measurement experts to generate items, responses, and instructions for the new scale. Cognitive interviews were conducted with an additional 15 idiopathic RLS patients (aged 25–68) to understand the new measure and explore its comprehensiveness, and to identify any necessary revisions to the items and conceptual framework. RESULTS: Twenty-five items were generated from patient quotes obtained during cognitive interviews. Impacts on next day functioning spontaneously attributed to disturbed sleep due to RLS symptoms included: activities of daily living (i.e., work, household chores), cognitive functioning (i.e., concentration, forgetfulness, mental alertness), sleepiness, emotional functioning (i.e., irritability, depression), physical functioning (i.e., physical tiredness, active leisure activities), energy, daytime sleepiness, and social functioning (i.e., relationships, social activities/situations). Concept saturation was achieved. Modifications to questions and responses were based on patient feedback provided during cognitive interviews. The final measure consisted of 14 items assessed “today” and rated on a severity numeric rating scale. CONCLUSIONS: The RLS-NDI is an evaluative tool with demonstrated content validity to assess the impact of disturbed sleep due to RLS symptoms on RLS patients’ next day functioning.

REFINING THE MEASUREMENT OF MOTOR AND NON-MOTOR SYMPTOMS IN PARKINSON’S DISEASE PATIENTS WITH FLUCTUATING SYMPTOMS

Buck PD1, White MK1, Castelli-Haley J1, Rendas-Baum R2

1Teva Neuroscience, Kansas City, MO, USA, 2QualityMetric Incorporated, Lincoln, RI, USA

OBJECTIVES: Parkinson’s disease (PD) is the second most prevalent neurodegenerative disorder in the US. The Scales for Outcomes in Patients with Parkinson’s disease (SCOPA-D) is a daily diary designed to measure motor impairment in PD patients with fluctuating symptoms. Consistent with the FDA’s final guidance on patient-reported outcome measures, this study aimed at evaluating the psychometric properties of the SCOPA-D in the US and determine the feasibility of adding items that measure non-motor symptoms using qualitative techniques. METHODS: A literature review identified the most dominant non-motor symptoms experienced by PD patients with fluctuating symptoms. Three focus groups were conducted with PD patients (n = 24) to identify items that specifically addressed the study objectives. The original SCOPA-D was modified based on findings from the literature review and patient input. A fourth focus group (n = 9) consisted of a cognitive debriefing of the revised SCOPA-D format that included additional items and modified structure based upon the previous results. RESULTS: Findings from the focus groups demonstrated support for the content of the original SCOPA-D, generally finding it to be clear and intuitive, despite difficulties with some item definitions, time frames, and response labels. With respect to non-motor symptoms, seven domains were consistently mentioned: fatigue/concentration/memory, anxiety, pain, difficulty swallowing, frequent urination, and sweating. The cognitive debriefing focus group reported that the revised SCOPA-D format was easier to use, provided better focus on the items and time frames, and more adequately captured experiences throughout the day as compared to the original. CONCLUSIONS: Non-motor symptoms occur frequently in PD patients with fluctuating symptoms and have a significant impact on health-related quality of life. A reliable and validated patient-reported daily diary may improve the ability to describe PD progression by accurately measuring both motor and non-motor symptoms. Additional quantitative research is needed to evaluate the psychometric properties of the revised SCOPA-D.

VALIDATING USE OF THE MIGRAINE-SPECIFIC QUALITY OF LIFE QUESTIONNAIRE VERSION 2.1 (MSQ) ACROSS MIGRAINE DISORDERs

Buck CL1, Maglinte GA2, Rendas-Baum R3, DeRosa M3, Yang M4, Varon SF4

1University of Georgia, Athens, GA, USA, 2Allergan, Inc, Irvine, CA, USA, 3QualityMetric Incorporated, Lincoln, RI, USA, 4International, London, UK

