



Domain Comparison Between 6 Validated Questionnaires Administered to Women With Urinary Incontinence

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OBJECTIVES To compare patients' questionnaire-reported urinary incontinence (UI) symptoms to determine which have the best concordance.

METHODS Women with self-reported mixed UI were asked to report quality of life (QoL) due to urinary problems on a visual analog scale and complete 6 standardized validated questionnaires with questions on mixed UI (Medical Epidemiological and Social Aspects of Aging questionnaire, the Urogenital Distress Inventory short form [UDI-6], the Incontinence impact questionnaire short form [IIQ-7], the International Consultation on Incontinence Questionnaire Urinary Incontinence short form [ICIQ-SF], the King's Health Questionnaire [KHQ], and Patient Global Impression of Severity Scale [PGI-S]). Specific questions related to stress urinary incontinence (SUI), urgency urinary incontinence (UUI), UI severity, and QoL were compared within surveys from each patient with a Pearson correlation coefficient.

RESULTS Twenty consecutive women participated in the study with a mean age of 64 ± 13 years and mean time to complete all surveys of 11.2 ± 5.4 minutes. In SUI and UUI subdomains, KHQ, UDI-6, and Medical Epidemiological and Social Aspects of Aging questionnaire were well correlated, however, specific ICIQ questions related to SUI and UUI were less often well correlated. For severity subdomains the UDI-6 score was poorly correlated with the KHQ, PGI-S, and ICIQ scores (all $P > .1$). KHQ correlated well with the PGI-S ($0.64, P = .003$) and ICIQ score ($0.58, P = .008$). PGI-S and ICIQ severity scores were also well correlated ($0.56, P = .012$). QoL on a VAS (range: 1-10) was significantly well correlated with both KHQ ($0.75, P < .001$) and the IIQ-7 ($0.64, P = .003$). KHQ and IIQ-7 were also well correlated ($0.64, P = .003$).

CONCLUSION In this pilot study, validated questionnaires with questions regarding UI are mostly well correlated in women for subdomains of SUI, UUI, QoL, and severity. For UI symptoms and UI symptom severity the ICIQ and UDI-6, respectively, are poorly correlated with other survey results and may be less indicative of patient's complaints. UROLOGY 132: 75–80, 2019. © 2019 Elsevier Inc.

Urinary incontinence (UI) is defined by the International Continence Society as the complaint of involuntary urinary leakage that is commonly associated with urgency (urge incontinence) or also with exertion, effort, sneezing, or coughing (stress incontinence) or both (mixed urinary incontinence, MUI).¹ Traditionally, a diagnosis of UI triggers clinicians to delineate

a predominant symptom of either stress urinary incontinence (SUI) or urgency urinary incontinence (UUI) and follow the appropriate treatment paradigm for that particular entity. However, it is often difficult for a woman to tease out her UI symptomatology and clearly provide a self-reported estimate of how much stress incontinence or urge incontinence affects her on a daily basis.

In an effort to clarify symptomology, severity and impact on quality of life, over 40 validated questionnaires² have emerged to try to quantitate UI symptoms. However, it appears that there is a significant divide geographically between the types of questionnaires commonly used across the world.³⁻⁵ Consequently, there exists no predominant questionnaire that is universally accepted by clinicians

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and researchers. This lack of consensus makes it difficult to compare or translate results of validated questionnaires in a variety of clinical and research settings, including meta-analysis of surgical repairs for UI.

The objective of this study is to compare scoring in selective subdomains of the most commonly used validated questionnaires for UI throughout the world to allow for comparison of results within research studies and across clinical practice.

METHODS

Following Institutional Review Board approval, adult women seen as a new patient with self-reported UI in a Female Pelvic Medicine and Reconstructive Surgery clinic were asked to participate in a questionnaire-based study. After obtaining informed consent, participants were asked to rate their quality of life on a visual analog scale of 1-10 and complete a total of 6 validated questionnaires. Their age and time to complete these 6 questionnaires was recorded in addition to their survey responses. Questionnaires were administered in random order to eliminate any potential bias.

Based on a prior comprehensive review of the medical literature between 2010 and 2015 indicating the most commonly used questionnaires in women undergoing UI surgery,⁶ the

following validated questionnaires were administered: the King's Health Questionnaire (KHQ), the International Consultation on Incontinence Questionnaire Urinary Incontinence short form (ICIQ-SF), the Urogenital Distress Inventory short form (UDI-6), the Incontinence impact questionnaire short form (IIQ-7), Medical Epidemiological and Social Aspects of Aging questionnaire (MESA), and the Patient Global Impression of Severity Scale (PGI-S).

