Chapter 2

Measuring Health-related Quality of Life in women with urogenital dysfunction: The Urogenital Distress Inventory and Incontinence Impact Questionnaire revisited.

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Introduction

Symptoms of urogenital dysfunction are common in the female population.[1,2] In the last two decades, there is an increasing awareness that the consequences of these symptoms for general well-being is not only determined by the type and severity of the symptoms but also by the individual's psychosocial adjustment to it. This is especially true for chronic disorders like urinary incontinence or genital prolapse that are often not characterized by severe physical abnormalities or have impact on mortality. Although these symptoms are not life-threatening, women affected often report limitations in their physical, social and emotional functioning. However, it is known that these physical and psychosocial limitations are poorly associated with objective tests like urodynamic assessment.[3] Objective tests, how accurate they may be in establishing a diagnosis, do not account for the patient's perception of the problem. It is therefore recommended to include measurements of well-being or Health-related Quality of Life (HRQOL) in the outcome assessment of treatment for urogenital dysfunction.

Essentially, there are two approaches for measuring HRQOL. First, a general profile of perceived health, with dimensions such as physical, psychological and social health can be assessed using generic measures. These instruments are not specific to any particular condition and therefore allow comparisons among different conditions. However, these instruments do not determine the specific impact a given condition has on HRQOL. Condition- or disease specific HRQOL instruments are designed to measure the specific consequences a particular disease has on quality of life. Therefore, they allow a more in-depth assessment of specific concerns pertinent to that particular condition. An example of a disease-specific HRQOL questionnaire for urogenital symptoms is the Urogenital Distress Inventory (UDI) and the Incontinence Impact Questionnaire (IIQ).[4]

In the Netherlands, no disease-specific HRQOL measurement for urogenital symptoms was available that has passed the process of translation and validation adequately. Simple translation is not enough to consider a questionnaire to be valid.

Cultural differences may reflect themselves in different perception of the impact of particular symptoms and therefore validity of a translated version has to be tested. Three types of validity are distinguished: content validity, criterion validity and construct validity. Content validity refers to the adequacy with which a specific domain or content is sampled. Criterion validity refers to how well the instrument correlates with a "golden standard" measure. A "golden standard" for different urogenital symptoms does not exists and therefore criterion validity has to be accounted for by known-groups comparison. Construct validity refers to whether the questionnaire scales measure the underlying construct adequately.

Besides problems that may occur due to cultural differences, the original UDI/IIQ was developed in a selected population of higher educated women, aged 45 years or older. This implies that it is possible that using the UDI/IIQ in a population with different characteristics will yield different results. If this is true, comparing data obtained with the UDI/IIQ between different study groups may not accurately reflect true differences. Ideally, a disease-specific HRQOL questionnaire on urogenital symptomatology should be tested in a broad population sample, adequately representing different age groups and socio-demographic characteristics.
The aim of this study was to report on the prevalence of urogenital symptoms in a large random population sample and on the psychometric qualities of the Dutch translation of the UDI and IIQ.

Material and Methods

Study population

The study population consists of two samples of women. The first sample is a random population sample of 3200 women, between 20 and 70 years of age, that was obtained from the population registration office of a suburban area in the central part of the Netherlands in 1999. These women were invited to participate in a study on the prevalence and consequences of urogenital and defecation symptoms in the female

community. All women received a questionnaire with an accompanying letter explaining the purpose of the study. Care was taken to encourage women without any urogenital symptoms to participate, emphasizing the importance of their cooperation to compare their situation with that of women with symptoms. All women were sent a reminder after four weeks. Two-thousand forty-three women responded (63.8%).

The second sample consists of 196 consecutive women who reported themselves with urogenital dysfunction to the gynecologic outpatient clinic of the University Medical Center Utrecht, The Netherlands. These women represent 85% of women that were eligible (34 out of 230 women refused to participate). Women that refused to participate did not differ from participators regarding their age and main symptoms.

