4 scores correlated moderately with the Visual Analogical Scale of the EQ-5D. The dimensions which measure secondary effects of immunosuppression (Side Effects of Corticosteroids-SEC; Increased Growth of Gum and Hair-IGGH) showed low correlation with SF-36 and EQ-5D although they correlated with the episodes of acute rejection (r > 0.4). The correlations with clinical variables were low, but in accordance with expectations. The correlations of the scores at 3 and 6 months were moderate (r = 0.7). 6 patients suffered initial allograft dysfunction and these showed worse scores than the rest. Cronbach's Alpha, which evaluate the reliability, were: 0.92 for the whole questionnaire; 0.86, LPC; 0.79, LCC; 0.66, CRD; 0.63, SEC; 0.74, IGGH; 0.78, TAPD. CONCLUSIONS: The feasibility, validity and reliability of the Spanish version of the ESRD-scl were adequate to evaluate the PHS of kidney transplant bearers.

THE IMPACT OF THE OVERACTIVE BLADDER ON QUALITY OF LIFE (SF36) AND UTILITY (EQ5D)

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OBJECTIVES: To demonstrate the contribution of problems associated with an overactive bladder; namely continence, urgency and frequency, on health related quality of life and utility. METHODS: Patients treated by an academic urology unit in the UK were sent a self-completed survey that included the EQSD and SF36 and urology disease-specific questions. Potentially confounding factors were controlled using multivariate linear regression analysis. The survey was undertaken with the Health Outcomes Data Repository (HODaR) framework, a large representative dataset linking clinical data to routine QoL and utility survey responses. RESULTS: In a routine survey without reminders, 609 surveys were returned (28% response rate). The mean age of respondents was 65 years (SD 15.5) and 68% were male. Sixty percent of valid responses reported some degree of incontinence. Of these, 60% reported stress incontinence; 85% had urinary frequency problems and 91% had urgency. Among the generally continent: 12% reported stress incontinence; 60% reported frequency problems and 54% reported urgency. Controlling for age, gender and body mass index (BMI), incontinence was associated with a reduction in the EQSD (−0.11; SE 0.026, p < 0.001) and SF36 scores across all domains (max: physical role −14.51 (SE 3.92; p < 0.001)). Under similar analytic conditions in continent respondents, urgency significantly reduced social and mental-role functioning (−8.55; p = 0.069 & −14.51; p = 0.080, respectively) whilst frequency reduced the energy domain (−9.09; p < 0.05). Among the incontinent, urgency reduced social functioning by −17.61 (p < 0.05), and the mental domain by −11.58 (p < 0.05) whilst frequency again reduced the energy domain by −9.07 (p < 0.05). CONCLUSIONS: Incontinence has a detrimental impact on quality of life comparable with diseases and conditions traditionally regarded as being more serious. Urinary urgency reduces social functioning and mental well-being, whilst increased urinary frequency increases tiredness.

PSYCHOMETRIC VALIDATION OF THE UK ENGLISH INCONTINENCE-SPECIFIC QUALITY OF LIFE MEASURE (I-QOL)

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OBJECTIVE: The I-QOL is a 22-item incontinence-specific measure originally developed in the USA and subsequently adapted into numerous other language versions. The British-English language version has not yet been validated. The purpose of this presentation is to report the psychometric performance characteristics of the UK version of the I-QOL. METHODS: The I-QOL was included in a cross-sectional, descriptive health outcomes study among female care-seekers at 17 large primary care clinics throughout the UK. A total of 2400 women between 18 and 91 years of age took the survey while waiting to be seen by their care providers. Twenty-two percent (n = 503) of these women reported symptoms of stress urinary incontinence; 21% (n = 538) mixed and 4% (n = 85) urge incontinence without overactive bladder. Other measures included the Scale for Activity Interference and Limitation (SAIL, incontinence-specific individualized activity limitations), the Symptom Frequency and Bothersomeness scale (SFb-SUI), self-perceived severity, self-reported episodes, and a variety of other demographic and descriptive variables. Psychometric testing was conducted using standardized procedures. Reproducibility could not be assessed within the study design. RESULTS: Principal component analyses confirmed the original measurement model of three subscales (avoidance and limiting behavior, psychosocial impacts, and social embarrassment) and a total summary score. Internal consistency values were acceptable (alpha ranged between 0.87 and 0.95) and, as hypothesized, the I-QOL had strong associations with both the SFb-SUI (symptoms) (>0.60) and the SAIL (limitations) (>0.67) scales. Quality of life scores became significantly worse as the patients’ perception of severity increased (p < 0.001) and number of incontinent episodes increased (p < 0.001). CONCLUSION: This cross-sectional assessment of the British-English version has shown it to have similar psychometric performance to those previously published for the original measure, making this I-QOL language version a valid PRO for incorporation in community based studies of patients with varying types and severity of urinary incontinence.

