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# QUALITY OF LIFE ASSESSMENT FOR PATIENTS WITH URINARY INCONTINENCE

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## ABSTRACT

In order to improve the quality of medical care, an assessment of patients' quality of life (QOL) has been recognized to be important as well as an assessment of physical impairment. Since diseases affect a wide range of QOL facets, including physical, emotional, and social conditions, disease severity and treatment efficacy should not be assessed only by clinical parameters. Urinary incontinence has a strong influence on patients' QOL. Health-related QOL is a multidisciplinary and subjective construct that refers to an individual's perception of his/her state of health or disease. The treatment of urinary incontinence should be selected based on questionnaires. Since 1987, various questionnaires for QOL assessment in patients with urinary incontinence have been developed. During the meeting of the International Consultation on Incontinence (ICI), held in 1998, 2001, and 2004, various QOL questionnaires for urinary incontinence were assessed and ranked based on scientific verifications. This paper describes the influence of urinary incontinence on QOL and the measurement of QOL in patients with several urinary problems.

Key Words: Quality of life, Urinary incontinence, Questionnaire

## INTRODUCTION

We acquire a urinary habit as an essential behavior in social life through toilet training, which starts in early childhood. In the process of acquiring the urinary habit, we form a mental and social concept that urination is a very personal matter that should be kept private. Therefore, leakage of urine in public is one of the most miserable incidents in social life both for infants and adults. The mental trauma associated with leakage is severe and it may induce a feeling of embarrassment, alienation, isolation, or depression. Urinary frequency or urinary incontinence affects a person's relationships both with the surrounding people and society as a whole. In the case of the elderly, urinary frequency or urinary incontinence variously affects even their caretakers' lifestyles.

The assessments of disease severity and treatment efficacy, and the treatment selection for urinary incontinence, have traditionally been performed based on objective findings obtained by urodynamic examination and the pad test. However, since 1987, various QOL assessment questionnaires have been developed for patients with urinary incontinence, and in recent years, subjective symptoms and QOL have become more important than objective findings. The first International Consultation on Incontinence (ICI), supported by the World Health Organization (WHO), was held in Monaco (1998), and the second and third were held in Paris (2001) and

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Monaco (2004), respectively. The Subcommittee of Symptom and QOL Assessment of the ICI has confirmed the importance of symptom and QOL assessment for patients with urinary incontinence. Moreover, the subcommittee has assessed the validity of questionnaires for QOL assessment, the findings of which have been previously reported. Furthermore, the subcommittee has been developing a simple questionnaire for symptom and QOL assessment that can be used internationally.[1)] Although a QOL assessment for urinary frequency has not been developed, a QOL assessment for overactive bladder —a condition in which patients feel urgency accompanied by urinary frequency or urge incontinence— has been developed in recent years.

## I. The questionnaire for subjective symptom and QOL assessment

There are various methods used to assess the symptoms and QOL of patients with urinary incontinence. Although medical history taking has traditionally been employed, a questionnaire to be filled in by patients has been adopted in recent years. Medical history taking is not a standardized method and its contents differ according to doctors and patients. Generally, doctors' QOL assessments tend to be lower than patients' QOL assessments. Regarding urinary incontinence, it is difficult for patients to express their symptoms and impediments to doctors because of shame. Therefore, a questionnaire for symptom and QOL assessment filled in by patients is recommended. The questionnaire can measure the existence and degree of urinary symptoms, including urinary incontinence, and the influence of urinary symptoms on patients' daily life and QOL.

## II. Conditions of the questionnaire

The questionnaire is an objective method designed to measure subjective phenomena such as symptoms and QOL. The process of developing the questionnaire is not simple and many trials may be required in order to confirm that a certain questionnaire can measure the desired parameters, and that it addresses the relevant objectives. Since the questionnaire is a tool for assessing QOL scientifically, the arbitrary development of questionnaires should be avoided, and the reliability and validity of the questionnaire as a measurement tool should be scientifically verified. Reliability includes factors such as internal consistency and the test-retest method whereas validity includes criterion and construct validity. Moreover, the responsiveness to a change before and after medical treatment should be verified. Furthermore, if the questionnaire is to be used in clinics, simplicity is an additional important criterion.