Questionnaire scores were compared to select specific subdomains specific to SUI and UUI symptoms, incontinence severity, and quality of life (Table 1). Missing data were treated as a score of zero when needed for scoring.

Questionnaire Content and Development

The KHQ is a self-administered questionnaire validated in patients with urinary incontinence consisting of 21 items in 3 parts.⁷ Part 1 consists of 1 question on general health perception and incontinence impact, respectively. Part 2 contains a total of 11 items specific to role limitations, physical limitations, social limitations, personal limitations, emotional problems, sleep/energy disturbance, and symptom severity. Each of these subdomains is scored from 0 (best) to 100 (worst). Part 3 consists of 10 single items focusing on frequency, nocturia, urgency, urge, stress, intercourse incontinence, nocturnal enuresis, infections, pain, and difficulty in voiding which are scored from 1 (best) to

Table 1. Subdomains of validated questionnaires compared for patients with mixed urinary incontinence

	SUI	UUI	Incontinence severity	QoL
Patient self-report	—	—	—	Visual analog scale (0-10)
KHQ	Severity symptom scale question E: "How much does stress incontinence: urinary leakage with physical activity, eg, Coughing, running affect you?"	Severity symptom scale question D: "How much does urge incontinence: a strong and difficult to control desire to pass urine affect you?"	Incontinence impact score (question 2): "How much do you think your bladder problem affects your life?"	Severity measure (question 8) A calculated score answering "Do you do any of the following?": <ul style="list-style-type: none"> • Wear pads to keep dry? • Be careful how much fluid you drink? • Change your underclothes because they get wet? • Worry in case you smell?
ICIQ-SF	Question 4: "When does urine leak?" subsection c: e: "leaks when you are physically active/dressing"	Question 4: "When does urine leak?" subsection b: "leaks before you can get to the toilet" & d: "leaks when you are asleep"	ICIQ Score (Q1: How often do you leak urine? +Q2: How much urine do you usually leak?+Q3: Overall, how much does leaking urine interfere with your everyday life?)	—
UDI-6	Question 3: "Do you experience and how much are you bothered by urine leakage related to physical activity, coughing, or sneezing?"	Question 2: "Do you experience and how much are you bothered by urine leakage related to the feeling of urgency?"	Total score/Q 2+3	—
IIQ-7	—	—	—	Total score
MESA	Stress incontinence score	Urge incontinence score	—	—
PGI-S	—	—	Score	—

4 (worst). The validity and reliability of the KHQ was initially tested by completion of the questionnaire by 293 consecutive women referred for investigation of urinary incontinence at King's College Hospital in London, UK. Criterion validity was measured by comparison to, a generic quality of life measure, the UK version Short form 36 questionnaire.⁸ KHQ has subsequently been adopted for male patients and for overactive bladder with validation in over 33 languages.^{9,10}

The ICIQ-SF is a 4-item incontinence-specific self-administered questionnaire developed by the ICI with the intention to create a brief, simple, and easily adoptable outcome measure.¹¹ The first 3 items are scored and summed to create a severity score ranging from 0 (slight) to 3 (very severe). The last item is an unscored self-diagnostic item with 8 subsections. The ICIQ-SF underwent a rigorous development process to assess its psychometric properties with a variety of sampling methods with a diverse sample of patients. For convergent validity, a total of 118 women's responses were correlated with the Bristol Female Lower Urinary Tract Symptoms questionnaire¹² "incontinence" and "quality of life" factors and 91 women's responses were correlated with the KHQ.

The UDI-6 and IIQ-7 were short forms derived from the original 19-item UDI and 30-item IIQ, developed to assess the type and bother associated with UI, and the impact of UI on activities of daily living.¹³ The UDI-6 consists of 6 items examining 3 subscales including irritative symptoms, obstructive/discomfort, and stress symptoms. The IIQ-7 is comprised of 7 items evaluating subscales of activity, travel, social relationships, and Emotional Health. Responses for both questionnaires are scored on a scale of 0 (not at all) to 3 (greatly) and calculated to provide a total score ranging from 0 to 100.¹⁴ Psychometric evaluation of the original IIQ and UDI questionnaires was conducted via administration in a population of community-dwelling women and comparison to incontinence severity on a 1-hour pad test. The short forms were subsequently correlated with long-form scores for validity.