LONG-TERM DARIFENACIN TREATMENT FOR OVERACTIVE BLADDER: QUALITY OF LIFE OUTCOMES FROM A 2-YEAR, OPEN-LABEL EXTENSION STUDY

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OBJECTIVES: To investigate the impact of long-term treatment with darifenacin, a muscarinic M3-selective receptor antagonist, on quality of life (QoL) in patients with overactive bladder (OAB). METHODS: Patients with OAB for ≥6 months who participated in two 12-week, placebo-controlled, double-blind feeder studies of darifenacin controlled release 3.75, 7.5 or 15 mg qd were enrolled into this 2-year, multicentre, open-label extension. During the first 2 weeks of the extension all patients received darifenacin 7.5 mg, after which titration between darifenacin 15 mg and 7.5 mg was permitted. The King’s Health Questionnaire [KHQ] was used to assess QoL. Here, we report data from patients who received darifenacin 7.5 or 15 mg during the feeder studies and had a gap of ≥3 treatment days before entering the extension. RESULTS: A total of 303 patients who had received darifenacin 7.5 or 15 mg during the feeder studies entered the extension (22–89 years; 86.5% female) and 199 patients (65.7%) completed the study. Darifenacin 7.5/15 mg was associated with significant improvements in eight of nine KHQ domains (Incontinence impact, Severity measures, Role limitations, Physical limitations, Social limitations, Emotions, Personal relationships and Sleep/energy) from baseline to the end of the 12-week, double-blind feeder studies (all p < 0.001 vs.
feeder study baseline). These changes were maintained or further improved during the open-label extension, such that significant improvements (p < 0.001 vs. feeder study baseline) were observed for darifenacin 7.5/15 mg in the same eight KHQ domains after a further 24 months of treatment. Darifenacin was well tolerated and the overall long-term safety profile was consistent to that observed in the 12 week phase III studies. CONCLUSIONS: Darifenacin significantly improves QoL in patients with OAB, with improvements maintained for 2 years during open-label treatment.

**PUK29**

**DEVELOPMENT AND VALIDATION OF A COMPREHENSIVE SYMPTOM CHECKLIST IN URINARY INCONTINENCE**


**OBJECTIVE:** To develop and validate a unique tool specific to urinary incontinence (UI) symptoms covering all types of incontinence among both men and women. METHODS: An Advisory Committee (AC) of 5 urologists was set up, involved at all stages of questionnaire development and validation. A test questionnaire was developed by AC with content validity being assessed simultaneously on 3 men, 4 women suffering from UI and 3 clinicians. Clinicians were asked to comment items’ relevance and comprehensiveness; patients completed the scale and were asked to provide general comments regarding the scale and detailed comments regarding each element. The scale was redrafted and tested on 235 other patients. A longitudinal, multi-centre, anonymous, observational study was carried out to validate the scale. The scale was administrated by 21 urologists to 258 stable patients (206 UI sufferers and 32 not UI sufferers) until June 15th 2005. Patients filled in the scale, the ICQ-SF and a diary twice at one-week interval and clinicians completed a medical form at baseline. RESULTS: The test scale contained 11 items covering urge, SUI, dysuria and pollakiuria. After initial cognitive debriefing and comments of patients and clinicians, 3 items were significantly modified. The pilot questionnaire still included 11 items. The validation study allowed assessing the internal consistency reliability, the test-retest reliability and the clinical validity of the scores. CONCLUSION: For the first time, psychometric properties were established for a simple-to-use, unique and UI specific symptom scale for men and women. This new instrument could be helpful for use in everyday medical practice and in clinical research.