Study design

All women received a self-administered questionnaire. The community sample in the second half of 1999. The clinical sample received the questionnaire between April 1999 and June 2000, at the time of their first visit to our clinic. The study was approved by the local ethics committee, with the restriction that contacting non-responders of the community-sample was not allowed.

Socio-demographic data were collected for all women, including age, marital status, parity and educational level. The educational level was dichotomized in analysis into primary only (low education) and secondary or higher (higher education).

Quality of life is measured with a generic and disease-specific questionnaire. The Rand-36 is a generic HRQoL questionnaire that measures functioning on 8 domains: general health, physical functioning, mental health, social functioning, vitality, bodily pain, role limitation because of physical functioning and role-limitation because of emotional functioning [5,6]. The domain scores range from 0 to 100, with 100 representing the best HRQoL. Disease-specific quality of life is measured with the Urogenital Distress Inventory (UDI) and the Incontinence Impact Questionnaire (IIQ).[4] The UDI consists of 19 items and every item consists of two parts: whether or not a *symptom* is present and

the amount of the bother the woman experiences from that symptom. The latter is measured with a four-point Likert scale ranging from not at all to greatly. The original UDI consists of three domains, namely: stress incontinence symptoms, irritative symptoms and obstructive/discomfort symptoms. For factor analysis, the scores of both parts of each question were transformed into: 1 = no symptom, 2 = symptom present, no bother, 3 = symptom present, slightly bothersome, 4 = symptom present, moderately bothersome, 5 = symptom present, greatly bothersome. In calculating domain scores, women not having a symptom or having a symptom without bother are scored equally. The domain scores are transformed into a continuous scale ranging from 0 to 100. A high score on the UDI domains indicates more bothersome symptoms on that particular domain. The original IIQ consists of 30 items about the impact of urogenital symptoms on four aspects of quality of life: physical functioning, emotional functioning, travel/mobility and social functioning. The impact on each item is measured with a four-point Likert scale, ranging from not at all (1) to greatly (4). The domain scores are transformed into a scale ranging from 0 to 100. A high score on the IIQ domains indicates that the person's well-being on that particular domain is negatively affected. The original UDI and IIQ was translated by the process of forward-backward translation by two native speakers.[7]

Data about the diagnosis and the grading of the genital prolapse were collected from the medical records of the clinical sample. A distinction was made between anterior vaginal wall prolapse (cystocele), posterior vaginal wall prolapse (rectocele), descensus uteri and enteroceles. Grading of the prolapse was performed at maximal straining in the 45° supine position and was graded as follows: 0 = no prolapse, 1 = prolapse ≥1 cm above the hymenal ring, 2 = prolapse between 1 cm above and < 1cm below the hymenal ring and grade 3 = prolapse >1 cm below the hymenal ring.
In analysis the grading of the prolapse was used as an interval variable.

Statistical analysis

Principal axis factoring with varimax-rotation was used to test the construct validity of the Dutch translation of the UDI and IIQ. Cronbach's alpha was used as a measure for internal consistency of the domains.[8] A Cronbach's alpha value > 0.70 is considered to represent a good internal consistency. Pearsons' correlation coefficients were calculated between the UDI/IIQ domains and the RAND-36 domains.

We hypothized that women from the clinical sample ("clinical cases") had more severe complaints as compared to women from the community sample with urogenital symptoms ("community cases"). This difference should be reflected in statistical significant differences on the IIQ domains. An unpaired t-test was used to compare the two samples on the IIQ domains. If statistical significant unequal variances were identified with the Levene's test for equality of variance, the significance level was adjusted for these unequal variances.

As a second indication for criterion validity we tested how well the individual UDI domains could predict the existence of a genital prolapse or urinary incontinence. We therefore had to assume that the diagnosis made by the physician was accurate enough to be used as a "Golden standard" in this analysis. Receiver Operating Characteristics (ROC) curves were calculated to test the quality of the individual UDI domains as a diagnostic test for making a diagnosis of genital prolapse or urinary incontinence. All statistics were performed with the statistical package SPSS 10.0.