OBJECTIVES: To provide evidence for the reliability and validity of the Migraine-Specific Quality of Life Questionnaire Version 2.1 (MSQ) for use across migraine disorders. METHODS: Cross-sectional data were collected via web-based survey in nine countries/regions. Participants were classified per ICHD-2 criteria as having chronic migraine (CM, ≥15 headache days/month), high-frequency episodic migraine (HEM, 10–14 headache days/month), or low-frequency episodic migraine (LEM, ≤9 headache days/month). Three MSQ domains include Role Function-Painful (RP), Role Function-Restrictive (RR), and Emotional Function (EF). T-tests were conducted to compare CM, HEM, and LEM, respectively, with controls (A142). RESULTS: Data from the Global Parkinson’s Disease Survey (GPDS) used the thirty nine item Parkinson’s Disease Questionnaire (PDQ-39) as a major outcome measure. In this study, we evaluate results from the PDQ-8 (Single Index Score PDQ-8-SI) with results from the parent form (from which the PDQ-8 was derived), of the instrument in the USA, Canada, Spain, and Japan. RESULTS: We evaluate response rate (97% of the 819 respondents completed all items on PDQ-8), data quality, score reliability (internal reliability of the eight items of the PDQ-8 was calculated for all countries using Cronbach’s alpha, USA = 0.88, Canada = 0.83, Italy = 0.87, Spain = 0.79 and Japan = 0.73) and scaling assumptions of the instrument in the USA, Canada, Spain, and Japan. CONCLUSIONS: The evidence suggests that PDQ-8-SI seems a useful measure in studies where a short measure, providing an overall index of self perceived health in PD, is required. The PDQ-8 is a practical and informative instrument for the evaluation of overall quality of life of PD patients in cross-cultural studies.

CONCLUSORY FACTOR ANALYSIS AND DIFFERENTIAL ITEM FUNCTIONING ANALYSIS OF THE MIGRAINE-SPECIFIC QUALITY OF LIFE QUESTIONNAIRE VERSION 2.1 IN CHRONIC MIGRAINEs

Rendas-Baum R1, Maglinte GA2, DeRosa M3, Yang M4, Varon SF4

1University of Arizona, Tucson, AZ, USA, 2University of Arizona College of Pharmacy Center for Health Outcomes and Pharmacoeconomic Research, Tucson, AZ, USA

OBJECTIVES: Migraine-Specific Quality of Life Questionnaire Version 2.1 (MSQ) is a 14-item health-related quality of life instrument that measures the functional impact of migraine across three domains: Role Function-Painful (RP), Role Function-Restrictive (RR), and Emotional Function (EF). This study evaluated the factor structure and cross-cultural comparability of the MSQ in Chronic Migraine (CM) sufferers. METHODS: Cross-sectional data were collected via web-based survey, across eight countries. Respondents were classified as having CM per ICHD-2 criteria with ≥15 headache days/month (n = 499). Confirmatory factor analysis (CFA) of the 3-factor model was conducted using the robust maximum likelihood estimator (MLR) assuming multivariate normality. Goodness-of-fit was assessed by the comparative fit index (CFI), Tucker-Lewis Index (TLI), and root mean square error of approximation (RMSEA). Differential item functioning (DIF) was tested using ordinal logistic regression of MSQ item scores on group membership and trait level. RESULTS: The 3-factor model demonstrated good fit (CFI = 0.97; TFI = 0.96; RMSEA = 0.07) among CM sufferers. Factor loadings ranged between 0.72 and 0.89, and had similar values across the three factors. Most MSQ items showed absence of DIF. Non-Uniform DIF was identified in items 5 (inability to concentrate; p = 0.028) and 12 (feel up or frustrated; p = 0.037). Item 12 also presented non-uniform DIF related to language (p = 0.010). CONCLUSIONS: Among Chronic Migraineurs, the MSQ provides a valid measure of RP, RR, and EF, yielding domain scores that can be reliably compared across languages and countries.

CROSS CULTURAL EVALUATION OF THE SHORT FORM 8 ITEM PARKINSON’S DISEASE QUESTIONNAIRE: RESULTS FROM AMERICA, CANADA, JAPAN, ITALY AND SPAIN

Jenkinson C1, Fitzpatrick R2, Findley L1, Churchill DM, Hughes R1


OBJECTIVES: Increasingly health status measures, used to measure the subjective functioning and well being of respondents, are being used in trials of treatments which are undertaken in a variety of countries. The purpose of this study was to evaluate the psychometric properties of a short form health survey, the Parkinson’s Disease Questionnaire (PDQ-8), cross-culturally, by comparing results gained from this instrument to the original longer form instrument—the PDQ-39. METHODS: Data are derived from the Global Parkinson’s Disease Survey (GPDS) a cross national survey which utilised the thirty nine item Parkinson’s Disease Questionnaire (PDQ-39) as a major outcome measure. In this study, we evaluate results from the PDQ-8 (Single Index Score PDQ-8-SI) with results from the parent form (from which the PDQ-8 was derived), of the instrument in the USA, Canada, Spain, Italy and Japan. RESULTS: We evaluate response rate (97% of the 819 respondents completed all items on PDQ-8), data quality, score reliability (internal reliability of the eight items of the PDQ-8 was calculated for all countries using Cronbach’s alpha, USA = 0.88, Canada = 0.83, Italy = 0.87, Spain = 0.79 and Japan = 0.73) and scaling assumptions of the instrument in the USA, Canada, Spain, and Japan. CONCLUSIONS: The evidence suggests that PDQ-8-SI seems a useful measure in studies where a short measure, providing an overall index of self perceived health in PD, is required. The PDQ-8 is a practical and informative instrument for the evaluation of overall quality of life of PD patients in cross-cultural studies.

