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A new questionnaire to assess the quality of life of urinary incontinent women

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Objectives To design and validate a condition-specific quality of life questionnaire for the assessment of women with urinary incontinence, and to use the questionnaire to assess the quality of life of women with specific urodynamic diagnoses.

Setting A tertiary referral urogynaecology unit at King's College Hospital, London

Design The questionnaire was designed following six different pilot studies; in this study it was tested for validity and reliability using standard psychometric techniques. The questionnaire was used in 293 consecutive women referred for investigation of urinary incontinence.

Results The questionnaire was shown to be reliable both by test-retest analysis and by measurement of its internal consistency. The construct of the questionnaire and the answers by respondents confirmed its face and content validity. Criterion validity was measured by correlation with scores obtained on a validated generic measure of quality of life, the Short Form 36. Women with detrusor instability had greater quality of life impairment than women with other urodynamic diagnoses.

Conclusion The questionnaire was easy for the women to use and was a valid and reliable instrument for the assessment of quality of life in women with urinary incontinence. It will be useful for the rapid appraisal and follow up of women with urinary incontinence in many different clinical settings, including the evaluation of new treatments of urinary incontinence in controlled clinical trials.

INTRODUCTION

Urinary incontinence is a distressing and disabling condition causing significant morbidity, affecting the social, psychological, occupational, domestic, physical, and sexual lives of 15% to 30% of women of all ages . Sufferers give up many aspects of their usual life with obvious detriment to their social interactions, interpersonal and sexual relationships, careers, and psychological wellbeing.

Evaluation of the severity of urinary incontinence usually involves a record of urinary symptom scores, a urinary diary and objective urodynamic data. It is clear that while these are essential measures they provide little information regarding the impact of urinary incontinence on women's lives. Many factors other than the severity of incontinence and the burden of symptoms contribute to morbidity[2]. It is perhaps for this reason that a recent draft proposal by the International Continence Society for the standardisation of outcome measures in clinical trials of continence care has strongly suggested the inclusion of quality of life data[3].

'Quality of life' is an abstract and highly subjective concept influenced by personal and cultural values, beliefs, self concepts, goals, age and life expectancy. Similarly, it is affected by a broad spectrum of human experiences, including diseases, accidents, treatments, interpersonal relationships and social support. It is usually measured using structured questionnaires which can be completed by the woman, or by the woman and her carer as part of a structured interview. They contain a variable number of sections (or domains), which gather information focused on particular aspects of health. These usually include physical function, emotional function, social function, role performance, pain, sleep and disease-specific symptoms.

There are two major types of quality of life questionnaire—*generic* and *disease specific*. Generic measures are designed to assess a broad range of populations, rather than patients with particular medical conditions. Examples include the Nottingham Health Profile[4], Sickness Impact Profile[5], Psychosocial Adjustment to Illness Scale[6], and UK version Short Form 36[7], and each of these show an impairment in the quality of life of incontinent women[8–11]. Generic quality of life questionnaires are readily available, are reliable and valid, and therefore easy to include in clinical studies. Unfortunately they are often used inappropriately[12], and in many cases fail to address many of the issues relevant to the study population. This problem has been encountered in studies on incontinent women, and generic questionnaires appear to be relatively insensitive

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measures of the effect of urinary symptoms on quality of life, and of its improvement after treatment[8].

In order to overcome the problems of poor sensitivity associated with generic questionnaires it is necessary to use a disease or condition-specific quality of life measure. These assess the same multidimensional aspects of quality of life, but are designed to be more applicable and therefore sensitive to the quality of life issues that affect women with particular medical conditions. This is important if they are to be used as reliable outcome measures in clinical trials, but necessitates the design and validation of a new questionnaire, which can be a lengthy process.

Understanding patient health status or quality of life is, however, essential to the performance of appropriate investigations and interventions, and to the evaluation of new forms of treatment. Increasingly, new treatments for urinary incontinence, such as laparoscopic colposuspension, urethral devices, urethral prostheses, and new drugs, are advocated on the basis that they reduce the severity of incontinence, judged by objective urodynamic assessment. While in randomised trials objective measurements of cure are necessary, it is equally important to assess the improvement in the woman's quality of life.

The purpose of this study was to create a new condition-specific quality of life questionnaire, the King's Health Questionnaire for rapid assessment of urinary incontinence in women. It was assessed for validity (the extent to which it measures what is intended), and reliability (the extent to which it measures quality of life in a consistent manner)[13]. Another aim of the study was to use the questionnaire to measure the quality of life of women with specific urodynamic diagnoses.

