The objective of this study was to cross-culturally adapt and validate the Incontinence-Specific Quality of Life Instrument - I-QOL for Brazilian women with urinary incontinence. METHODS: The I-QOL is a scale devised to assess quality of life impairment due to urinary incontinence. This questionnaire has been used in numerous studies to evaluate the consequences of the disease in daily life or the effects of different treatments. Seventy patients with urinary incontinence, were enrolled from the Department of Urogynecology and Vascular Surgery Section of the Gynecology Department of the Federal University of Sao Paulo (UNIFESP). Initially, we translated the I-QOL into Brazilian Portuguese language following international methodological recommendations. Due to language and cultural differences we performed cultural, structural, conceptual, and semantic adaptation on the I-QOL, in order that patients were able to fully understand the questions. All patients answered I-QOL twice on the same day with an interval of 30 minutes, applied by two different interviewers. Also the Kings Health Questionnaire (KHQ), already translated and validated to Brazilian Portuguese was applied to the patients. After 7 to 15 days, by phone interview, only I-QOL was applied again. Reliability (intra and inter observer internal consistency), construct and discriminative validity were tested. RESULTS: Several cultural adaptations were necessary until we reached the final version. The intra-observer internal consistency (alpha of Cronbach's) of the several dimensions varied from 0.77 to 0.93, and the inter-observer internal consistency varied from 0.63 to 0.88. Moderate to strong correlation was detected among the I-QOL domains and the validated Brazilian Portuguese version of KHQ. CONCLUSIONS: I-QOL was adapted to the Portuguese language and to the Brazilian culture, showing good reliability and validity. This questionnaire is now being evaluated in clinical trials on new therapeutic strategies for urinary incontinence in Brazil.

The FDA draft guidance on patient-reported outcomes (PROs) outlines methods for developing disease-specific PROs. The aim of the present study was to develop pictogram descriptions of healthcare status and utility in patients who have anemia associated with chronic kidney disease (CKD) by adapting the FDA methods for developing PROs to derive health state utilities. METHODS: Interviews with people with CKD (n = 12) provided detailed qualitative data regarding patients' HRQOL. Qualitative analysis identified how HRQOL varied among levels of anemia (mild > 12.5 g/dL, moderate 12.5–10.5 g/dL, and severe < 10.5 g/dL); set according to the recent National Institute of Clinical Excellence (NICE) clinical guidelines on CKD and three states of CKD (pre-dialysis, peritoneal dialysis, and hemodialysis). Pictograms for each level of anemia were developed for each state, and patients and clinicians assessed content validity. Pictograms were rated by 100 members of the general public in the UK using the time trade-off interview to estimate health state utilities. RESULTS: The qualitative data produced very detailed vignettes that were determined by patients and clinicians to have good content validity. Utilities varied for pre-dialysis (0.787–0.431), peritoneal dialysis (0.725–0.351), and hemodialysis (0.629–0.331) between mild to severe levels of anemia, respectively. CONCLUSIONS: The vignette descriptions were based upon qualitative data and validated through content validation interviews with clinicians and patients. To our knowledge, this is the first study in which vignettes have been developed entirely based on qualitative data from patient interviews. This is a useful method for estimating utilities when no data from generic instruments are available.

Patient preference for tamsulosin ocas (oral controlled absorption system) over tamsulosin modified release capsules

The Brazilian Portuguese validation of the urinary incontinence-specific quality of life instrument - I-QOL