MESA is a 15-item questionnaire designed to evaluate the predominance of UUI (based on 6 questions) or SUI (based on 9 questions) in patients with MUI. Questions are scored from 0 to 3 with the resultant scores calculated to provide a percentage score for both UUI and SUI. Both scores can range from 0% to

100%.¹⁵ This measure was developed to examine the pattern of UI in a representative sample of adults 60 years and over in Michigan County. Responses were correlated with a clinical evaluation for urinary incontinence at the University of Michigan Medical Center involving history, physical examination, and a simple provocative stress test.

The PGI-S is a 1-item questionnaire which aims to quantify the patient's perception of incontinence severity.¹⁶ It is scored on a 4-point scale from 1(normal) to 4(severe). The PGI-S was validated analyzing data from 2 double-blind placebo controlled trials studying duloxetine for the treatment of SUI in the United States. PGI-S construct validity was confirmed with statistically significant correlation of PGI-S responses with mean incontinence episode frequency, median fluid loss on stress pad test, and mean I-QOL scores.

Statistical Analysis

Based on our null hypothesis that the baseline correlation of the questionnaire subdomains is 0, the minimum required sample size for this study was calculated to be 19 to obtain a minimum correlation coefficient of 0.6, with 80% power and alpha of 0.05. Descriptive statistics were calculated as means, ranges, and standard deviation for continuous variables. Selected subdomains of validated questionnaires were assessed for correlation using the Pearson's correlation coefficient. All analyses were performed using SAS, version 9.4.

RESULTS

A total of 20 consecutive women over a 3-month enrollment phase participated in this pilot study with a mean age of 64 ± 13 years and mean time to complete all 5 surveys of 11.2 ± 5.4 minutes. Results of the comparison of both SUI and UUI subdomains of the questionnaires are displayed in [Table 2](#).

SUI Subdomains

On the ICIQ question 4, "When does urine leak?," the answer to the subsection "leaks when you are physically active/dressing"

Table 2. Correlation between questionnaires for SUI and UUI subdomain scores

	Pearson Correlation, <i>P</i> Value			
	UDI-6 Q3	MESA SUI	ICIQ Q4c	ICIQ Q4e
SUI subdomain				
KHQ SUI	0.69 0.0007	0.54 0.0145	0.51 0.0218	0.35 0.1298
UDI-6 Q3	-	0.59 0.0058	0.65 0.0018	0.45 0.0467
MESA SUI	-	-	0.54 0.0150	0.25 0.2965
ICIQ1 Q4c	-	-	-	0.69 0.0008
UUI Subdomain				
KHQ UUI	0.76 0.0001	0.66 0.0017	0.59 0.0067	0.48 0.0314
UDI-6 Q2	-	0.67 0.0012	0.44 0.0496	0.33 0.1510
MESA UUI	-	-	0.50 0.0234	0.34 0.1423
ICIQ Q4b	-	-	-	0.25 0.2878

SUI questions are compared on the top; UUI questions are compared on the bottom.

was poorly correlated with the KHQ question “How much does stress incontinence: urinary leakage with physical activity, eg, Coughing, running affect you?” (Pearson correlation 0.35, $P = .13$) and the MESA Stress Incontinence Score (Pearson correlation 0.25, $P = .30$). All remaining questionnaire subdomains for SUI were well correlated to one another.

UUI Subdomains

the answer to ICIQ question 4 subsection “leaks when you are asleep” poorly correlated with UDI-6 question 2 “Do you experience and how much are you bothered by urine leakage related to the feeling of urgency?” (Pearson correlation 0.33, $P = .15$), the MESA Urge Incontinence Score (Pearson correlation 0.35, $P = .14$), and the ICIQ question 4 answer to “leaks before you can get to the toilet” (Pearson correlation 0.25, $P = 0.29$). However, other questionnaire subdomains for UUI were well-correlated to each other.

Symptom Severity Subdomains. Correlation for questionnaire subdomains for severity is seen in Table 3. The UDI-6 total score was poorly correlated with the KHQ incontinence impact score (Pearson correlation 0.29, $P = .22$), PGI-S (Pearson correlation 0.33, $P = .17$), and the ICIQ score (Pearson correlation 0.28, $P = .23$). The UDI-6 score questions 2 and 3 which specifically assess UUI and SUI severity were also found to be poorly correlated with the above questionnaires. However the KHQ, PGI-S, and ICIQ score were well correlated with one another.