## III. Relationship between the questionnaire and other clinical assessments

The relationship among subjective symptoms, QOL assessment, and urodynamic findings is complicated. Generally, with urinary symptoms, the relationship among subjective symptoms, QOL assessment, and objective urodynamic assessment is not clear: however, each of these facets is considered important for assessing patients with urinary incontinence. Recently, QOL assessment using a questionnaire has been recognized as a method of assessing the influence of urinary symptoms on patients' lives.

## IV. The recommendation ranking of questionnaires for symptoms and QOL

During the second ICI, studies on symptoms and QOL were investigated based on reports

**Table 1** Criteria for recommendation of questionnaires for urinary incontinence at the third consultation

| Grade of recommendation | Evidence required (published) |
|---|---|
| Grade A (highly recommended) | Validity, reliability and responsiveness established with rigour in several data sets. |
| Grade $A^{new}$ (highly recommended) | Validity, reliability and responsiveness indicated with rigour in one data set. |
| Grade B (recommended) | Validity, reliability and responsiveness indicated but not with rigour. Validity and reliability established with rigour in several data sets. |

**Table 2** Criteria for recommendation of questionnaires for pelvic organ prolapse and fecal incontinence at the third consultation

| Grade of recommendation | Evidence required (published) |
|---|---|
| Grade A (highly recommended) | Validity, reliability and responsiveness established with rigour. |
| Grade B (recommended) | Validity and reliability established with rigour, or validity, reliability and responsiveness indicated. |
| Grade C (with potential) | Early development-further work required and encouraged. |

obtained from databases such as Cochran, Medline, and Pub-Med, and a recommendation ranking of various questionnaires, mainly for urinary incontinence, was decided based on the degree of the verification. In this study, databases such as Pub-Med, Medline, PsychInfo, and LOCATORolus were searched between January 2001 and June 2004. Questionnaires on the symptoms of and the QOL of patients with, extensive abnormalities additional to urinary incontinence, such as lower urinary tract symptoms, fecal incontinence, sexual dysfunction, and pelvic organ prolapse were assessed. Based on this assessment, a recommendation ranking of these questionnaires was decided. Tables 1 and 2 show the criteria of the recommendation ranking of questionnaires adopted by the subcommittee.[2-31)]

## V. The recommended questionnaires for symptoms and QOL

The questionnaires for symptoms and QOL include generic questionnaires and disease-specific questionnaires. The generic questionnaires have been developed to generally measure the QOL of patients with extensive diseases and conditions. In contrast, the disease-specific questionnaires have been developed to assess the influence of specific disease on QOL and changes in QOL due to treatment. Although the generic questionnaires are a generally useful means of assessing differences in QOL according to diseases and conditions, they are unable to assess the specificity of specific diseases. Therefore, the disease-specific questionnaires are used clinically. Since QOL questionnaires are required to include multidisciplinary assessments, factors such as physical function, social activity, personal relations, work, mentality, health satisfaction, life satisfaction, sexual life, sleep, pain, fatigue, and vitality should all be assessed.

The questionnaires for the symptoms and QOL of urinary incontinence, lower urinary tract symptoms, fecal incontinence, sexual dysfunction, and pelvic organ prolapse, which have been

recommended by the ICI Subcommittee of Symptom and QOL Assessment are shown in Tables 3–7.

**Table 3** Recommended questionnaires for the evaluation of urinary incontinence and urinary incontinence/lower urinary tract symptoms/overactive bladder-Grade A

| | |
|---|---|
| Combined symptoms and quality of life impact of urinary incontinence | |
| Men and women | ICIQ (grade A$^{new}$) [2] |
| Women | Bristol Female LUTS-SF (grade A) [3]<br>SUIQQ (grade A$^{new}$) [4] |
| Men | ICSmaleSF (grade A) [5] |
| Combined symptoms and quality of life impact of overactive bladder | |
| Men and women | OAB-q (grade A$^{new}$) [6] |
| Symptoms of urinary incontinence | |
| Women | Urogenital Distress Inventory (grade A) [7]<br>UDI-6 (grade A) [8]<br>Incontinence Severity Index (grade A) [9]<br>BFLUTS (grade A) [10] |
| Men | ICSmale-LUTS primarily (grade A) [11]<br>DAN-PSS-LUTS primarily (grade A) [12] |
| Quality of life impact of urinary incontinence | |
| Men and women | Quality of life in persons with UI(I-QOL) (grade A) [13]<br>SEAPI-QMM [14] |
| Women | King's Health Questionnaire (KHQ) (grade A) [15]<br>Incontinence Impact Questionnaire (IIQ) (grade A) [16]<br>IIQ-7 [16]<br>Urinary Incontinence Severity Score (UISS) (grade A$^{new}$) [17]<br>CONTILIFE (grade A$^{new}$) [18] |
| Men | None |