Results

The baseline characteristics of the community sample and clinical sample are shown in Table 1. Women from the clinical sample were statistical significantly older, lower educated and reported more symptoms on the UDI as compared to the community sample. A total of 1644 women (79.5%) from the community sample had at least one positive symptoms on the UDI.

Table 1. Characteristics of the study population

	Community sample n = 2043	**Clinical sample** n = 196
Mean age	46.5 (0.3)	54.7 (0.8)‡
Educational level		
Primary only	439 (21.5)	81 (41.0)‡
Secondary or higher	1604 (78.5)	115 (59.0)
Marital status		
Married	1360 (66.6)	152 (77.6)
Divorced	146 (7.1)	23 (11.5)
Widow	98 (4.8)	13 (6.9)
Never married	439 (21.5)	8 (4.0)
Race		
White	2002 (98.0)	190 (97.0)
Non-white	41 (2.0)	6 (3.0)
Diagnosis *		
Genital prolapse	-	142 (72.4)
Urinary incontinence	-	88 (44.9)
Positive symptoms on UDI		
0	399 (20.5)	-
1-5	1132 (55.2)	37 (18.9)‡
6-10	464 (22.6)	111 (56.6)
11-15	53 (2.6)	47 (24.0)
16-19	3 (0.1)	1 (0.5)

Values are expressed as numbers (%) or means (standard error)
* For clinical sample only. Diagnosis made by the physician, combination of genital prolapse and urinary incontinence possible.
‡ $p<0.01$ Pearsons chi-square or unpaired t-test

Factor solution and internal consistency

Data from the community sample were used to perform a factor analysis on the UDI and IIQ. The results of the UDI factor analysis is presented in Table 2.

Table 2. Factor analysis of the 19-items Urogenital Distress Inventory

	Factor loading				
	1	2	3	4	5
Lower abdominal pressure	0.74	0.10	0.21	0.01	0.15
Pain or discomfort lower abdomen	0.72	0.01	0.11	0.01	0.12
Heaviness or dullness in pelvic area	0.68	0.01	0.10	0.18	0.02
Pelvic discomfort while physically exerting	0.64	0.10	0.01	0.29	0.03
Pain when urinating	0.28	0.10	0.02	0.01	0.14
Push on vaginal wall to have bowel movement	0.27	0.20	0.01	0.01	0.15
Urine leakage related to a feeling of urgency	0.15	0.72	0.29	0.01	0.01
Small amounts of urine leakage (drops)	0.19	0.70	0.16	0.01	0.12
Urine leakage without physical activity/urgency	0.12	0.68	0.01	0.01	0.18
Urine leakage related to physical activity	0.19	0.65	0.14	0.01	0.01
Large amounts of urine leakage	0.04	0.53	0.02	0.01	0.12
Frequent urination	0.12	0.20	0.79	0.01	0.17
Strong feeling of urgency to empty the bladder	0.21	0.30	0.59	0.01	0.01
Frequent nighttime urination	0.15	0.12	0.52	0.01	0.18
See a bulging or protrusion in the vaginal area	0.12	0.01	0.01	0.87	0.01
Feel a bulging or protrusion in the vaginal area	0.27	0.10	0.10	0.78	0.01
Feeling of incomplete bladder emptying	0.32	0.22	0.21	0.11	0.73
Difficulty emptying the bladder	0.20	0.21	0.14	0.18	0.72
Bed-wetting	0.01	0.01	0.06	0.01	0.15

Principal axis factoring with Varimax rotation. Factor solution explained 58.8% of variance in the model.

The following five domains explained 58.8% of the variance in the model: Discomfort/Pain (6 items; Cronbach's alpha .78), Urinary incontinence (5 items; Cronbach's alpha .77), Overactive bladder (3 items; Cronbach's alpha .74),

Genital prolapse (2 items; Cronbach's alpha .82) and Obstructive micturition (2 items; Cronbach's alpha .80). One item (bed-wetting) had a low factor loading on all domains and did not explain an additional proportion of variance in the factor analysis model. Therefore this item was deleted from the UDI. The same domains emerged when performing factor analysis on the data of the clinical sample. Finally, we tried to identify if different factor solutions occurred when comparing data of the lower educated with the higher educated women and between women younger and older than 45 years. No differences were found.

