**PUK32**

### VALIDATION OF THE INTERNATIONAL PROSTATE SYMPTOMS SCORE IN ITALIAN WOMEN WITH LUTS. THE FLOW STUDY

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**OBJECTIVES:** The International Prostate Symptom Score (IPSS), a condition-specific questionnaire originally addressed to men, comprises seven items investigating symptoms (summed into a total score), plus 1 item on quality of life (QoL). The IPSS was translated into Italian and adapted to women. The so-obtained W-IPSS was thus validated by the FLOW study group in a sample of Italian women with lower urinary tract symptoms (LUTS). **METHODS:** The validation process consisted of forward and backward translation, test of comprehension, discriminant validity and test-retest reliability. A first set of women was interviewed after filling-in the questionnaire and a comprehension rate was built as the percentage of correctly understood questions and pre-coded answers. A case-control study was then performed. Women aged °Ý 18 year affected by LUTS for at least three months and with negative dipstick were consecutively enrolled as cases. Controls were defined as healthy women of comparable age. In order to evaluate reliability, cases were retested after seven days from baseline and a correlation analysis was performed (Pearson's r). Discriminant validity was assessed by comparing the scores of cases and controls with ANOVA. **RESULTS:** During the translation process the QoL question about "prostate symptoms" was changed into "urinary symptoms" to adapt the IPSS to a female population (now "W-IPSS"). The comprehension rate obtained on 15 women was 86%. Eighty cases and 80 controls were then enrolled at baseline. All cases were eligible for the test-retest. Pearson's coefficient between ratings was 0.81 for the symptom score and 0.89 for QoL. Cases and controls were discriminated by ANOVA ($p < 0.001$) for all items. **CONCLUSION:** Women-IPSS shows overall a satisfactory comprehension rate, a good test-retest reliability and high discriminant validity.

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### DEVELOPMENT AND TESTING OF A COMPOSITE SCALE TO ASSESS THERAPEUTIC RESPONSE IN STRESS URINARY INCONTINENCE

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**OBJECTIVE:** Clinicians in charge of Stress Urinary Incontinence (SUI) patients miss specific tools taking into account patients' perspective to support treatment decision. Our aim was to develop a global medical judgment scale to assess therapeutic response. **METHODS:** The concepts useful to assess SUI treatment outcomes were identified from a literature review and 30 clinician interviews. A test version of the pragmatic assessment form (PAF) was developed. Eight clinicians involved in the care of SUI were interviewed to assess concept relevance, comprehensiveness, validity, accessibility to source information, clarity, applicability to various situations in real life, usefulness in clinical practice to form global medical judgment. The PAF was updated accordingly. Ten SUI patients reviewed the PAF for concept relevance, reliability and applicability in clinical practice. **RESULTS:** Eight broad concepts covering symptom and functional status, impact on daily life activities, well-being, coping, satisfaction and expectations were included in the test PAF. Seven of 8 clinicians found the PAF complete, relevant, and specific to SUI, clear and valid to support medical judgment. The clinicians were happy to have an assessment guide to support judgment, but did not request a formal scoring procedure to support decision. Satisfaction was divided into treatment benefit, undesirable effects and constraints. Patient's intention was added. After validation by 10 SUI patients, the pilot version of the PAF was finalised in double A4 format including instructions. Concept elicitation can be pragmatic for clinical practice, or standardized for clinical research. **CONCLUSION:** This short, simple and pragmatic composite tool will help the clinicians to easily manage the complexity of patients' perspective by comprehensively covering the relevant outcomes to assess therapeutics and support medical decision making in SUI. Its properties in clinical practice and clinical research will be assessed in specific validation studies.

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### EVALUATION OF TWO TENSION FREE VAGINAL TAPES WITH URODYNAMICS AND ICIQ-UI SF QUESTIONNAIRE

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**OBJECTIVE:** To compare results of two surgical procedures for stress urinary incontinence (SUI) using conventional urodynamic study (objective measure) and the ICIQ-UI SF questionnaire (patient's perspective outcome measure). **METHODS:** Prospective study of 120 women with urodynamic diagnosis of SUI who received treatment with tension free vaginal tape by retropubic tract (RP) or by transobturador tract (TO). All the patients underwent urogynaecological history, physical examination, ICIQ-UI SF and urodynamic study. The treatment outcome was evaluated 6–12 months later by urodynamic study and ICIQ-UI SF. Patients were divided into 3 groups, "cured", "improved" or "failed treatment", according to the observed stress leakage during postoperative filling cystometry. According to the ICIQ-UI SF post-treatment score, patients were also divided into 3 groups: "cured" when it was 0; "improved" when it was lower than pre-treatment and "failed treatment" when it was equal or higher than pre-treatment score. **RESULTS:** Tension free vaginal tape (RP) was applied to 77 women (64.2%) and (TO) to 43 (35.8%). No statistical differences in demographic and basal data were found between the two groups. According to the post-treatment urodynamic evaluation, 74 patients (96%) were "cured or improved" in the RP group and 39 (91%) in the TO group ($p = 0.208$). According to the ICIQ-UI SF, 71 (92.2%) were "cured or improved" in the RP and 37 (86%) in the TO group ($p = 0.221$). Considering cured and improved patients independently, in the RP group 66 patients showed no leakage during postcystometry stress test (86%) and 26 were cured (61%) in the TO group (p.003). According to the ICIQ-UI SF only 55 (71.4%) felt cured of their symptoms in the RP vs. 22 (51.2%) in the TO group. **CONCLUSIONS:** There are important differences when evaluating the treatment outcome in urinary incontinence depending on what is considered a good outcome (cure improvement vs. cure alone) and on what method is used to assess the outcome (urodynamic study vs. self-reported questionnaire).