or feedback, and no kinds of incentives were offered. We had no initial contact with potential participants. Respondents claiming that they had no urinary incontinence had to go through four web pages, while those stating urinary incontinence had to go through six web pages. Some of these pages were larger than normal screen resolution size, and had to be scrolled. All navigation buttons were in English language. There were no "Back" buttons, only "Next Page" or "Clear" on each page. Users were not provided a summary of their responses before the results were submitted.

The Survey Database

The survey used the Inquisite software Version 3.1 (1999) (Inquisite Inc., Austin, TX, USA). DATA were deployed to a database located at a web hotel at UNI·C, The Danish IT Centre for Education and Research. No passwords were used for entering the form to be completed. Colleagues piloted the usability and technical functionality of the survey before it was fielded. Log files were checked, and contained no person identification items, e-mail addresses, or IP-addresses. Cookies were not used. The participation rate, page views, and completion rates were not determined. No check was performed to prevent users accessing the survey several times. All data were time stamped, but there was no track of the length of time used to fill in the form.

Recruitment and Respondents

Female users of three major Norwegian Internet sites were asked to join the study: A general health web site, the health section of a general purpose Internet portal, and Norway's largest newspaper web site (see below). The first two used fixed placed banners containing the logo of the University of Bergen.

Between February 23 and April 22, 2002 women accessing the front page of the NettDoktor web site (www.NettDoktor.no) were recruited by a banner with the text: "Join the large women's health study at the University of Bergen." NettDoktor was at that time the Norwegian part of Europe's largest general health web site. Between April 25 and August 20, 2002 women were able to access the study via StartSiden (www.startsiden.no), a general-purpose portal, where we used the text "UiB/Join the women's health study" at the front page of the health section. The newspaper VG's web portal "VG på Nett" (www.vg.no) interviewed one of the authors (AK) about the study and urinary tract disorders, incorporating a direct link to the study in the web text, easily accessible in the period from March 4 to 6, 2002.

The Incontinence Severity Index (ISI)

The ISI is a multiplicative score based on two items assessing the frequency and volume of incontinence [1] "How often do you experience urinary leakage?" (Four levels: 1 "Less than once a month," 2 "A few times a month," 3 "A few times a week," 4 "Every day and/or night") and [2] "How much urine do you lose each time?" (Three levels: 1 "Drops," 2 "Small splashes," 3 "More"), resulting in an eight-level multiplicative index score with values from 1 to 12. The index score is then further categorized into four levels of incontinence severity: "Slight" (scores 1 and 2), "Moderate" (scores 3, 4 and 6), "Severe" (scores 8 and 9) or "Very severe" (score 12).[2] The ISI has later been scored "0" for no incontinence, after being used in studies where, for example, treatments lead to no incontinence.

The ISI has been validated against pad weighing.[2–4] Slight incontinence was found to indicate a leakage of 6 g/24 hr (95% CI, 2–9), moderate incontinence 23 g/24 hr (95% CI, 15–30), severe incontinence 52 g/24 hr (95% CI, 38–65), and very severe incontinence 122 g/24 hr (95% CI, 84–159).[2] The four-level ISI is thus a semi-objective and quantitative measure, which does not include a quality of life dimension or other subjective perceptions of leakage as being a problem or not. ISI was used in its original form in Norwegian.

The International Consultation on Incontinence Questionnaire—Urinary Incontinence Short Form (ICIQ-UI SF)

The ICIQ-UI SF is a sum-score developed by the International Consultation on Incontinence Modular Questionnaire study group (for further information contact www.iciq.net).[5,24] The ICIQ-UI SF is developed for assessing the prevalence, severity, impact on quality of life, and type of UI.[5,16] The three scored items of the ICIQ-UI SF are: [1] "How often do you leak urine?" (0 "Never," 1 "About once a week or less often," 2 "Two or three times a week," 3 "About once a day," 4 "Several times a day," 5 "All the time"), [2] "How much urine do you usually leak (whether you wear protection or not)?" (0 "None," 2 "A small amount," 4 "A moderate amount," and 6 "A large amount"), and [3] "Overall, how much does leaking urine interfere with your everyday life?" (Visual analogue scale ranging from 0 "Not at all" to 10 "A great deal"). The answers result in a sum, with minimum score of 0, and maximum score of 21. Preliminary cut-off scores were set to 0 = "no incontinence" and ≥1 = "urinary incontinence." We

used a Norwegian version of the ICIQ-UI SF that was translated from English.

The ICIQ-UI SF also comprises a fourth non-scored self-diagnostic item included by the expert committee because it was thought to be useful in clinical practice, to understand patients' perception of the cause and type of leakage.[5]

Statistical Methods

The four levels of the ISI were plotted against the ICIQ-UI SF total sum-score with and without the QoL dimension. The association between the ISI and ICIQ-UI SF scores was investigated by Spearman's rank correlation coefficient (rho).