The results of the factor analysis of the IIQ is presented in Table 3a and Table 3b. Besides the four domains as described by Schumaker (factor 1 = mobility/travel; factor 2 = emotional functioning; factor 3 =physical activity; factor 4 = social functioning), we identified an extra domain that contains 4 items about embarrassment (factor 5). Cronbach's alpha for these five domains ranged from 0.83 (embarrassment) to 0.93 (mobility). The factor solution of the IIQ explained 65.1% of the total variance. Again in subgroup analysis (age and educational level) the same domains emerged.

For both the UDI and IIQ the factor solution data showed that there was a high item discriminant validity (the correlation of an item with its own scale as compared with other scales). Only one of the items of the IIQ (physical health) had a factor loading > 0.40 on both the IIQ emotional (0.47) and IIQ physical (0.45) domain. For obvious reasons we decided to add this items to the IIQ physical domain.

Table 3a. Results of factor analysis of the 30 items of the IIQ.

		Factor loading				
	Original domain*	1	2	3	4	5
Travel > 30 minutes	T	0.73	0.21	0.28	0.22	0.13
Places - not sure of rest rooms	T	0.70	0.26	0.21	0.10	0.23
Entertainment	T	0.67	0.25	0.24	0.39	0.13
Shopping	A	0.65	0.26	0.21	0.15	0.31
Social activities	So	0.59	0.26	0.33	0.39	0.22
Travel < 30 minutes	T	0.59	0.15	0.33	0.38	0.01
Physical recreation	A	0.57	0.25	0.28	0.14	0.21
Hobbies	A	0.54	0.31	0.27	0.10	0.19
Vacation	T	0.50	0.30	0.21	0.32	0.25
Church/Temple attendance	So	0.44	0.27	0.10	0.36	0.16
Nervousness	E	0.18	0.69	0.10	0.21	0.24
Frustration	E	0.22	0.66	0.22	0.18	0.27
Fear	E	0.21	0.65	0.17	0.20	0.21
Depression	E	0.15	0.63	0.14	0.11	0.11
Emotional health	E	0.23	0.60	0.19	0.30	0.29
Anger	E	0.22	0.52	0.17	0.01	0.10
Physical health	A	0.30	0.47	0.45	0.14	0.01
Sleep	E	0.34	0.42	0.32	0.11	0.01

Principal axis factoring with Varimax rotation. Factor solution explained 65.1% of variance in the model. * Original domains; T = Travel; A = Physical activity; E = Emotional: So = Social.

Table 3b. Results of factor analysis of the 30 items of the IIQ.*

		Factor loading				
	Original domain	1	2	3	4	5
Volunteer activities	So	0.36	0.10	0.59	0.36	0.19
Household chores	A	0.34	0.32	0.58	0.13	0.11
Employment	T	0.38	0.16	0.57	0.29	0.24
Sexual relations	So	0.15	0.32	0.57	0.21	0.21
Relationship with friends	So	0.32	0.28	0.22	0.79	0.21
Having friends visit	So	0.37	0.19	0.25	0.66	0.25
Relations with family	So	0.22	0.29	0.38	0.62	0.24
Fear of odor	So	0.16	0.16	0.10	0.17	0.76
Fear of embarrassment	E	0.26	0.29	0.21	0.22	0.66
Embarrassment	E	0.25	0.32	0.16	0.10	0.54
Way dress	So	0.23	0.30	0.37	0.34	0.45

* Legend as Table 3a.

Construct validity

Construct validity was investigated by comparing the scores of the UDI domains and IIQ domains with scores on the RAND-36 domains. Because of the disease-specific character of the IIQ, only women who replied positively to one or more questions of the UDI were invited to fill out these IIQ questions. A total of 960 out of the 1644 women (58.4%) with UDI symptoms answered the IIQ questions. The relationship between the number of UDI symptoms and answering the IIQ questions was as follows. Of the 1132 women with 1 to 5 positive UDI symptoms, 529 (46.7%) answered the IIQ questions. Eighty-one percent of women with 6-10 positive UDI symptoms, 98.1% of women with 11-15 positive UDI symptoms and 100% of women with more than 16 positive UDI symptoms answered the questions of the IIQ.

