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# RELIABILITY AND VALIDITY OF A QUESTIONNAIRE TO REGISTER SYMPTOM SEVERITY AND QUALITY OF LIFE IN STRESS AND URGE INCONTINENT FEMALES.

#### Aims of Study

To design a short form questionnaire recording symptom severity and quality of life (QoL) among stress and urge incontinent females, before and after surgical treatment. The questionnaire is designed to be applied in all gynaecological departments in our country performing incontinence operations. Reliability and validity of the questionnaire are evaluated.

## Methods

Formerly aquired experience with questionnaires has been taken into account when the present questionnaire was developed (1, 2, 3, 4). The questionnaire consists of symptoms and quality of life (QoL) sections. Two indices are constructed from the symptom section. A stress incontience index (SII) is constructed from 3 sub-indices. One subindex is a composite of 9 questions about situations where stress leakage occurs. The second and third sub-indices pertain to how often and how much stress incontinence is experienced. An urge incontinence index (UII) is composed of 2 questions about how often and to which extent urge incontinence is experienced. A QoL index (QoLI) is constructed of 3 sub-indices about how often activities, places or situations are avoided due to fear of leakage, and how leakage may influence vacations, family life, social life and sleep. In all items a scale of 5 categories are possible choices with the scores 0, 1, 2, 3, 4 respectively. The 9 questions from the first stress subindex has the possible choices yes, no and not relevant. Scores for these questions are 1, 0 and 0 respectively. The sum of the scores from the 9 questions are recalculated to a score from 0 to 4 Four questions were not implemented in an index the number of pads used, the number of urinary infections per year, treatment satisfaction and how sexual life is influenced by the leakage. The questionnaire is intended to be completed before the operation, 6 to 12 months and 3 years after the operation. Completed questionnaires are mailed twice a year to a centre who scans them into a database. A report comparing datas from the actual department with mean data from all departments is generated twice every year. In a pilot study the questionnaire was tested on 50 patients for comprehensibility,

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ambiguity and redundancy. To assess the test-retest reliability, the questionnaire was mailed a second time to 65 patients. Fifty nine questionnaires were accomplished. The interval between the completion of 2 questionnaires was mean 22 (SD 14) days. Spearman correlation index was calculated. From September 1<sup>st</sup> 1998 till today we have recieved 628 preoperative forms from 2/3 of all departments in our country. Internal consistency of the indices were tested using Chronbachs alpha. Criterion validity was evaluated by comparing the SII with a stress test and SII and UII with a 24 hours pad test. Stress test and 24 hours pad test were performed in 581 and 495 of the patients respectively.

## Results

During the pilot study several changes were made to the content and wording of the questions to improve face and content validity. Only few data were missing from the 622 questionnaires. From the 9 questions concerning stress incontinence data were missing in a range from 0.1 to 2.4 %. Data were missing in 0.2, and 0.6 % of the 2 additional stress incontinence sub-indices respectively. In the UII the 2 sub-indices had missing data in 0.3 and 2.9 % respectively. In the 3 sub-indices of the QoLI data were missing in 0.5, 1.3 and (2.9, 2.9, 3.7, 2.7)% respectively. Data about number of pads used, urinary infections per year were missing in 0.5% and 1.3%. Data if sexual life was influenced by the leakage was missing in 4.3% and 35% answered the question was not relevant. The SII was skewed to the higher end of the scale with a median and range of 9 (0-12). The UII and QoLI were both symmetrical with medians and ranges 4 (0-8) and 6 (0-12) respectively. The internal consistency of SII, UII and QoLI were acceptable with Chronbach alpha 0.73, 0.75 and 0.74 respectively. Conserning criterion validity: SII tested against stress test and UII and SII tested against 24 hours pad test revealed low correlation's with Spearmans rho 0.31, 0.23 and 0.3 respectively. The correlation indices of the test-retest of SII, UII and QoLI were 0.76, 0.83 and 0.94 respectively.

## Conclusions

Our questionnaire is easy to both understand and answer. Mean 98.1 % of all questions in the indices were completed. Internal consistency reliability testing produced adequate results and test-retest reliability analysis demonstrated that responses to the questionnaire are consistent. Correlation between the SII and UII and the objective outcome values 24 hours pad test and stress test were low. This is to be expected when indices made up of subjective variables are compared with objective variables.

1. Neurourol Urodynam 1996 15: 630-40

2. Neurourol Urodynam 199514: 131-39

3. Brit J Urol 1996 77: 805-12

4. Brit J Obst Gyn 1997 104: 1374-79