**Table 4** Recommended questionnaires for the evaluation of symptoms and quality of life impact of pelvic organ prolapse

| |
|---|
| Grade A |
| None |
| Grade B |
| Pelvic Floor Distress Inventory (PFDI) [19]<br>Pelvic Floor Impact Questionnaire (PFIQ) [19] |
| Grade C |
| P-QOL/St. Mary's Questionnaire<br>Pelvic Floor Dysfunction Questionnaire<br>e-PAQ Pelvic Floor Symptoms Questionnaire<br>Danish Prolapse Questionnaire<br>ICIQ-Vaginal Symptoms Questionnaire (not published) |

**Table 5** Recommended questionnaires for the evaluation of symptoms and quality of life impact of fecal incontinence

| Grade A |
|---|
| None |
| **Grade B** |
| Fecal Incontinence Quality of Life Scale [20] |
| Manchester Health Questionnaire [21] |
| Birmingham Bowel and Urinary Symptom Questionnaire (BBUS-Q) [22] |
| **Grade C** |
| Wexner score |
| Faecal Incontinence Survey |
| Elderly Bowel Symptoms Questionnaire |
| Postpartum Flatal and Faecal Incontinence Quality of Life Scale |
| Bowel Disease Questionnaire |
| Gastrointestinal Quality of Life Index |

**Table 6** Recommended generic questionnaires for the evaluation of symptom and QOL impact of urinary incontinence, fecal incontinence and pelvic organ prolapse

| Grade A |
|---|
| SF-36 / SF-12 [23] |
| Rand-36 [24] |
| EuroQoL EQ-5D [25] |
| Nottingham Health Profile [26] |
| Sickness Impact Profile [27] |

**Table 7** Recommended questionnaires for the evaluation of sexual function impact of urinary incontinence

| Grade A | |
|---|---|
| Men and women | Golombok-Rust Inventory of Sexual Satisfaction [28] |
| Men | International Index of Erectile Function [29]<br>ICS sex [30]<br>BPHQOL9 [31] |
| **Grade B** | |
| Men and women | Psychosocial Adjustment to Illness Scale |
| Women | Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire<br>Brief Index of Sexual Function for Women |
| Men | Brief Sexual Function Inventory |

## VI. Development of an ICIQ-SF for urinary incontinence

In order to clinically utilize the questionnaires and to internationally compare the studies on urinary incontinence, a simple questionnaire for symptoms and QOL, which can be used as an international criterion for assessment, is required. The Subcommittee of Symptom and QOL Assessment has been developing its original questionnaire for the symptoms of and QOL of patients with, urinary incontinence since the first ICI, and has developed an ICI Questionnaire-Short Form (ICIQ-SF) for urinary incontinence. The ICIQ-SF includes 10 questions on the frequency of urinary incontinence, degree of hindrance, frequency in use of a napkin, type of napkin, subjective assessment of the amount of urinary incontinence (the ordinary amount of urinary incontinence and the largest amount of urinary incontinence), influence on daily life, influence on social life, influence on sexual life, and quality of general life. Moreover, age, gender, and a subjective assessment of the cause of urinary incontinence are also included in the ICIQ-SF. The ICIQ-SF was verified and recommended as "grade A new" by the ICI. During the verification of the ICIQ-SF, considerable duplications were observed among the questions. Therefore, the ICIQ-SF was amended such that the final edition had only 3 questions related to the frequency of urinary incontinence, the ordinary amount of urinary incontinence, and the influence on daily life. These 3 questions were assessed on the basis of the data from 469 cases. Moreover, since the assessment of the cause of urinary incontinence is important for clinicians, a question related to the subjective assessment of the cause of urinary incontinence was included in the final edition. However, this question was not scored. The scores of the 3 questions were summed and the resulting totals ranged between 0 and 21 points. The ICIQ-SF was developed for all patients with urinary incontinence regardless of gender and age. The validity, reliability, and responsiveness of the ICIQ-SF for urinary incontinence were verified in Britain, and by 2004 the verified ICIQ-SF had been translated into 27 languages including Japanese, Dutch, Spanish, and Swedish. The translation into Japanese was performed using a standard method based on linguistic validation.[32] The validity, reliability, and responsiveness of the Japanese edition of the ICIQ-SF for urinary incontinence were also verified, and the results were comprehensively discussed in the report.[33]

