

PUK30

MAPPING THE OVERACTIVE BLADDER QUESTIONNAIRE-SHORT FORM (OABQ-SF) TO EQ-5D PATIENT PREFERENCES IN PATIENTS WITH OVERACTIVE BLADDER IN SPAINVillacampa-Aubá F¹, Ruiz MA², Arlandis-Guzmán S³, Errando-Smet C⁴, Lizarraga F⁵, Rejas J⁶¹Department of Urology, Hospital 12 de Octubre, Madrid, Spain; ²Universidad Autónoma de Madrid, Madrid, Spain; ³Department of Urology, Hospital Universitario La Fe, Valencia, Spain; ⁴Department of Urology, Fundación Puigvert, Barcelona, Spain; ⁵Medical Unit, Pfizer España, Alcobendas, Madrid, Spain; ⁶Pfizer España, Alcobendas/Madrid, Spain

OBJECTIVES: To develop a mapping algorithm to transform the Overactive Bladder Questionnaire-Short Form (OABq-SF) questionnaire responses into EQ-5D derived utilities in patients with OAB in Spain. **METHODS:** The culturally adapted Spanish versions of OABq-SF and EQ-5D questionnaires were self-administered on two occasions 3 months apart to a set of patients of both genders, above 18 years, diagnosed of OAB according with standard criteria and a score > 8 in the OAB-V8 scale and able to understand PRO instruments written in Spanish. Patients were recruited consecutively in clinics of Urology all over the country. Linear correlations between symptoms severity and health-related quality-of-life (HRQoL) domains of the OABq-SF and EQ-5D (VAS and TTO-tariffs) were computed. a combined score of both domains of OABq-SF was used to obtain a unique scoring per patient, although mapping was developed for both combined and separated punctuations of the OABq-SF using regression modelling. **RESULTS:** A total of 199 OAB patients (58.4 years, 74% women, 99% Caucasian, 37% workers and 36% primary schooling) from 18 urological clinics were evaluated. Utility values ranged from 1 to 0.01; mean value = 0.7623 (SD = 0.2292) and median = 0.79. Correlations with EQ-5D were -0.282 and -0.301 for the severity of symptoms domain at baseline an after 3 months of a medical intervention, and 0.329 and 0.369 for the HRQoL domain, respectively. Pearson coefficients for combined scoring were -0.331 and -0.351, respectively. All coefficients were significant at $P < 0.001$ level. Observed relation between utilities and combined score followed a linear although heterocedastic pattern. Utilities distribution was clearly positively skewed with benign utilities prevailing. **CONCLUSIONS:** Utilities values for Spanish patients with OAB were mostly mild to moderate in the 0–1 range. a utility map was obtained for different levels of scoring in the OABq-SF questionnaire, which is useful to derive Quality-adjusted Life-year gain in economic evaluations.

PUK31

PSYCHOMETRIC VALIDATION OF THE SPANISH VERSION OF THE OVERACTIVE BLADDER QUESTIONNAIRE SHORT-FORM (OABQ-SF) TO ASSESS SEVERITY OF SYMPTOMS AND PATIENT HEALTH RELATED QUALITY OF LIFE IN SUBJECTS WITH OVERACTIVE BLADDERArlandis-Guzmán S¹, Ruiz MA², Errando-Smet C³, Villacampa-Aubá F⁴, García-Vargas M⁵, Arumi D⁶¹Department of Urology, Hospital Universitario La Fe, Valencia, Spain; ²Universidad Autónoma de Madrid, Madrid, Spain; ³Department of Urology, Fundación Puigvert, Barcelona, Spain; ⁴Department of Urology, Hospital 12 de Octubre, Madrid, Spain; ⁵Health Outcomes Research Department, Corporate Affairs and Market Access Unit, Pfizer Spain, Alcobendas, Madrid, Spain; ⁶Pfizer Inc., Madrid, Spain, Alcobendas, Madrid, Spain

