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## **INCONTINENCE STORAGE PHASE SYMPTOM SCORE (ISSS) – A NEW SYMPTOM QUESTIONNAIRE FOR URINARY INCONTINENCE AND OVERACTIVE BLADDER SYNDROME**

### **Hypothesis / aims of study**

Among the lower urinary tract symptoms (LUTS), urinary incontinence (UI) is the most distressing one. A number of symptom questionnaires have been developed for assessing UI and associated symptoms. However, most of them are applicable only for women or specific types of incontinence. This poses difficulty in evaluating LUTS in incontinent men and women of any type or of combined types of UI. A questionnaire that can be used for incontinence in general is needed.

### **Study design, materials and methods**

From the literature survey and panel discussion, the questionnaire prototype 1 was proposed, which contained 27 items of LUTS and 4 items on impact by the symptoms. The prototype 1 was examined in 104 incontinent patients (21 men and 83 women) for the prevalence of being symptomatic, correlation between symptom and global influence by the symptoms. Cluster analysis was used to identify symptom groups that address similar aspects of LUTS. After excluding less important symptoms, which means rare symptoms or symptoms with least correlation with global impact, the questionnaire prototype 2 that contained 15 items of LUTS was developed. The questionnaire prototype 2 was administered to 87 incontinent patients, 15 patients with voiding difficulty and 15 controls. Each symptom was asked for the degree of influence (none, a little, moderately, severely). The analysis was similar to Study 1, leaving 8 items of LUT for the prototype 3. In prototype 3 it was decided to measure the symptoms by a Likert-type scale from 0 (least frequent) to 4 (most frequent), and to approximate score 2 to the frequency at which a half of patients with the frequency felt moderately or severely influenced by the symptom. Validity of the prototype 3 was tested in 231 patients (26 men and 205 women) and 15 controls. Reliability was examined by kappa test. Principle component analysis was used for examining construct validity. QOL was quantified by King's Health Questionnaire (KHQ) and served as the external criteria. KHQ is incontinence specific QOL measure containing 8 domains (general health, incontinence impact, social activity, personal relationship, daily activity), with each domain scored from 100 (worst) to 0 (best). The tool was validated in patients of our language with urinary incontinence or OAB.

### **Results**

Response rate was more than 99% for all items. Floor effect or ceiling effect (more than 40%) was not observed. Weighted kappa was 0.72 or more for individual item score and 0.97 for the total score. Principle component analysis identified the first component (Eigen value of 3.73) that correlated positively with any items (Spearman's  $r = 0.12$  to  $0.43$ ). The total score correlated with any KHQ scores (Spearman's  $r = 0.27$  to  $0.70$ ) and responded more sensitively to therapeutic effects (effect size: 1.43) than any KHQ scores (effect size: 0.35 to 0.78). The validity was maintained, when patients were analyzed separately for stress incontinence and urge incontinence. After minor changes in wordings, the final form of questionnaire was proposed (Table).

### **Interpretation of results**

The questionnaire is applicable to any incontinence type of both genders. It may be also applicable to OAB patients, as it contains all the symptoms included in OAB syndrome (urgency, frequency and urge incontinence).

### **Concluding message**

The questionnaire is valid for incontinence and OAB.

### Incontinence Storage Phase Symptom Score (ISSS)

Please circle the number of answer that applies best to your urinary conditions during these 4 weeks.

How many times have you typically urinated from the waking time in the morning until the sleeping time at night?	7 or less	8-9	10	11-14	15 or more
	0	1	2	3	4

How many times have you typically waked up to urinate from the sleeping time at night until the waking time in the morning?	0	1	2	3	4 or more
	0	1	2	3	4

	not at all	less than once a day	about once a day	2-4 times a day	5 times or more
How often have you had sudden desire to urinate, which was difficult to defer?	0	1	2	3	4
How often have you had urinary incontinence?	0	1	2	3	4
How often have you changed the pads?	0	1	2	3	4

	not at all	rarely	sometimes	often	always
Have you leaked urine, because you could not defer the sudden desire to urinate?	0	1	2	3	4
Have you leaked urine at coughing or during walking?	0	1	2	3	4
Have you found you wet without noticing leak?	0	1	2	3	4

Total score (0-32)