METHODS

Between August 1991 and September 1993, 1105 consecutive women referred to a tertiary urogynaecology unit were asked to complete a generic quality of life questionnaire, the results of which have been presented elsewhere[14,15]. In addition, the women also completed a detailed urinary symptom questionnaire and were asked to document the problems associated with their urinary symptoms which caused them the greatest concern. The most frequently cited problems are shown in Table 1. It was decided that a condition-specific questionnaire should include not only quality of life questions, but also strategies for coping with urinary incontinence and subjective measures of the severity of urinary symptoms.

The questions were chosen from a number of different sources including generic questionnaires, condition-specific questionnaires already published, following discussion with clinical colleagues, and following discussion with the women themselves. The questionnaire was printed in large letters so that women with poor eyesight could read it. Six different pilot versions of the questionnaire were studied consecutively, and each analysed for ambiguity, redundancy of items (those having a similar meaning) and ease of comprehension; the final version was reduced to 21 questions presented in eight different domains, with a separate scale for measurement of the severity of urinary symptoms. We used a four-point scoring system for each of the items, and included an inapplicable option for questions relating to personal relationships to enable all respondents to answer each item of the questionnaire. This system allows each of the domains to be scored out of the same total and therefore each contributes similarly to the overall questionnaire score. Scores in each domain range between zero and 100, a higher score indicating a greater impairment of quality of life.

Table 1. The most frequently described severity measures associated with urinary incontinence.

- The need to wear perineal pads
- The need to restrict fluid "to be careful how much you drink"
- The need to change underclothes when they become wet
- Worry in case of smell
- Embarrassment
- Being unable to wear ordinary clothes

The final version of the questionnaire was posted to 293 consecutive women referred for urodynamic investigations, approximately three weeks before the proposed date of their urodynamic studies. An accompanying letter asked women to complete the questionnaire at home and bring it with them to the hospital. If they encountered any difficulties, they were asked to discuss this with the doctor performing their urodynamic investigations.

The reliability of the questionnaire was assessed by its internal consistency, and by measurement of its test-retest reliability. Internal consistency was measured using Cronbach's alpha statistic[16]. Internal consistency refers to the degree of correlation between the items forming a scale. It is expected that items forming a domain of the questionnaire should correlate moderately with each other but should contribute independently to the overall score in that domain. A perfect correlation of 1·0 suggests that questions are measuring an almost identical construct, resulting in item redundancy; whereas a poor correlation suggests that items may be testing a number of different traits. It has been suggested that an alpha value of $\geq 0{\cdot}7$ is acceptable[17], although Carmines and Zeller[18] recommend values $> 0{\cdot}8$.

In order to measure test-retest reliability, 110 women chosen at random were asked to complete the questionnaire again on arrival in the department without

Table 2. Internal consistency (Cronbach's alpha statistic) and test-retest reliability scores for the King's Health Questionnaire (KHQ) (Spearman's rho nonparametric correlation coefficient). All results are significant at less than 1% level ($P < 0.01$). Values are given as mean (SD) unless otherwise indicated.

Domain of KHQ	Internal consistency	Test	Retest scores	Rho
Limitations				
Role	0·785	Test 1	35·89 (29·41)	0·94
		Test 2	37·84 (27·33)	
Physical	0·725	Test 1	42·79 (28·92)	0·96
		Test 2	44·29 (28·20)	
Social	0·758	Test 1	20·32 (22·65)	0·80
		Test 2	22·87 (21·57)	
Personal	0·892	Test 1*	10·51 (14, 72)	0·87
		Test 2*	12·61 (15·27)	
Emotional problems	0·876	Test 1	37·34 (28·30)	0·92
		Test 2	39·16 (26·64)	
Sleep/energy disturbance	0·784	Test 1	46·40 (26·05)	0·88
		Test 2	48·10 (25·30)	
Severity measures	0·778	Test 1	44·44 (28·77)	0·94
		Test 2	47·00 (25·62)	

*64 respondents (57·7%) scored 0·0 on test 1, and 56 (50·5%) scored 0·0 on test 2; of these 28/64 and 26/56 answered 'not applicable' to the questions in this section.

reference to their previously completed forms. The responses of the two completed questionnaires were then compared. A short interval between responses was desirable to ensure as far as possible that womens' urinary symptoms were unchanged.