The objective of this study was to cross-culturally adapt and validate the Incontinence-Specific Quality of Life Instrument - I-QOL for Brazilian women with urinary incontinence. METHODS: The I-QOL is a scale devised to assess quality of life impairment due to urinary incontinence. This questionnaire has been used in numerous studies to evaluate the consequences of the disease in daily life or the effects of different treatments. Seventy patients with urinary incontinence, were enrolled from the Department of Urogynecology and Vascular Surgery Section of the Gynecology Department of the Federal University of Sao Paulo (UNIFESP). Initially, we translated the I-QOL into Brazilian Portuguese language following international methodological recommendations. Due to language and cultural differences we performed cultural, structural, conceptual, and semantic adaptation on the I-QOL, in order that patients were able to fully understand the questions. All patients answered I-QOL twice on the same day with an interval of 30 minutes, applied by two different interviewers. Also the Kings Health Questionnaire (KHQ), already translated and validated to Brazilian Portuguese was applied to the patients. After 7 to 15 days, by phone interview, only I-QOL was applied again. Reliability (intra and inter observer internal consistency), construct and discriminative validity were tested. RESULTS: Several cultural adaptations were necessary until we reached the final version. The intra-observer internal consistency (alpha of Cronbach's) of the several dimensions varied from 0.77 to 0.93, and the inter-observer internal consistency varied from 0.63 to 0.88. Moderate to strong correlation was detected among the I-QOL domains and the validated Brazilian Portuguese version of KHQ. CONCLUSIONS: I-QOL was adapted to the Portuguese language and to the Brazilian culture, showing good reliability and validity. This questionnaire is now being evaluated in clinical trials on new therapeutic strategies for urinary incontinence in Brazil.

Impact of solifenacin on symptom bother, health-related quality of life, work productivity, treatment satisfaction, and symptoms in patients with overactive bladder: Results from Vibrant

The impact of solifenacin on symptom bother, health-related quality of life, work productivity, treatment satisfaction, and symptoms in patients with overactive bladder was assessed by IPSS and EuroQol EQ-5D. Disease severity and health-related quality of life were assessed by IPSS and EuroQol EQ-5D. Patients who received solifenacin versus placebo also showed a significantly greater improvement in bother (−1.58 vs. −0.52, P = 0.0001), HRQL total (−25.3 vs 16.7, P = 0.0001) and all domain scores (−0.19 to −0.01, P < 0.0001). Importantly, the preferential effect of being willing to pay about $72 more per month for tamsulosin OCAS; the actual cost differential between the two formulations is 11.27GBP. REFERENCES: [1] Chapelle CR, Charters-Kautler E. BJU Int 2006; 98(Suppl):29–32; [2] Chapelle CR, et al. Eur Urol 2005;4(Suppl):S33–44; [3] Michel MC, et al. Eur Urol 2005;4(Suppl):S53–60.

Urinary/Kidney disorders—Health care use & policy studies

Profiling common co-morbidities and medications prescribed among patients with chronic kidney disease

OBJECTIVES: Patients with chronic kidney disease (CKD) often have five to six other co-morbid conditions thus requiring extensive therapeutic treatment. Therefore, the objective of this study was to examine the most common co-morbid conditions and medications prescribed among patients with CKD, using a recent national population based ambulatory care survey. ME-HODS: This study utilized the National Ambulatory Medical Care Survey (NAMCS) and the National Hospital Ambulatory Medical Care Survey (NHAMCS) data from 2002 through 2005. The NAMCS and NHAMCS are national probability surveys of visits to office-based physicians and ambulatory services in hospital outpatient and emergency departments. CKD-related visits were identified using diagnosis codes (ICD-9-CM: 190.0, 572.4, 580–588, 591, 593.9, 572.4, 753.1, 753.3, 753.2, V18.6,794.6) or prescription for CKD specific medications (brand and generic drug codes: calcium acetate,sevelamer,lanthanum carbonate). Frequency and distribution of the CKD visits by setting and demographics characteristics was performed. Similarly, frequency analysis was performed to identify the most common co-morbid condition and medications prescribed among CKD patients. National estimates on visits were estimated using patient visits weights provided by NHAMCS. RESULTS: In 2005, 69% of the NAMCS and NHAMCS visits related to CKD, 8.1 million physician office visits, 0.9 million emergency department, and 0.7 million outpatient hospital department visits, representing a 140% increase compared to 7.1 million visits in 2002. The most common co-morbid conditions among CKD patients were essential hypertension (22.3%), diabetes mellitus (17.5%)