In order to develop a four-level categorical scale for the ICIQ-UI SF sum-scores, the original sample (n = 343) was randomly split into two samples by using a "random selection of cases"—function in SPSS. The first file (n = 171) was used to develop the scale for the four severity levels for the ICIQ-UI SF scores, while the second file with the remaining cases (n = 172) was used to validate these scales.

The sum-scores for the ICIQ-UI SF with (total score 0 to 21) and without the QoL item (total score 0 to 11) were recoded into four levels: slight, moderate, severe, and very severe. The degree of four-level agreement between the ICIQ-UI SF with and without the quality of life dimension, and the four-level ISI was explored using Cohen's unweighted Kappa statistics for the different cut-off limits for the four levels. This was done by cross-tabulating the four ICIQ-UI SF and ISI levels repeatedly using the first file (n = 171), until maximum unweighted Cohen's Kappa value ($Kappa_{max}$) was achieved. Looking at the distribution of cases in the cells of the 2×2-table helped deciding how the intervals should be adjusted to obtain unweighted Cohen's $Kappa_{max}$.

These final recoding intervals were then applied to the second sample (n = 172) and also tested by Kappa statistics. Since SPSS cannot calculate Kappa with linear and quadratic weighting without programming, this was easily calculated by entering these 4×4 tables into Professor Richard Lowry's VassarStats (http://faculty.vassar.edu/lowry/kappa.html).

Statistical significance was accepted at the 5% level ($P < 0.05$).

RESULTS

Altogether 1,812 women completed the entry questionnaire. Of these, 343 (19%) declared having any involuntary urinary leakage, and were subsequently branched into the urinary incontinence arm of the study. Mean age (SD) for these women was 36.5 (11) years and the distribution of stress, urge, mixed, and other incontinence was 41%, 17%, 39%, and 3%, respectively. We found no statistically significant differences between corresponding variables from the three different web sites. All data were therefore analyzed as a whole.

Responses (n = 343) to the ISI item assessing frequency were 14% "less than once a month," 34% "a few times a month," 34% "a few times a week," and 18% "every day and/or night." Responses to the ISI item assessing volume were 54% "drops," 42% "small splashes," and 4% "more." The mean ISI score (SD) was 1.82 (0.70). The mean (SD) ICIQ-UI SF total score was 7.4 (3.6) with, and 4.3 (1.7) without the QoL item.

There were strong correlations between the four-level ISI severity index and ICIQ-UI SF scores with versus without the QoL item, Spearman's rho was 0.62, $P < 0.01$ versus 0.71, $P < 0.01$. The mean ICIQ-UI SF scores corresponding to the four levels of the ISI are shown in Table I.

TABLE I. Mean (SD) ICIQ-UI SF Score With and Without the QoL Dimension for Each Level of ISI

	ICIQ-UI SF with QoL		ICIQ-UI SF without QoL	
ISI levels	Mean	SD	Mean	SD
Slight	5.0	1.9	3.1	0.5
Moderate	7.5	2.8	4.3	1.2
Severe	12.4	3.4	6.8	1.1
Very severe	16.3	3.8	9.4	1.2

By adjusting the intervals for the ICIQ-UI SF total score for the study subjects in the first scale development file to obtain maximum agreement with the four levels of the ISI, we could define the following intervals for the ICIQ-UI SF (n = 171) (Table II): slight (1–5), moderate (6–12), severe (13–18), and very severe (19–21) (Kappa with quadratic weighting = 0.61). Similarly, for the ICIQ-UI SF without the QoL item, we could define the following levels: slight (1–3), moderate (4–5), severe (6–9), and very severe (10–11), (Kappa with quadratic weighting = 0.71) (Table II). Applying these intervals to the second sample (n = 172) in order to validate our findings, Kappa with quadratic weighting for ICIQ-UI SF with and without the QoL item was 0.61 and 0.74, respectively (Table III).

DISCUSSION

So far, this study is the first study designed to propose a severity categorization for the ICIQ-UI SF. We found a strong and statistically significant positive linear correlation between the ISI and ICIQ-UI SF scores with and without the QoL dimension.

All the women filled in the two validated questionnaires, and those who were continent were not branched into this comparative part of the study. This may easily occur in standard postal epidemiologic studies: respondents saying "No" to an entry question, but still filling in data as if they had answered "Yes." This is possible to avoid in web-based studies, and we regard this to be an advantage.

One disadvantage of using the Internet is that if respondents hit the "Back" button, this might corrupt data. We discovered that the Inquisite software did not handle this technicality properly, and this seems to be a common problem for most web-based questionnaires. We checked the log files in order to detect any signs of data corruption, but discovered none. Still, this is principally a weak point for such studies. One solution might be to use one-page only web forms.