Quality of Life Subdomains. The KHQ severity measure for quality of life, the QoL VAS, and IIQ-7 scores were well correlated to each other on QoL subdomain comparison: KHQ was well correlated to QoL (Pearson correlation 0.75, $P < .001$) and IIQ-7 (Pearson correlation 0.64, $P = .003$). The QoL and IIQ-7 were also significantly correlated to each other (Pearson correlation 0.64, $P = .003$).

Unanswered Questions. Unanswered or blank questions were relatively rare. Less than 5% of questions were left unanswered (71/1440 questions; Supplementary Table 1). The IIQ-7, ICIQ-SF, and PGI-S had only 1 question that was unanswered by 1 participant (5%). The MESA had 2 questions that were left unanswered, 1 by 2 participants (10%) and 1 by 1 participant (5%). When asked to specifically answer only problems that affected the participant in part 1 of the KHQ, 7-14 participants (35%-70%) left 5 items blank. The most commonly unanswered question was waterworks, which 14 (70%) participants left blank. In the KHQ, 1 question regarding role limitations and

3 questions regarding personal relationships were left blank 5%-25% of the time.

DISCUSSION

In this pilot study, comparing patient’s questionnaire reported symptoms of SUI, UUI, incontinence severity, and quality of life; we found that the prespecified subdomains of the MESA, ICIQ-SF, KHQ, IIQ-7, UDI-6, and PGI-S were generally well correlated with few exceptions. For UI symptoms and UI symptom severity the ICIQ subdomains, specifically answer of yes to “leaks when you are asleep” for UUI or “leaks when you are physically active/dressing” for SUI did not correlate well with other subdomains. A negative answer to these specific questions may not exclude the presence of UUI or SUI respectively. The total UDI-6 score as well as questions 2 and 3 which specifically indicate the presence and bother associated with UUI and SUI, respectively, were not correlated with other questionnaire subdomains for incontinence severity. This suggests that incontinence severity may be better determined by the use of the KHQ or ICIQ-SF in place of the UDI-6 or the addition of a short one-question PGI-S. However, this does not preclude the use of these surveys in clinical practice or research investigations.

For severity of incontinence, the PGI-S, KHQ, and ICIQ score were well correlated. Again, this suggests the scores within these surveys are comparable and translatable. The UDI-6 total score was not comparable in terms of incontinence severity. Given the heterogeneity of the questions that comprise the UDI-6 score, this is not surprising. The UDI-6 score is made up of questions that are not specific to UI severity and addresses other “distress” subdomains such as bladder pain, voiding dysfunction and urgency, frequency. Surprisingly, the PGI-S with only 1 item is able to capture the severity of incontinence similar to that of the KHQ and ICIQ. This may be favorable for use in clinical practice as it is efficient and user-friendly for patients to complete.

In regards to impact on QoL, the KHQ and IIQ-7 subdomains correlate well with one another and with the patient-self reported QoL due to urinary problems on a visual analog scale. QoL is an often used, easy to administer/interpretable and generalizable, broad tool and can be

Table 3. Correlation between questionnaires for severity scores

	Pearson Correlation, P Value			
	UDI-6	UDI-6 (Q2 and Q3 Only)	PGI-S	ICIQ1
KHQ	0.29 0.2165	0.35 0.1361	0.64 0.0030	0.58 0.0080
UDI-6	-	0.64 0.0023	0.33 0.1654	0.28 0.2258
UDI-6 (Q2 and Q3 only)	-	-	0.36 0.1314	0.34 0.1389
PGI-S	-	-	-	0.56 0.0121

Table 4. Validated questionnaire subdomain score comparison for patients with mixed urinary incontinence

		SUI/UII* Scores									
KHQ Severity Scale Question E/D		1	2	3	4						
UDI-6 Question 3/2		0	1	2	3						
MESA SUI/UII		0-24	25-49	50-74	75-100						
		Incontinence severity scores									
KHQ IIS		0	33	66	100						
ICIQ Score		0	1	2	3						
PGI-S		1	2	3	4						
		QoL scores									
VAS	0	1	2	3	4	5	6	7	8	9	10
KHQ	0	1-10	11-20	21-30	31-40	41-50	51-60	61-70	71-80	81-90	91+
IIQ-7	0	1-10	11-20	21-30	31-40	41-50	51-60	61-70	71-80	81-90	91+