The Pearsons' correlation coefficients between the five IIQ domains and the eight RAND-36 domains are shown in Table 4.

Table 4. Correlation coefficients between the RAND-36 and IIQ domains

	Incontinence Impact Questionnaire				
	Mobility	Physical functioning	Social functioning	Emotional health	Embarrassment
RAND 36					
Physical functioning	- .46	- .47	- .33	- .40	- .28
Social functioning	- .34	- .37	- .27	- .35	- .22
Role limitations physical	- .33	- .37	- .23	- .33	- .20
Role limitations emotional	- .22	- .25	- .19	- .31	- .21
Vitality	- .29	- .32	- .20	- .34	- .21
Mental health	- .24	- .28	- .17	- .35	- .23
Pain	- .31	- .36	- .17	- .29	- .16
General health	- .29	- .33	- .22	- .33	- .20

Pearsons correlation coefficients. All significant at $p<0.001$

All correlations were significant at $p<0.001$. However, because of the large sample size, statistical significant correlations occur at relatively low correlation coefficients. In general the IIQ mobility, physical and social functioning domains correlated moderately to good (correlation coefficient > 0.30) with corresponding RAND-36 scales.
The IIQ emotional health domain also correlated moderately well with the emotional/mental health domains of the RAND-36.

Because of the condition-specific nature of the IIQ we expected the correlation coefficients between the UDI domains and the IIQ domains to be higher than those

between the UDI domains and the RAND-36 domains. The Pearsons' correlation coefficients between the UDI domains and RAND-36 domains ranged from -0.06 to -0.30. The only correlation coefficient > 0.30 was that between the UDI obstruction/discomfort domain and the RAND-36 pain domain. The Pearsons' correlation coefficients between the domains of the UDI and the five IIQ domains are shown in Table 5.

Table 5. Correlation coefficients between the UDI domains and IIQ domains

	Incontinence Impact Questionnaire				
	Mobility	Physical functioning	Social functioning	Emotional health	Embarrassment
UDI					
Discomfort/Pain	.34	.38	.28	.36	.25
Overactive bladder	.44	.31	.25	.36	.24
Obstructive micturition	.39	.33	.27	.36	.30
Genital prolapse	.16	.25	.18	.23	.12
Urinary incontinence	.30	.24	.21	.28	.38

Pearsons correlation coefficients, all correlations are significant at $p<0.0001$

Overactive bladder, discomfort/pain and symptoms of obstructive micturition correlated best with the IIQ mobility, physical functioning and emotional domains (correlation coefficient between .31 and .44). Genital prolapse symptoms showed a weak correlation with all IIQ domains. Urinary incontinence symptoms showed the highest correlation with the IIQ embarrassment domain (correlation coefficient 0.37).

Criterion validity

The criterion validity of the IIQ and UDI was tested in several ways.

First, we used the data of the diagnosis made by the physician in the clinical sample. These data were used to analysis the correlations between the type and grade of genital prolapse and the UDI domains. The UDI prolapse domain score showed a statistical significant positive correlation with the severity of the descensus uteri (Pearsons' correlation .37) and enterocele (Pearsons' correlation .27). The UDI discomfort/pain domain was only significantly positively correlated with the enterocele grading (Pearsons' correlation .23).

Secondly, data about the diagnosis were also used to assess how well the UDI domain scores could predict the presence or absence of genital prolapse or urinary incontinence. When we used the UDI prolapse score to try to identify women with a diagnosis of genital prolapse we found an area under the ROC curve of .81. Thus, with the UDI prolapse scale, the score of a randomly selected prolapse patient exceeds that of a randomly selected non-prolapse patient an estimated 81% of time. The areas under the ROC curve for the other four domains of the UDI in relation to genital prolapse were approximately 0.50 (0.35 - 0.57). The same analysis was performed for the diagnosis urinary incontinence obtained from the medical record. The UDI incontinence scale showed an area under the ROC curve of .81. Again the area's under the ROC curve for the other four domains of the UDI in relation to urinary incontinence were approximately 0.50 (0.35 - 0.60).

