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PODIUM SESSION II: PATIENT REPORTED OUTCOMES II

PR5

VALIDATION OF POMS QUESTIONNAIRE IN POSTMENOPAUSAL WOMEN

Yu H¹, Wyrwich K², Bobula J¹

¹Wyeth Research, Collegeville, PA, USA, ²Saint Louis University, St. Louis, MO, USA

OBJECTIVES: The Profile of Mood States (POMS) is a widely used instrument designed to assess current mood states and changes. It has been frequently used to assess a variety of patients, but its psychometric properties have never been evaluated in postmenopausal women. The objective of this analysis was to examine the reliability and validity of the POMS using data from postmenopausal women with moderate-to-severe hot flushes (HF). METHODS: Postmenopausal women with ≥50 HF/wk were enrolled in a multicenter, randomized, doubleblind, placebo-controlled study of the efficacy and safety of desvenlafaxine succinate (DVS) to control vasomotor symptoms (VMS). Subjects (N = 541) were asked to complete daily HF and sleep diaries, and at baseline and week 12 the POMS, and Greene Climacteric Scale (GCS), providing unique and valuable data sources to validate the criteria and discriminant validity of POMS. Floor and ceiling effects were explored, as well as subscale internal consistency. Confirmatory factor analysis was conducted to investigate construct validity. Finally, the POMS's stability and responsiveness to change was established through known-groups comparisons of change over time. RESULTS: POMS demonstrated excellent baseline internal consistency (Cronbach's alpha range 0.84-0.94) across the 6 subscales and Total POMS score; however, some items suffered floor effects. Results from the confirmatory factor analysis were supportive of the second order interpretation (RMSEA = 0.07). Correlations with GCS, HF, and sleep measures provided consistent criteria and discriminant validity. For women with POMS scores better than the female norms, there was little change at week 12 in both groups (stability) but marked improvement in DVS groups among women worse than the norm (responsiveness). CON-CLUSION: Our data demonstrate the reliability and validity of the 6 POMS subscales and the Total POMS score to measure mood among postmenopausal women with moderate-to-severe

PR6

PATIENT CHARACTERISTICS IMPACTING QUALITY OF LIFE (EQ-5D) OF FEMALES WITH STRESS URINARY INCONTINENCE SYMPTOMS

<u>Tincello D</u>¹, Sculpher M², Tunn R³, Quail D⁴, Timlin L⁴, Manning M⁵

¹University of Leicester, Leicester, UK, ²University of York, York, UK,

³St Hedwig Hospitals, Berlin, Germany, ⁴Eli Lilly and Company Limited, Surrey, UK, ⁵Lilly Deutschland, BadHomburg, Germany

OBJECTIVES: Describe the characteristics of women seeking treatment for symptoms of stress urinary incontinence (SUI) and to investigate their association with generic quality of life (QOL). **METHODS:** Stress Urinary Incontinence Treatment Study (SUIT) is a 12-month, observational study in four European countries, evaluating cost-effectiveness of duloxetine compared to other forms of non-surgical intervention in the treatment of

symptoms of SUI. Baseline data is presented. A total of 431 physicians observed women seeking treatment for their SUI and recorded the care provided and the outcomes of that care at enrolment, and 3, 6 and 12 months later. The impact of SUI on QOL was assessed using the EuroQol (EQ-5D). Multivariate linear regression was performed on the EQ-5D health state index. RESULTS: A total of 3762 women were enrolled into SUIT; the largest patient group from Germany. The majority were post-menopausal, with a mean age of 58.0 years, were not current smokers and tended to be overweight (mean BMI = 27.7), with at least one co-morbidity. Health state index (HSI) scores were significantly (p < 0.0001 for all factors except previous surgery, where p = 0.049) and independently influenced by, in order of the strength of the association, the total number of incontinence episodes, presence of co-morbidity(ies) affecting QoL, socio-economic status, presence of co-morbidity(ies) affecting incontinence, BMI, urinary incontinence (UI) subtype and previous surgery. Each additional incontinence episode was associated with a decrease in HSI score of 0.002 points, each comorbidity affecting OoL was associated with a HSI score reduction of 0.072 points and each comorbidity directly affecting incontinence was associated with a reduction of 0.040 points. Mixed Urinary Incontinence had a greater negative influence on HSI score than pure SUI. CONCLUSION: This analysis describes the characteristics of patients at the enrolment visit, and demonstrates that the number of incontinence episodes has the greatest impact on the EQ-5D Health State Scores.

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PATIENT'S PREFERENCES FOR OSTEOPOROSIS DRUG TREATMENT: A DISCRETE CHOICE EXPERIMENT

<u>De Bekker-Grob EW,</u> Essink-Bot ML, Meerding WJ, Pols HAP, Koes BW, Steyerberg EW

Erasmus MC, Rotterdam, The Netherlands

OBJECTIVES: Active case finding for osteoporosis is increasingly popular. However, it is not known if subjects, once identified as having osteoporosis, are willing to take preventive drug treatment, and what determines this willingness. We investigated patients' preferences for preventive osteoporosis drug treatment in a discrete choice experiment. METHODS: A discrete choice experiment (DCE) was administered to community dwelling females aged over 60 years (n = 120; including women with high fracture risk (n = 60)), identified by osteoporosis case finding in 34 GP-practices in and around Rotterdam. We investigated the effects on acceptance of preventive drug treatment of treatment effectiveness, side effects (nausea), total treatment duration, route of drug administration, and costs. The relative importance of the treatment attributes, the trade-offs that elderly women are willing to make between these attributes, and willingness to pay were estimated using conditional logistic regression analysis. RESULTS: All treatment attributes were important to respondents (p < 0.05). Absence of side effects of drug treatment was the most important treatment attribute of treatment acceptance. The negative utility of side effects such as nausea was totally compensated for when the drug reduced the relative lifetime risk of hip fracture by 35% or more. Women were prepared to pay an out-of-pocket contribution if the treatment was coherent with their preference. CONCLUSION: Women identified by active osteoporosis case finding are highly prepared to adhere to preventive drug treatment, even if side effects (nausea) are expected and some out-of-pocket contribution is required.