Criterion validity is tested by measuring the correlation of the new measure with an established and previously validated measure of quality of life. As no suitable condition-specific questionnaire existed it was decided to perform validity testing against the UK version Short Form 36 questionnaire; 193 women were therefore also sent a copy of the Short Form 36 to complete at the same time as the King's Health Questionnaire.

Data analysis was performed using the SPSS statistical package, version 6.0. Women attending for urodynamic assessment underwent uroflowmetry, subtracted cystometry and videocystourethrography to establish an accurate urodynamic diagnosis.

The full questionnaire is available from the authors on request.

RESULTS

Two hundred and eighty-five (97·3%) correctly completed questionnaires were returned by the women on the day of their urodynamic assessment. Five questionnaires were received that had been completed incorrectly. Three questionnaires were not returned: two of these women also failed to attend for their urodynamic assessment. The women found the questionnaire easy to complete.

Table 3. Domains covered by the King's Health Questionnaire and the UK Short Form 36 health survey questionnaire applicable to women with urinary incontinence. Correlation coefficients (Spearman's [SCC]) between common domain scores on the two questionnaires. NA = no domain common to both questionnaires.

Domain	SCC	*P*
General health	−0·648	< 0·001
Incontinence Impact	NA	
Urinary symptoms	NA	
Incontinence severity measures	NA	
Changes in health	NA	
Physical function	−0·342	< 0·01
Role limitations	−0·461	< 0·005
Social limitations	−0·512	< 0·001
Mental health	−0·465	< 0·001
Energy / vitality	−0·617	< 0·001

The mean age of the women was 51·4 years (range 17–85). Videourodynamic investigations were performed on all women (genuine stress incontinence 133; detrusor instability 80; mixed incontinence 11; low compliance 29; sensory urgency 11; normal urodynamics 14).

Reliability studies

Internal consistency using Cronbach's alpha statistic exceeded the minimum requirements for reliability in all domains of the questionnaire (Table 2). Test retest reliability was performed in 110 women all of whom completed the questionnaire correctly on two occasions. The questionnaire was completed easily by the women in the short time while awaiting their urodynamic studies. The mean time between completion of the questionnaires was 9·2 days (range 2 to 16 days). The mean and standard deviation of the individual domain scores and the correlations of the two test results (Spearman's rank correlation coefficient) are shown in Table 2.

Criterion validity testing

One hundred and ninety-three women who completed the King's Health Questionnaire also completed the Short Form 36 questionnaire. A major difference between these two questionnaires is that high scores on the King's Health Questionnaire and low scores on the Short Form 36 represent a worse quality of life. In addition, several of the domains of the King's Health Questionnaire questionnaire are not covered in the generic Short Form 36 questionnaire. Spearman's correlation coefficients were used to correlate the results of the King's Health Questionnaire and the Short Form 36 in the common domains (Table 3). There was a highly