Finally, we tested the criterion validity of the IIQ by known-group comparison. We compared the community sample cases and the clinical sample with regard to their mean scores on the IIQ domains. Table 6 shows the results of this analysis.

Table 6. IIQ domain scores for the community sample and the clinical sample

	Community sample (n=960)	Clinical sample (n=196)
IIQ domains		
Mobility	8.3 (0.5)	24.1 (1.7)*
Physical	4.9 (0.4)	24.1 (1.7)*
Social	3.3 (0.4)	10.0 (1.4)*
Emotional	6.8 (0.4)	18.8 (1.5)*
Embarrassment	6.8 (0.4)	14.7 (1.7)*
Total	30.1 (1.7)	91.6 (6.5)*

Independent sample t-test. * $p < 0.0001$

Women from the clinical sample had a significant higher score (worse HRQoL) on all the IIQ domains as compared to women from the community sample.

Discussion

Our study shows that urogenital symptoms are common among adult women. As measured with the UDI, four out of five women will have at least one urogenital symptom. Increasing number and bothersomeness of symptoms were positively correlated with a reduction in well-being, especially when measured with the disease-specific IIQ. Furthermore we found that, when used in a large population of adult women, the UDI and IIQ showed a different scale construction as compared to the original version. Five domains were identified in the UDI namely: Discomfort/Pain, Urinary incontinence, Overactive bladder, Genital prolapse and Obstructive micturition. In addition to the four original domains, factor analysis of the IIQ showed a fifth domain with 4 items related to embarrassment. In the analysis of the psychometric qualities of these UDI domains and IIQ domains we demonstrated an adequate internal consistency, content-, criterion- and construct validity.

Questionnaires that are used to identify urogenital symptoms should be easy to understand, applicable to a broad defined domain, and most important of all be able to distinguish clinical relevant conditions. The original UDI was developed with data from a selected population of 162 women with urinary incontinence. These women were well educated, had upper-middle incomes and were > 45 years old. Among the exclusion criteria were lower urinary tract infection and urinary obstruction. Excluding these women while developing a questionnaire on urogenital symptoms somehow seems odd. Furthermore, some of the items that were originally pre-selected to belong to one of the three domains (Stress -, Irritative - or Obstructive/Discomfort symptoms), proved to fit better in another domain after factor analysis. However, in the original UDI, the scale membership of these items was not adjusted after factor analysis. This is in part reflected by the poor internal consistency of the original UDI Stress domain (Cronbach's alpha .48). Therefore, the reliability and validity of the original UDI has only been established for the selected domain it was derived from. The strength of our study is that we applied the UDI to a random sample of women, both low and higher educated, in a broad age-range, and did not make a domain division of items before factor analysis. The domains that emerged are clinically sound, reliable, have good discriminative properties and proved to be of adequate criterion validity when comparison was made with the clinical diagnosis.

Questionnaires that are used to estimate condition-specific HRQoL should include the three principal dimensions of HRQoL, namely physical, emotional and social functioning. In addition, specific domains of the condition-specific HRQoL should reflect specific consequences of the disease state itself. The main difference between our version of the IIQ and the original one is that we identified a fifth domain with four items about embarrassment. Several studies showed that embarrassment (fear of odour, fear of embarrassing situations) is an important factor by which urinary incontinent women report to be bothered substantially.[9,10] Our results confirm this. We found that the UDI Incontinence domain had the highest positive correlation with the IIQ

embarrassment domain. The higher correlation coefficients between the UDI and IIQ as compared to the UDI and RAND-36 further supports the validity of the IIQ as condition-specific HRQoL instrument for urogenital symptoms.

