episodes), condition specific quality of life (Incontinence Quality of Life Questionnaire [I-QOL]), and SF-6D preference scores were measured at enrollment and 24 weeks after treatment with a single injection of botulinum toxin type A or placebo. We measured the correlation between SF-6D, I-QOL and UI episode change scores. We used multiple linear regressions to estimate the impact on SF-6D scores of 50%; 50%–99% and 100% reductions in UI episodes and a 10-point improvement in I-QOL. These thresholds are thought to be clinically significant and are often reported as trial outcomes. RESULTS: SF-6D change scores between enrollment and 24 weeks were moderately correlated with I-QOL change scores (rho = 0.41; p < 0.01) but non-significantly correlated with UI episode change scores (rho = -0.19; p = 0.20). At 24 weeks, mean (95% CI) daily UI episodes fell by 0.85 (0.04, 1.3) and mean I-QOL scores improved by 18 (12, 24). SF-6D scores increased by 0.03 (0.003, 0.058), due, primarily, to improvements in the role limitations domains. A 50% reduction in UI episodes was achieved by 49% of patients and corresponded to a 0.09 (0.02, 0.16) SF-6D increase. A 10-point increase in I-QOL was attained by 65% of patients and was associated with a 0.05 (–0.02, 0.12) SF-6D increase, CONCLUSIONS: These estimates provide preliminary data for decision analysts wishing to map UI outcomes to preference scores. The results demonstrate that clinically important changes in condition specific quality of life are reflected in SF-6D preference scores.

ESTIMATING THE QUALITY OF LIFE IMPACTS OF TOLTERODINE AND TAM SULOSIN TREATMENT IN MEN WITH LOWER URINARY TRACT SYMPTOMS AND OVERACTIVE BLADDER

Verheegen BG1, Treur MJ2, Heeg BMS3, Botteman MF4, Van Hout BA5, Trocio JN6
1PharmClic Europe, Rotterdam, The Netherlands, 2PharmClic North America LLC, Bethesda, MD, USA, 3Pfizer Inc, New York, NY, USA

OBJECTIVES: A randomized clinical trial (TIMES) demonstrated that combination therapy with tolterodine extended release (ER) plus tamsulosin for 12 weeks provides clinical benefits over monotherapy with either agent or placebo in men with moderate to severe lower urinary tract symptoms (LUTS) and overactive bladder. However, the TIMES study did not report the impact of these therapies on utility. We developed a statistical model to predict the utility and quality-adjusted life-years (QALYs) associated with the various TIMES therapies. METHODS: The statistical model was developed using urinary tract symptoms and quality of life (SF-12) data collected from 9416 males participating as part of a separate epidemiologic survey (EpiLUTS). The model was a multinomial regression, which predicted the level of responses to each of the 12 domains of the SF-12. The predictors were daytime and nighttime urinary frequency, urgency episodes, and mean I-QOL scores improved by 18 (12, 24). SF-6D scores increased by 0.03 (0.003, 0.058), due, primarily, to improvements in the role limitations domains. A 50% reduction in UI episodes was achieved by 49% of patients and corresponded to a 0.09 (0.02, 0.16) SF-6D increase. A 10-point increase in I-QOL was attained by 65% of patients and was associated with a 0.05 (–0.02, 0.12) SF-6D increase, CONCLUSIONS: These estimates provide preliminary data for decision analysts wishing to map UI outcomes to preference scores. The results demonstrate that clinically important changes in condition specific quality of life are reflected in SF-6D preference scores.

VALIDATION OF THE URINARY SENSATION SCALE (USS)

Coyne KS1, Margolis MK1, Jumadilova Z2, Vats V2, Hsieh R1
1United BioSource Corporation, Bethesda, MD, USA, 2Pfizer Inc, New York, NY, USA

OBJECTIVES: To assess the validity of the Urinary Sensation Scale (USS) in women with overactive bladder (OAB) and men with OAB and prostate symptoms (OAB-BPH). METHODS: Data from 2 clinical trials of tolterodine treatment for OAB were used to test the validity of the USS. A 5-point rating scale to assess the amount of urinary urgency associated with each urination. The USS ranges from “No feeling of urgency; I could continue activities until I chose to use the bathroom” to “Unable to hold; leak urine: I had a wetting accident before arriving at the bathroom.” The USS was administered with a daily bladder diary in the 2 trials. Two methods to evaluate the USS are to establish a mean urgency score (Mean USS) of all voids or to sum all urgency ratings (Sum USS). Concurrent validity, discriminant validity, and responsiveness of the USS were assessed. RESULTS: Data from 580 men (Trial 1) and 331 women (Trial 2) were analyzed. Mean age was 65.2 (men) and 47.8 (women); in both studies, 70% were Caucasian. Correlations of USS scores with bladder diary variables were small to moderate and higher among Sum USS than Mean USS. Correlations among the USS with OAB-q, Perception of Bladder Condition (PBC), and Perception of Treatment Benefit (PTB) were moderate to strong and higher with Sum USS. Both the Mean and Sum USS significantly discriminated (all p < 0.001) among all bladder diary variables (except men, nocturia and UUI) when grouped as improved/not improved as well as by the OAB-q, PBC, and PTB. Effect sizes for men and women respectively were –0.52 and –1.09 for Mean USS and –0.72 and –1.36 for Sum USS. CONCLUSIONS: The USS is a valid and highly responsive measure of urinary urgency in women with OAB and men with OAB-BPH.

PSYCHOMETRIC EVALUATION OF THE KHQ IN TEN LANG UAGES

Coyne KS1, Margolis MK1, Weinstein D2, Ebel-Bitoun C2
1United BioSource Corporation, Bethesda, MD, USA, 2Pfizer France, Pari s, France

OBJECTIVES: To evaluate the psychometric properties of 10 language versions of the King’s Health Questionnaire (KHQ). METHODS: The KHQ, a 21-item instrument to assess health-related quality of life in patients with urinary incontinence and OAB, has been translated into numerous languages. Data from a multicenter, randomized, double-blind, placebo- and active-controlled trial of fesoterodine for OAB patients were analyzed to assess the psychometric properties of the KHQ in ten languages. Patients completed the KHQ at Baseline (BL) and Week 12 of treatment and bladder diaries for 3 days before each visit. Mean BL scores, Cronbach alphas, and subscale change scores were calculated for the KHQ in each language. RESULTS: Data from 839 patients were analyzed (Australia = 104; Bulgaria = 58; Czech Republic = 55; Estonia = 59; Germany = 59; New Zealand (NZ) = 82; Poland = 84; Romania = 66; Russia = 81; and South Africa = 191). Mean age was 56.7 ± 13.9 years; 80% were female; 96% were white. BL subscale scores ranged from 16.8 (General Health Perceptions [GHP]; NZ English) to 83.6 (Impact on Life; German). Six of 7 multi-item KHQ subscales (Role

Abstracts

A655