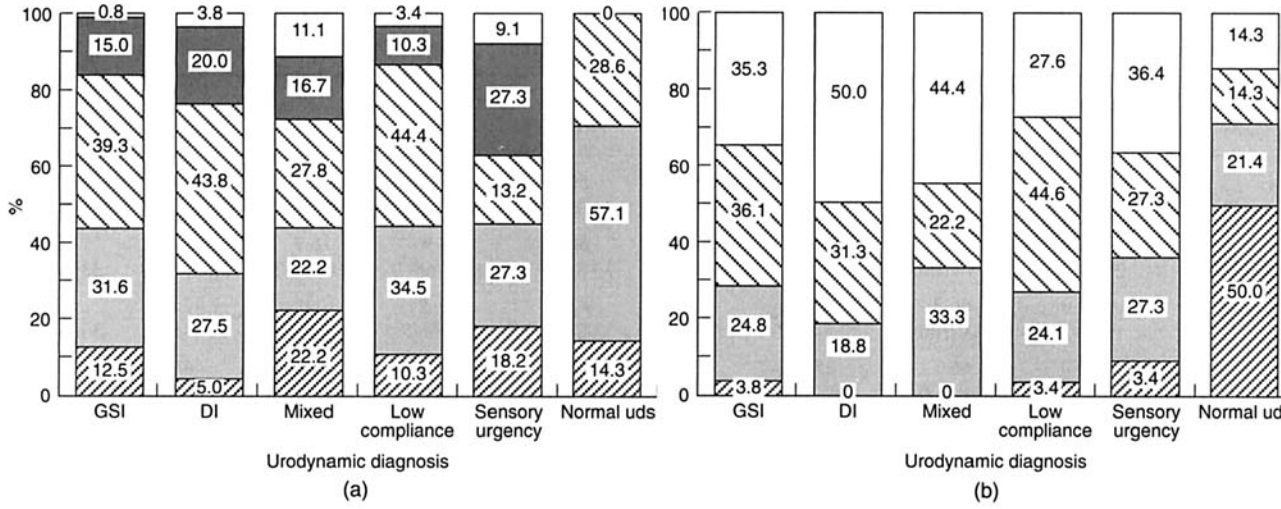

Fig. 1. Results on Part 1 of the King's Health Questionnaire by urodynamic diagnosis. (a) 'How would you describe your health at present?' (□ = very poor; ■ = poor; ▨ = fair; ▩ = good; ▨ = very good). (b) 'How much do you think your bladder problem affects your life?' (□ = a lot; ▨ = moderately; ▩ = a little; ▨ = not at all). Total: $n = 285$; genuine stress incontinence (GSI): $n = 133$; detrusor instability (DI): $n = 80$; mixed: $n = 18$; low complicance: $n = 29$; sensory urgency: $n = 11$; normal urodynamics (uds): $n = 14$.

significant correlation between the common domain scores for the two questionnaires, and both were found to be easy to complete by the women.

Results of the King's Health Questionnaire in the assessment of urinary incontinence

The first part of the questionnaire dealt with the perceptions of general health and the impact of the incontinence. Over 70% of women with genuine stress incontinence, detrusor instability, low compliance, mixed incontinence and normal urodynamics considered their health to be fair or better than normal (Fig. 1a). Women with sensory urgency reported a worse overall general health, although this difference was not statistically significant.

Although the majority of women felt that their general health was good, in many cases the impact of their urinary incontinence was considerable; consequently the correlation between the scores in these two sections of the questionnaire was modest (Spearman's rho = 0·23). Incontinence impact scores were significantly higher for women with detrusor instability ($n = 80$) than genuine stress incontinence ($n = 133$) ($P < 0·05$, Mann-Whitney U test), and significantly lower for women with normal urodynamic investigations ($n = 14$) than those with other diagnoses ($P < 0·01$, Mann-Whitney U test) (Fig. 1b and Table 4).

The second part of the questionnaire explored six domains: role, physical and social limitations, personal relationships, emotions and sleep. In addition, the woman's perception of the severity of her incontinence was measured. Women with detrusor instability had significantly higher scores in all domains other than physical limitations, than women with genuine stress incontinence (Mann-Whitney U test, $P < 0·05$) (Table 4). Women with sensory urgency scored higher in the domain of personal limitations than those with other diagnoses, and women with normal urodynamic investigations had significantly lower scores in all domains of the questionnaire, other than personal limitations, than women with any other urodynamic diagnosis. Interestingly, although this finding is not statistically significant, the perception of severity of urinary incontinence was greater in women with genuine stress incontinence (mean 57·2) than women with detrusor instability (mean 48·2) Table 4, despite the latter group experiencing higher scores in nearly all of the remaining domains.

DISCUSSION

We have demonstrated that the King's Health Questionnaire is easy to understand and answer. Consequently 97·3% of respondents representing a wide age range and level of physical and intellectual ability completed it correctly. Undoubtedly in this study the high response rate was due to the fact that questionnaires were collected when women attended for their urodynamic assessment and not returned to us by post.

The reliability of the questionnaire was excellent in terms of its internal consistency and its test-retest reliability. Scores on the second completion of the questionnaire tended to be higher than the first although these differences were not statistically significant. This may be because the questionnaire was completed in the surroundings of the busy urodynamic clinic on the second occasion rather than in the privacy of the women's own homes. Ideally test and retest conditions should be

Table 4. Domains of the King's Health Questionnaire by urodynamic diagnosis. Kruskall-Wallis test (5 df). Values are given as median with interquartile range below. GSI = general stress incontinence; DI = detrusor instability; uds = urodynamics; NS = not significant.