OBJECTIVES: To carry out the psychometric validation of the Spanish version of the self-administered OABq-SF questionnaire, a tool measuring severity of symptoms and health-related quality of life (HRQoL) of patients with symptomatic overactive bladder (OAB). **METHODS:** The culturally adapted Spanish version of OABq-SF was administered on two occasions separately 3 months to a set of patients of both genders, above 18 years old, diagnosed of OAB according with standard criteria and a score > 8 in the OAB-V8 scale and able to understand PRO instruments written in Spanish. Patients were recruited consecutively in clinics of Urology all over the country. Feasibility, internal consistency (Cronbach's alpha), test-retest reliability, structure of instrument, criteria and construct validity and responsiveness were examined using classic test theory statistics. Minimally Important Difference (MID) was also calculated. **RESULTS:** Data from 199 OAB patients (58.4 years, 74% women, 99% Caucasian, 37% workers and 36% primary schooling) from 18 urological clinics were evaluated. Floor and ceiling effect ranged between 0.5% and 31.2%, and missing items was below 1%. Cronbach's alphas attained 0.795 and 0.923 for severity and HRQoL domains. These two instrument domains showed to be one-dimensional with explained variances above 50% in both domains, which correlated moderately with EQ-5D [-0.335 and +0.405, respectively ($P < 0.01$ in both cases)] and with self-perceived general valuation symptoms of OAB. a significant change in OABq-SF domains scoring [-23.3 (-26.0; -20.6) and +17.1 (14.7; 19.5), $P < 0.001$ in both cases (effect sizes: 1.34 and 1.50)] were observed after a 3-month medical intervention. MID values were, respectively, 6.6 and 8.1 for severity and HRQoL domains. **CONCLUSIONS:** The Spanish version of OABq-SF demonstrated strong reliability, validity and responsiveness psychometric properties to be used in the measurement of severity and Health-related Quality of life symptoms of OAB.

PUK32

CONTENT VALIDITY OF A PATIENT-REPORTED URINARY URGENCY RATING SCALE: RESULTS OF A COGNITIVE INTERVIEW STUDYChen WH¹, Notte S¹, Marshall TS², Lee M², Hakimi Z², Revicki DA¹¹United BioSource Corporation, Bethesda, MD, USA; ²Astellas Pharma Global Development—US, Deerfield, IL, USA; ³Astellas Pharma Global Development—EU, AC Leiderdorp, The Netherlands

OBJECTIVES: The Patient Perception of Intensity of Urgency Scale (PPIUS) measures the urgency severity of urinary episodes, and was developed based on the definition of urgency

presented by the International Continence Society (ICS) (Abrams et al. 2002) as well as recommendations from the Committee for Proprietary Medical Products (CPMP) (EMA 2002). The PPIUS is a single item scale with five levels of urgency severity, from “No urgency” to “Urge incontinence,” each with its definition provided. While the PPIUS has been used in previous trials, its content validity has not been established in overactive bladder (OAB) patients. The objective of this study was to determine comprehensibility and understanding of the scale through cognitive interviews with OAB patients. **METHODS:** Forty-one OAB patients participated in a non-interventional study assessing reproducibility of the PPIUS by completing a three-day micturition diary each week for three consecutive weeks. Following successful completion of the test-retest study, twelve participants were selected to participate in a 30-minute in-person interview discussing their experience with the PPIUS. Interviews were conducted by a trained interviewer and followed a semi-structured guide with think-aloud approach. **RESULTS:** N = 12; mean (SD) age = 61.6 (13.5) years; 66.7% Caucasian; 91.7% female; mean (SD) years with symptoms = 5.8 (4.6); 83.3% reported medication use for treatment. Nine participants found it simple to choose a PPIUS rating for each of their daily micturition episodes. Most agreed with the definitions provided for the ratings of “No urgency” (n = 9), “Mild urgency” (n = 7), “Moderate urgency” (n = 8), “Severe urgency” (n = 9) and “Urge incontinence” (n = 9). Three suggested distinction between daytime and nighttime episodes could be made clearer. **CONCLUSIONS:** Content validity of the PPIUS was supported by the results of the cognitive interviews. PPIUS was well understood and the urgency definitions were generally accepted. Participants found the diary easy to complete and did not have difficulty selecting their ratings.