**PUK30**

**BENIGN PROSTATE HYPERPLASIA: RELATION BETWEEN IPSS, SPI AND QUALITY OF LIFE IPSS ITEM SCORES**

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**OBJECTIVES:** The International Prostatic Symptom Score (IPSS) evaluates the frequency of symptoms associated with lower urinary tract symptoms (LUTS). An eighth question (q8) evaluates the patient’s overall satisfaction dealing with his urinary tract status but does not study in detail his bothersomeness. The SPI score (Symptom Problem Index) evaluates the degree of discomfort associated with each question on the IPSS. Our objective was to determine the relations between IPSS, SPI and quality of life IPSS item (q8) scores. METHODS: A cohort of 907 male patients with BPH has been monitoring by French general practitioners. The IPSS and SPI self-administered questionnaires have been evaluated on the 722 patients with complete data. Relationships between SPI, IPSS and q8 have been investigated through the correlation between those scores and by showing the individual answers dispersion of IPSS and SPI scores when one was fixed. RESULTS: The mean IPSS score was 12.6 +/- 6.4, the mean SPI score was 12.2 +/- 6.5. The correlation coefficient between the IPSS and SPI scores was 0.70; the scores from the two rating scales showed a very high variability. Q8 was also weakly related to SPI (r = 0.56) and to IPSS (r = 0.57). The response to the question on quality of life corresponded to highly varying SPI and IPSS scores. CONCLUSIONS: IPSS and SPI questionnaires do not collect the same information. One scale cannot be replaced by another. Quality of life question of the IPSS questionnaire isn’t enough to capture all the aspects of bothersomeness explored by the SPI questionnaire. Among patients suffering from LUTS, the joint use of the IPSS and SPI seems appropriate.

**PUK31**

**DEVELOPMENT AND PILOT TESTING OF A NEW SCALE SPECIFICALLY MEASURING THE IMPACT OF STRESS URINARY INCONTINENCE (SUI) ON COMMON PHYSICAL ACTIVITIES OF DAILY LIFE**

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**OBJECTIVE:** Since stress incontinence episodes frequency is highly related to maintenance or avoidance of activities causing leakages, the additional benefit of therapeutic options might be difficult to capture. Our objective was to develop a new specific and sensitive endpoint to evaluate treatment effects in Stress Urinary Incontinence (SUI) in clinical trials. METHODS: A comprehensive list of efforts provoking leakages was established from a systematic literature review and 30 clinician interviews. The list was updated according to comments collected during 8 semi-structured clinicians interviews. Clinicians were asked about the relevance, comprehensiveness, and ability of the listed activities to capture changes. They also reported how their patients managed to control the risk of leakage. Twenty SUI women were asked to assess the relevance, importance, and applicability of each effort, to reword the list and to describe with their own words how they control the risk of leakage. The scale was finalised according to their comments. RESULTS: A list of 72 daily life efforts provoking leakage was set from 15 UI specific scales and 21 studies selected from the literature. The clinician interviews allowed to group similar concepts and to establish a shortlist containing the 15 most relevant efforts. Answer choices covered the occurrence of leakage, and various behaviour adaptation such as seeking help, taking precautions, muscular control, and avoiding situations. After validation of format, items, wording, and answer choices, by the patients, the pilot scale was produced. CONCLUSION: This self-reported scale allows SUI patients to accurately describe their control on leakage risk in daily life efforts. This highly specific instrument will allow clinicians to better assess the true impact of therapeutics on patients’ life, in both clinical research and clinical practice. The scoring procedure and its properties will be assessed in a specific validation study.