Another weakness with our study is that our concealment procedure reduced the total number of respondents from 1,812 respondents to 343, as we could only use responses from women with UI, and we did not know the prevalence a priori. For the sake of statistical power, perhaps even more women should have been included. Also, there was a skewed age distribution, our Internet population being younger than in most other epidemiological samples. Consequently, the severity categories we identified might not be valid for an elderly population. A larger study is necessary to clarify the ICIQ-UI SF levels for very severe incontinence, since our study had limited statistical power in the category "very severe."

The correlation was stronger without the QoL item than with, partly due to the fact that the ISI is a two-item multiplicative score of frequency and amount of urinary leakage, compared to ICIQ-UI SF, which is a three-item sum-score of frequency, amount and a QoL item. Also, the

TABLE II. Maximum Kappa Values for Data in the Development Sample for ICIQ-UI SF With and Without the QoL-Item (n = 171)

	ICIQ-UI SF total score				
ISI	1 'Slight' (1–5)	2 'Moderate' (6–12)	3 'Severe' (13–18)	4 'Very severe' (19–21)	
1 'Slight'	**38**	**15**			53
2 'Moderate'	**25**	**62**	**4**		91
3 'Severe'		**11**	**5**		16
4 'Very severe'			**1**	**2**	3
	63	88	10	2	163
			95% CI		
Unweighted Kappa		0.39	0.27–0.52		
Kappa with linear weighting		0.48	0.36–0.60		
Kappa with quadratic weighting		0.61	0.30–0.92		
	ICIQ-UI SF score without QoL				
ISI	1 'Slight' (1–3)	2 'Moderate' (4–5)	3 'Severe' (6–9)	4 'Very severe' (10–11)	
1 'Slight'	**47**	**6**	**1**		54
2 'Moderate'	**27**	**49**	**15**		91
3 'Severe'			**16**		16
4 'Very severe'			**1**	**2**	3
	74	55	33	2	164
			95% CI		
Unweighted Kappa		0.53	0.42–0.64		
Kappa with linear weighting		0.61	0.51–0.71		
Kappa with quadratic weighting		0.71	0.46–0.96		

correlation between severity and QoL is probably non-linear. The ISI purposely does not include the "QoL" item, whereas the ICIQ does. We therefore chose to analyze the ICIQ-UI SF with and without the QoL dimension, and found higher Kappa-values without the QoL dimension. We were, however, able to develop a four-level scale for the ICIQ-UI SF both with and without the QoL item, and we found the categorization sufficiently accurate and valid. No other measure of bother was used in this survey—the main aim was a comparison of two validated UI severity scales, the ICIQ-UI SF, and the ISI. The proposed severity categories identified for the ICIQ-UI SF in this study have not been correlated against a QOL- or "bother"-measure. It has been acknowledged that severity and bother are two different concepts.[16]

The ISI and the ICIQ-UI SF questionnaires are both appropriate for use in epidemiologic studies, but more information on how these instruments perform in clinical practice and for clinical research in primary and secondary care settings, would be welcome.

CONCLUSIONS

This study showed a high correlation between the ICIQ-UI SF and the ISI, and we propose the following severity intervals

TABLE III. Maximum Kappa Values for Data in the Validation Sample for ICIQ-UI SF With and Without the QoL-Item (n = 172)

	ICIQ-UI SF total score				
ISI	1 'Slight' (1–5)	2 'Moderate' (6–12)	3 'Severe' (13–18)	4 'Very severe' (19–21)	
1 'Slight'	**35**	**25**			60
2 'Moderate'	**16**	**64**	**6**	**2**	88
3 'Severe'		**6**	**10**	**1**	17
4 'Very severe'				**2**	2
	51	95	16	5	167
			95% CI		
Unweighted Kappa		0.42	0.30–0.55		
Kappa with linear weighting		0.50	0.39–0.62		
Kappa with quadratic weighting		0.61	0.32–0.91		
	ICIQ-UI SF score without QoL				
ISI	1 'Slight' (1–3)	2 'Moderate' (4–5)	3 'Severe' (6–9)	4 'Very severe' (10–11)	
1 'Slight'	**47**	**5**			52
2 'Moderate'	**27**	**51**	**17**		95
3 'Severe'		**1**	**15**		16
4 'Very severe'			**2**	**3**	5
	74	57	34	3	168
			95% CI		
Unweighted Kappa		0.53	0.42–0.63		
Kappa with linear weighting		0.62	0.53–0.71		
Kappa with quadratic weighting		0.74	0.54–0.94		

for the ICIQ-UI SF: slight (1–5), moderate (6–12), severe (13–18), and very severe (19–21).

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