PUK33

TEST-RETEST RELIABILITY AND ACCLIMATION EFFECT OF PATIENT PERCEPTION OF INTENSITY OF URGENCY SCALE (PPIUS) FOR OVERACTIVE BLADDERChen WH¹, Notte S¹, Marshall TS², Lee M², Hakimi Z², Revicki DA¹¹United BioSource Corporation, Bethesda, MD, USA; ²Astellas Pharma Global Development—US, Deerfield, IL, USA; ³Astellas Pharma Global Development—EU, AC Leiderdorp, The Netherlands

OBJECTIVES: A three-day micturition diary has been designed to capture information on the number of urinary and incontinence episodes in overactive bladder (OAB) patients. Within the diary is the Patient Perception of Intensity of Urgency Scale (PPIUS), which captures the urgency associated with each episode. The PPIUS is a single item with five levels of urgency severity: “No urgency,” “Mild urgency,” “Moderate urgency,” “Severe urgency,” and “Urge incontinence.” The objective of this study was to assess the test-retest reliability and acclimation effect of the PPIUS. **METHODS:** OAB patients were recruited from five sites in the US for a non-interventional two-visit study. At the Screening Visit, participants were trained on how to complete the three-day diary at home for three consecutive weeks. In the diary, participants recorded the time of each micturition, a corresponding PPIUS rating, and whether the episode was accompanied by incontinence. Participants and clinicians completed overall treatment effect (OTE) questions at the Final Visit asking whether their bladder condition had changed since the Screening Visit. **RESULTS:** N = 39; mean age = 59.1 years; 69.2% Caucasian; 82.1% female; mean (SD) years with symptoms = 6.7 (6.78); 94.9% reported medication use for treatment. The mean number of micturitions per 24-hours = 10.5, mean number of incontinence episodes per 24-hours = 1.8; mean level of urgency severity = 1.9. There were 34 (87.2%) and 35 (89.7%) stable patients as defined by OTE-Patient and OTE-Clinician, respectively. Using Weeks 2 and 3 data from stable patients, the intra-class correlation (ICC) was 0.95 and the Spearman correlation was 0.89. The difference between the average ratings of any two weeks was non-significant using paired t-test. **CONCLUSIONS:** The PPIUS demonstrated excellent test-retest reliability as evidenced by ICC = 0.95. Acclimation effect was not observed in the PPIUS, as evidenced by non-significant differences in the average ratings across three weeks.

PUK34

PSYCHOMETRIC VALIDATION OF THE SPANISH VERSION OF THE TREATMENT BENEFIT SCALE (TBS) FOR ASSESSING SUBJECTIVE OUTCOMES IN TREATING PATIENTS WITH OVERACTIVE BLADDERErrando-Smet C¹, Ruiz MA², Villacampa-Aubá F³, Arlandis-Guzmán S⁴, García-Vargas M⁵, Arumi D⁶¹Department of Urology, Fundación Puigvert, Barcelona, Spain; ²Universidad Autónoma de Madrid, Madrid, Spain; ³Department of Urology, Hospital 12 de Octubre, Madrid, Spain; ⁴Department of Urology, Hospital Universitario La Fe, Valencia, Spain; ⁵Health Outcomes Research Department, Corporate Affairs and Market Access Unit, Pfizer Spain, Alcobendas, Madrid, Spain; ⁶Pfizer Inc., Madrid, Spain, Alcobendas, Madrid, Spain

OBJECTIVES: To carry out the psychometric validation of the Spanish version of the self-administered TBS scale, a tool assessing subjective outcomes in the treatment of subjects with overactive bladder (OAB). **METHODS:** The culturally adapted Spanish version of TBS was administered at the end-of-trial visit after 3 months of a medical intervention for OAB. Responses to the instruments were recorded in a set of patients of both genders, above 18 years old, diagnosed of OAB according with standard criteria and a score > 8 in the OAB-V8 scale, and able to understand PRO instruments written in Spanish. Patients were recruited consecutively in clinics of Urology all over the country. Scale variability, criteria, known-groups and construct validity and responsiveness (effect size) were examined using classic test theory statistics. **RESULTS:** Data from 199 OAB patients (58.4 years, 74% women, 99% Caucasian, 37% workers and 36% primary schooling) from 18 urological clinics were evaluated. The 2.5% of