## VII. Creation of an ICIQ unit

In order to create an international standard assessment tool for pelvic problems related to functional disorders of the lower urinary tract, vagina, and lower alimentary canal, the ICI is creating an ICIQ unit. The situation of creating the ICIQ unit is shown in Tables 8 and 9, and this will be gradually published on the ICIQ website (www.iciq.net).

## VIII. Items recommended by the Subcommittee of Symptom and QOL Assessment

During the third ICI, the following items for symptom and QOL assessment were recommended for use in clinics and studies.

1. Regarding the diagnosis and treatment of urinary incontinence, clinicians should select an appropriate questionnaire from the list indicated by the ICI in order to assess the situation of urinary incontinence and its influence on patients' life.
2. Clinicians are recommended to discuss the objective of using questionnaires in their medical examinations.
3. The grade A questionnaire is recommended for use in a randomized controlled trial related to the treatment of urinary incontinence.

**Table 8** ICIQ Units for symptom assessment

| Condition | Core Modules | Optional Modules |
|---|---|---|
| Symptoms | | |
| Lower urinary tract symptoms | Male ICIQ-MLUTS<br>Female ICIQ-FLUTS | Male ICIQ-MLUTS<br>Female ICIQ-FLUTS LF |
| Vaginal symptoms | ICIQ-VS | — |
| Anal symptoms | ICIQ-BS | — |
| Patients | | |
| Urinary incontinence | ICIQ-UI SF | ICIQ-UI LF |
| Nocturia | ICIQ-N | — |
| Overactive bladder | ICIQ-OAB | — |
| Neurogenic | ICIQ-Neuro | — |
| Children | ICIQ-LUTSC | — |

**Table 9** ICIQ units for QOL assessment

| Condition | Recommended add-on modules | |
|---|---|---|
| | QOL | Generic QOL |
| Lower urinary tract symptoms | ICIQ-LUTS qol | SF-12 |
| Vaginal symptoms | ICIQ-VS qol | SF-12 |
| Fecal symptoms | ICIQ-BS qol | SF-12 |
| Urinary incontinence | ICIQ-LUTS qol | SF-12 |
| Nocturia | ICIQ-N qol | SF-12 |
| Overactive bladder | ICIQ-OAB qol | SF-12 |
| Neurogenic | | SF-12 |
| Children | ICIQ-LUTSC qol | — |

4. Researchers are recommended to undertake further studies on the following items:
- Application of the grade A questionnaire to the wide range of examinations.
- Further examination of the sensitivity to a clinical change in grade A new, grade B, and insufficiently verified questionnaires.
- Development of a new questionnaire for special groups such as the elderly and infant.
- Description of the validity of the questionnaire as well as the method, objective, and statistical analysis used in the study.
- Examination of the influence of the questionnaire used in clinical treatment as well as an examination of the cost, participants' burden, and ease of performance in the randomized controlled trial.

## CONCLUSION REMARKS

In the third ICI, various questionnaires, which have been developed for the symptom and QOL assessment of fecal incontinence, sexual dysfunction, and pelvic organ prolapse, in addition to

urinary incontinence, were ranked based on appropriate verifications of validity, reliability, and responsiveness, and were recommended according to the subject (male or female). Moreover, in order to create an international standard assessment tool for pelvic problems related to functional disorders of the lower urinary tract, vagina, and lower alimentary canal, an ICIQ unit is currently being created by the ICI. In the future, the questionnaire recommended by the Subcommittee of Symptom and QOL Assessment is expected to be used as the international standard.

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