Our study has several possible limitations that need to be discussed. First, our study was performed with the Dutch translation of the UDI and IIQ on a Dutch population. Although we carefully handled the translation process (Forward-backward translations, native speakers, discussion after both translations) some small aberrations from the English version are inevitable. However, the UDI and IIQ factor solutions are solid, with a high item discriminant validity (the correlation of an item with its own scale as compared with other scales). We therefore do not believe that the translation is responsible for the differences between the original and the Dutch version.
Secondly, because of the design of our study the sensitivity to change of the UDI and IIQ could not be established. It is usually recommended to compare the sensitivity to change of a HRQoL questionnaire with a change in an objective parameter, preferably a "Golden standard". However, there is no golden standard in outcome analysis of treatments for urinary incontinence or genital prolapse. Symptoms of urinary incontinence were shown to correlate poorly with urodynamic assessment and the reliability of the "pad-test" (urine loss in weight per hour or 24-hour period) as measurement of the severity of urine loss is subject of discussion.[3,11] Only the frequency of incontinent episodes has been shown to have a positive correlation with the degree of bothersomeness.[1] The original UDI/IIQ proved to be sensitive to change and to correlate significantly with the number of incontinence episodes but not with the pad test results. However, the primary goal of a condition-specific HRQoL questionnaire is to account for the subjective intra-personal characteristics that are part of the complex mechanism by which a particular patient will respond to a particular symptom. Therefore, it is difficult to make statements about the responsiveness of an HRQoL measurement by comparing it to changes in an objective parameter. The latter may not give credit to changes in the perceived severity of the problem, which can be of more importance from

a patients point of view.

A final point of concern is the fact that only 58.4% of women with at least one urogenital symptom present answered the questions of the IIQ. There was a clear relationship between the number of reported symptoms on the UDI and the willingness to fill in the IIQ questionnaire. We believe that women with few symptoms were less likely to feel bothered by these symptoms and therefore decided to skip the IIQ questions in the questionnaire. Since the IIQ is intended to measure disease-specific HRQoL for urogenital symptoms, we believe that it is especially important that women with moderate to serious complaints answered the IIQ to give a valid impression of the specific problems they encounter (like embarrassment). Therefore, the fact that especially women with more symptoms responded to the IIQ questions is likely to have improved the face validity of the IIQ domains we found.

In the last few years, several other HRQoL questionnaires on urinary incontinence have been developed.[12-15] These instruments were all constructed in selected (small) populations and often do not contain information on both the different types of urogenital symptoms as well as on the disease-specific HRQoL like the combination of UDI and IIQ does. The Bristol Female Lower Urinary Tract Symptoms questionnaire evaluates the presence or absence of symptoms and the degree of bothersomeness.[12] It does not measure the impact of symptoms on HRQoL dimensions.
The I-QoL (Incontinence-Quality of Life) questionnaire was derived from interviews with 37 patients (gender not stated) and tested on 62 patients, both male and female.[13] It assesses only the impact of urinary incontinence and not of other urogenital symptoms. The total score of the I-QoL showed a good correlation with the generic MOS SF-36 domains. In a later version, factor analysis of the I-QoL revealed three domains namely; avoidance and limiting behaviour, psychosocial impact and social embarrassment.[14] These findings are in accordance with our results, showing a highly significant positive correlation between the UDI incontinence domain and the IIQ embarrassment domain. Finally, the York Incontinence Perception scale (YIPS) is an eight item questionnaire that

emphasises on psychosocial issues related to urinary incontinence.[15] Coping, control and acceptance of incontinence were assessed but dimensions like physical functioning or emotional well-being were not addressed.

Symptoms of urinary incontinence, frequency and urgency (overactive bladder), lower abdominal discomfort or pain, genital prolapse and obstructive micturition are common among adult women and many women experience more than one symptom. When measuring the impact of urogenital symptoms on quality of life a distinction between subgroups can be useful. For example, women with stress urinary incontinence are reported to experience less impact of their incontinence on HRQoL as compared to women with urge incontinence.[16-18] This could be due to the amount of urine loss but also to the effect of related symptoms. If women with urge incontinence also experience more often symptoms of overactive bladder or discomfort as compared to stress incontinent women, this may well be a confounder for the perceived HRQoL and therefore has to be accounted for in analysis. We strongly believe that the combined use of our version of the UDI and IIQ is suitable for both epidemiological as well as clinical studies on urogenital problems in women.