* ICIQ-SF Question 4 not included as the answer is binary and cannot be compared to a scale response.

used as a measure of improvement over time when used on each clinic visit. IIQ-7 is more specific on impact on activities of daily living which are translatable to condition-specific QoL.¹⁴

Based on our results, we have created a suggested score comparison for the subdomains of the validated questionnaires (Table 4). This allows a framework to compare validated questionnaire subdomains results between published studies or patient responses in clinical settings. Based on this comparable information, one can deduce the following answers are similar in terms of scoring: an answer of “a lot”/score of 4 on the KHQ severity symptom scale, a high score (75%-100%) on the MESA Score for SUI/UII, and an answer of “greatly”/score of 3 on question 2/3 of the UDI-6. While ICIQ question 4 is binary, a check on question 4 of the ICIQ-SF for “leaks when you cough and sneeze” for SUI and “leaks before you can get to the toilet” for UII were well correlated with higher scores on the above questionnaire subdomains. This framework may allow research studies utilizing differing validated questionnaires outcomes to be compared head-to-head. In addition, this may allow a practicing physician to translate results of validated questionnaire outcomes in research then converting them to the score of the questionnaire they chose to use in clinical practice.

Previous data comparing outcome measures to one another are limited. Most new outcome measures are compared to “gold standard” outcome measures at the time of creation to ensure construct validity. Of the above questionnaires only the ICIQ-SF was previously evaluated for correlation with the KHQ. However, this was done in a small sample of 91 consecutive females attending a single female urology clinic in King’s College Hospital, London.^{7,11} A previous study assessed the correlation of 7-day voiding diaries with the following questionnaires: UDI-6, IIQ-7, and MESA and found that UDI-6 and IIQ-7 were moderately correlated with total number of incontinence episodes.¹⁷ This confirms our results that UDI-6 questions 2 and 3 were well correlated with other validated questionnaire subdomains for SUI and UII.

We elected to utilize the abovementioned studies for a variety of reasons. In the OMIT study, we found that the

large majority of members of the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction utilized the UDI-6 and IIQ-7 for the postoperative evaluation of stress urinary incontinence.⁵ The KHQ is one of the oldest validated questionnaires and is highly regarded and utilized in the European continent.² The ICIQ-SF is a highly recommended patient-reported outcome (PRO) measure, given a grade A evaluation by the ICS for the assessment of urinary incontinence.¹⁸ Furthermore, recent meta-analysis on overactive bladder and MUI most commonly utilized the above noted PROs.^{19,20}

Despite our investigation, the question remains, what is the best validated questionnaire? Validated questionnaires are valuable for patient data collection, monitoring of improvement over time and standardization of research. However, they are variable in terms of length and often their use is determined by clinical constraints of time and provider familiarity and training. In addition, the creation of new and possibly improved validated questionnaires continues. In the absence of the requirement of mandated specific validated questionnaires for clinical research and lack of endorsement by subspecialty societies, there will likely never be a single “gold standard” option. The National Institutes of Health has created Patient-Reported Outcomes Measurement Information Systems or measures for global, physical, mental, and social health to standardize PRO measurement. The use of these measures specific to the study of UI has the potential to significantly improve and streamline collecting and reporting of subjective clinical patient outcomes. If universally accepted by providers, this can alleviate the difficulty achieving consensus on the “right” way to measure subjective improvement for clinical study design. Until a time that this is universally adopted, providers can utilize the results of our study to compare questionnaire subdomains allowing for some consensus and facilitating data comparison in meta-analyses.

This pilot study has several limitations including sample size and single-center recruitment. Although, we did not collect demographic information such as race or education level, most patients in our clinic population were Caucasian and with some level of graduate education, therefore, our results may not be generalizable to all patient populations. The rate of missing data in our study was acceptable less than 5%.

CONCLUSION

Validated questionnaires including the KHQ, ICIQ-SF, UDI-6, IIQ-7, MESA, and PGI-s for MUI subdomains of SUI, UUI, incontinence severity, and QoL are generally well correlated, with some exceptions. As there exists significant variation in their use based on geographic location, provider preference, and language translation; we have suggested a framework by which the individual scores can be compared across clinicians and research studies. This may require further validation in larger and more diverse patient populations.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.urology.2019.07.008>.

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