Diagnosis	General health	Incontinence impact	Severity	Role	Physical	Social	Personal	Emotions	Sleep
GSI	50·0	66·7	58·3	50·0	50·0	22·2	0·0	44·4	50·0
(n = 133)	25·0–50·0	33·3–100·0	33·3–83·3	16·7–66·7	33·3–83·3	0·0–55·6	0·0–33·3	22·2–77·8	33·3–66·7
DI	50·0	83·3	50·0	**50·0**	50·0	**38·9**	**16·7**	**61·1**	**66·7**
(n = 80)	25·0–50·0	66·7–100·0	25·0–83·3	**33·3–83·3**	33·3–83·3	**11·1–66·7**	**0·0–66·7**	**33·3–88·9**	**33·3–83·3**
Mixed	50·0	66·7	50·0	41·7	41·7	33·3	0·0	44·4	50·0
(n = 18)	18·8–75·0	33·3–100·0	37·5–75·0	16·7–66·7	33·3–66·7	0·0–66·7	0·0–25·0	19·4–80·6	33·3–70·8
Low compliance	50·0	66·7	25·0	33·3	33·3	22·2	0·0	44·4	50·0
(n = 29)	25·0–50·0	33·3–100·0	8·3–58·3	16·7–66·7	16·7–66·7	0·0–33·3	0·0–25·0	22·2–66·7	33·3–66·7
Sensory urgency	50·0	66·7	33·3	33·3	50·0	22·2	**33·3**	33·3	50·0
(n = 11)	25·0–75·0	33·3–100·0	16·7–50·0	0·0–50·0	0·0–50·0	0·0–55·6	**0·0–66·7**	22·2–100·0	33·3–66·7
Normal uds	25·0	16·7	16·7	**0·0**	**0·0**	**0·0**	0·0	**5·6**	**25·0**
(n = 14)	25·0–50·0	0·0–66·7	0·0–37·5	**0·0–33·3**	**0·0–37·5**	**0·0–18·06**	0·0–8·3	**0·0–33·3**	**0·0–37·5**
P	NS	< 0·01	NS	< 0·01	< 0·01	< 0·01	< 0·01	< 0·01	< 0·01
All diagnoses	50·0	66·7	50·0	33·3	50·0	22·2	0·0	44·4	50·0
(n = 285)	25·0–50·0	33·3–100·0	25·0–75·0	16·7–66·7	33·3–83·3	0·0–55·6	0·0–33·3	22·2–77·8	33·3–66·7

identical in order to avoid this potential form of bias; despite this in our study the overall test-retest reliability was excellent. The criterion validity of the King's Health Questionnaire was confirmed against the UK Short Form 36, the reliability and validity of which has been previously demonstrated[7].

Our study shows that the majority of women with urinary incontinence consider their general health to be good. For many women, however, their bladder problems are a major impediment to a good quality of life. This is an important observation and emphasises the need for condition-specific quality of life measures to assess the unique impact of urinary symptoms.

As we expected, women with genuine stress incontinence scored higher in the domain of physical impairment than women with detrusor instability, whereas the latter scored higher in all other domains and had an overall greater impairment of quality of life. This has been demonstrated previously using generic quality of life questionnaires. Despite this finding, women with genuine stress incontinence achieved higher scores in the domain of severity of incontinence (Table 4). This finding implies that although women with genuine stress incontinence are more likely to be incontinent and to develop incontinence avoidance strategies, they are less likely to suffer impairment of their quality of life because of their urinary symptoms. It is possible that the unpredictable nature of the urinary symptoms associated with detrusor instability, makes adaptation more difficult, and therefore the impairment of quality of life is greater for these women. Symptomatic women with normal urodynamic investigations scored lower in all domains of the questionnaire than women with any urodynamic diagnosis. This finding would indicate that the questionnaire truly measures the impairment of quality of life due to urinary symptoms[19].

The King's Health Questionnaire through its simplicity is likely to be a useful questionnaire for the routine clinical assessment of women presenting to a busy urodynamic clinic. At present it is being used in our own unit. Of even greater importance, however, may be the inclusion of quality of life questionnaires in clinical trials evaluating new treatments for urinary incontinence. Certainly condition-specific questionnaires such as the King's Health Questionnaire appear to be sufficiently sensitive to function well in this role.

Since work started on the design and validation of this questionnaire, interest in the use of health status assessed by the women has increased in many other areas of obstetrics and gynaecology, and many studies now include quality of life data. It is hoped that measurement of quality of life will become a routine part of the assessment of all incontinent women, as only by fully understanding the true impact of this condition can we expect to improve its evaluation and treatment.

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