References

1. Møller LA, Lose G, Jørgensen T. The prevalence and bothersomeness of lower urinary tract symptoms in women 40-60 years of age. *Acta Obstet Gynecol Scand* 2000; 79: 298-305.
2. Samuelsson EC, Victor A, Tibblin G, Svärdsudd. Signs of genital prolapse in a Swedish population of women 20 to 59 years of age and possible related factors. *Am J Obstet Gynecol* 1999; 180: 299-305.
3. Jackson S. The patient with an overactive bladder-symptoms and quality-of-life issues. *Urology* 1997; 50: 18-22.
4. Schumaker SA, Wyman JF, Uebersax JS, McClish D, Fantl JA. Health related quality of life measures for women with urinary incontinence: The Urogenital Distress Inventory and the Incontinence Impact Questionnaire. *Quality Life Res* 1994; 3: 291-306.
5. Hays RD, Sherbourne CD and Mazel RM. *Health Economics* 1993: 1-23.
6. Zee van der KI en Sanderman R. Het meten van de algemene gezondheidstoestand met de RAND-36. Noordelijk Centrum voor Gezondheidsvraagstukken. Rijksuniversiteit Groningen 1993.
7. Sprangers MAG, Cull A, Bjordal K, Groenvold M, Aaronson A. The European organization for research and treatment of cancer approach to Quality of Life assessment: Guidelines for developing questionnaire models. *Quality Life Research* 1993; 2: 287-295.
8. Cronbach LF. Coefficient alpha and the internal structure of tests. *Psycometricka* 1951; 16: 297-334.
9. Lagro-Jansen T, Smits A, van Weel C. Urinary incontinence in women and the effects on their lives. *Scan J Prim Health Care* 1992; 10: 211-216.
10. Norton PA, MacDonald LD, Sedgwick PM, Stanton SL. Distress and delay associated with urinary incontinence, frequency and urgency in women. *BMJ* 1988; 297: 1187-1189.
11. Ryhammer AM, Laurberg S, Djurhuus JC, Hermann AP. No relationship between subjective assessment of urinary incontinence and pad test weight gain in a random population sample of menopausal women. *J Urol* 1998; 159: 800-803.
12. Jackson S, Donovan J, Brookes S, Eckford S, Swithinbank L, Abrams P. The Bristol Female Lower Urinary Tract Symptoms questionnaire: development and psychometric testing. *Br J Urol* 1996; 77: 805-812.

13. Wagner TH, Patrick DL, Bavendam TG, Martin, Buesching DP. Quality of life of persons with urinary incontinence: development of a new measure. *Urology* 1996; 47: 67-72.
14. Patrick DL, Martin ML, Bushnell DM, Yalcin I, Wagner TH, Buesching DP. Quality of life of women with urinary incontinence: further development of the Incontinence Quality of Life Instrument (I-QoL). *Urology* 1999; 53: 71-76.
15. Lee PS, Reid DW, Saltmarche A, Linton L. Measuring the psychosocial impact of urinary incontinence: The York Incontinence Perception Scale (YIPS). *J Am Geriatr Soc* 1995; 43: 1275-1278.
16. Hunskaar S and Vinsnes A. The quality of life in women with urinary incontinence as measured by the Sickness Impact Profile. *JAGS* 1991; 39: 378-382.
17. Grimby A, Milsom I et al. The influence of urinary incontinence on the quality of life of eldery women. *Age and Ageing* 1993; 22: 82-89.
18. Simeonova Z, Milsom I, Kullendorf A-M, Molander U, Bengtsson C. The prevalence of urinary incontinence and its influence on the quality of life in women from an urban Swedish population. *Acta Obstet Gynecol Scand* 1999; 78: 546-551.