patients are faced with a choice of treatment options: radical prostatectomy or radio therapy. Although this different treatments may have no differences in terms of survival, they may have very different consequences on the subsequent quality of life (QoL). Prerequisite to answer these questions is a reliable and valid instrument to assess these differences. Since in Europe the EORTC QLQ-C30 became the standard instrument to evaluate QoL in cancer patients, the task was to develop a disease specific module in addition to the core questionnaire to assess not just general QoL but as well prostate specific symptoms.

METHODS: Between 1996 and 2000 different groups conducted historical cohort studies using the EORTC QLQ-C30 and a prostate specific module developed by Kuechler et al. The Reference Center Quality of Life in Germany put together these studies for an empirical meta-analysis. The main objective was to analyze the module’s psychometric properties. The total sample consisted of 1185 patients, of which 950 completed the QoL questionnaires. These 950 questionnaires were included in a detailed psychometric analysis. RESULTS: First step of this psychometric analysis was a principal component analysis, which revealed the scales: urinary problems, incontinence, erectile dysfunction, sexual problems, problems with partner, pain, heat, nutrition, and psychic strain. Their reliabilities indicated good to sufficient internal consistency with Cronbach’s alpha (0.70 to 0.89 except to two scales). The module showed good concurrent validity (correlations with “Global Health” from the EORTC QLQ-C30) and very good construct validity, since the module is able to discriminate between different treatment regimes, tumour stages and age. CONCLUSIONS: The prostate specific module is a reliable, valid and applicable measure for quality of life in patients with prostate cancer.

THE BARTHEL PREFERENCE INDEX (BPI): A NEW CONDITION-SPECIFIC PREFERENCE INDEX (COPI) FOR USE IN STROKE

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OBJECTIVES: Condition-specific preference indices (COPI’s) may provide a sensitive measure of treatment effect and economic impact in certain disorders. Our goal was to adapt the Barthel Index, a validated 10-item measure of physical disability, as a COPI for stroke clinical trials and practice settings. The resulting instrument is known as the Barthel Preference Index (BPI). METHODS: Preferences were elicited from 152 community members (≥45 years) using visual analog scaling (VAS) and discrete choice experiment (DCE). Ordinary least squares and probit regression models were developed from VAS and DCE data, respectively, and indexed from zero to one. Data from stroke inpatients were used to calculate preferences for commonly occurring stroke disability states. Tests of internal consistency, and construct, convergent and discriminant validity were performed. RESULTS: Thirty-one percent of the subjects were male, mean age was 61 years, 88% were Caucasian, 60% had more than a high school education, and 63% were married. VAS preferences ranged from 0.09 to 0.40 for severe and very severe stroke, 0.40 and 0.74 for moderate stroke, and 0.72 to 0.97 for mild stroke. DCE preferences ranged from 0.04 to 0.17, 0.17 to 0.76, and 0.47 to 0.88, respectively. Multiple preferences were observed within individual BI scores. Both models demonstrated internal consistency, and construct and convergent validity. Spearman correlations between VAS and DCE utilities, and BI scores were 96% and 91%, respectively. The correlation between VAS and DCE utilities was 94%. Overall, the VAS model was stronger and demonstrated superior discriminant validity. CONCLUSIONS: The Barthel Preference Index, a COPI intended for stroke clinical trials and practice, was found to be valid and reliable in this population. Multiple preferences within scores suggest that the BPI may be more sensitive to treatment effect than BI scores. Further validation and tests of responsiveness in clinical trials are required.

VALIDATION OF A PATIENT-ADMINISTERED QUESTIONNAIRE TO MEASURE THE SEVERITY OF LOWER URINARY TRACT SYMPTOMS IN UNCOMPLICATED URINARY TRACT INFECTION: THE UTI SYMPTOM ASSESSMENT (USA) QUESTIONNAIRE

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OBJECTIVES: To develop and validate a self-administered questionnaire assessing the “severity” and “bothersomeness” of the most frequently reported symptoms and signs of uncomplicated urinary tract infection (UTI). METHODS: The UTI Symptoms Assessment (USA) questionnaire—a 14-item instrument asking about the severity and bothersomeness of seven key UTI symptoms—was completed by 276 women with uUTI who had participated in a prospective, open-label, non-comparative multicentre clinical trial of CIPRO® XR (ciprofloxacin extended-release tablets). Subjects completed the USA in electronic format at baseline and at varying time intervals until the test of cure (TOC) visit. Baseline scores on the King’s Health Questionnaire (KHQ) were collected and Global Rating of Change (GRC) items were completed with each USA administration. An investigator performed a clinical evaluation of UTI symptoms at baseline and TOC visit. RESULTS: On unforced principal components factor analysis, the USA was found to comprise three four-item domains named Urination Regularity, Problems with Urination, and Pain Associated with UTI. Two questions asking about haematuria loaded on a fourth factor. The three domains were homogeneous and internally consistent, each having Cronbach’s alpha scores of 0.80–0.90. Convergent validity of the USA was shown by high correlations between similar USA and KHQ domains (all r > 0.40), and divergent validity by small correlations between unlike domains (all r < 0.15). The USA domains demonstrated excellent discriminant validity (to clinical symptom evaluations) and responsiveness to changes in clinical evaluation and GRC items. Symptom improvement was highest in the first three hours, leading to greater responsiveness and MID during this period. CONCLUSIONS: The three-domain USA has excellent psychometric properties: each domain shows high levels of internal reliability, convergent and divergent validity, discriminant validity and responsiveness. The USA is thus likely to prove an excellent tool for assessing uUTI outcome from a patient’s perspective, in both research and clinical settings.

DEVELOPMENT AND VALIDATION OF THE DIAPASON: A TREATMENT SATISFACTION QUESTIONNAIRE FOR INDIVIDUALS WITH TYPE-2 DIABETES

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OBJECTIVES: In non-insulin-dependent diabetes mellitus (NIDDm) where auto-treatment plays an important role in disease management, patient satisfaction is particularly impor-