AN ASSESSMENT OF DISEASE-SPECIFIC HEALTH-RELATED QUALITY OF LIFE INSTRUMENTS RELATING TO BLADDER DYSFUNCTION USED IN PATIENTS WITH MULTIPLE SCLEROSIS

Maul KM1, Armstrong E2, Skrepnek G2

1University of Arizona, Tucson, AZ, USA, 2University of Arizona College of Pharmacy Center for Health Outcomes and Pharmacoeconomic Research, Tucson, AZ, USA

OBJECTIVES: Bladder dysfunction is a common symptom in patients with multiple sclerosis (MS). This study assessed the current literature regarding instruments that have been used to measure the health-related quality of life (HRQOL) impact of this chronic illness, and to what extent bladder dysfunction affects HRQOL in this population. METHODS: Two searches using MEDLINE/PubMed’s MeSH database were made. Quality of life was isolated by checking the psychology subheading within the titles and abstracts.
multiple sclerosis heading term or by using quality of life and multiple sclerosis as separate MeSH terms. Urinary bladder was entered as a heading term, and all associated subheadings were included in the search box. Studies were included if a HRQOL instrument measuring bladder function or urinary incontinence was administered to a sample of MS patients. References in these articles were searched for any other studies that met inclusion criteria. RESULTS: Six articles initially met inclusion criteria. An additional 2 articles were found from their references. A total of 8 different instruments were used ranging from 6 to 30 items and tested across 3 to 10 different domains. Articles varied in terms of sample size (10 from 30 to 9,688 participants) design (cross-sectional vs. prospective cohort), and objectives (HRQOL impact vs. instrument validation). Six disease-specific HQRQL instruments were originally designed for use in other populations, and 3 were gender specific. Moderate to severe bladder dysfunction in patients with MS was prevalent in 49% to 79% of the study samples and the urinary symptoms negatively impacted HQRQL in all the studies. CONCLUSIONS: The use of HQRQL instruments specific to bladder dysfunction in patients with MS is limited. Study design variability made it difficult to assess overall impact and predictors of HQRQL further validating existing instruments that include both sexes and whose bladder dysfunction is of neurogenic origin is needed.

PNP10 NATALIZUMAB TREATMENT IS ASSOCIATED WITH AN IMPROVEMENT IN PATIENT-REPORTED FATIGUE AND COGNITIVE FUNCTION OVER TIME

Stephenson J1, Hou L1, Agarwal S2, Rajagopalan K1, Kamar SA1

HealthCore, Inc., Wilmington, DE, USA, 1Bogin Udc, Wellesley, MA, USA

OBJECTIVES: To evaluate changes in patient-reported fatigue and cognitive function after one year of natalizumab treatment in MS patients. METHODS: The study population consists of MS patients initiating natalizumab treatment who agreed to participate in a 12-month longitudinal study. The study assessed patient experiences with natalizumab using validated patient-reported outcome (PRO) measures prior to treatment initiation and after 3rd, 6th and 12th infusions. The current analysis reports change in fatigue and cognitive functioning from baseline through the 12th natalizumab infusion. Fatigue is measured by the 5-question Modified Fatigue Impact Scale-5 (MFIS-5, score range 0–20) with lower scores indicating lower impact of fatigue on physical, occupational, and psychosocial functioning; cognitive function is measured by the 6-question Medical Outcomes Study Cognitive Functioning Scale (MOS-Cog Scale, score range 6–36) with higher scores indicating better reasoning skills, memory, concentration. Fatigue is scored ability to start several actions at one time and ability to react to what is said or done. Regression analysis was used to control for baseline (BL) covariates such as age, years since MS diagnosis, number of natalizumab infusions received, MS level of disability, and functional status, number of MS drugs used prior to natalizumab and comorbidity burden. RESULTS: Results from this ongoing study are presented for 192 patients completing the BL through 12th infusion follow-up surveys. The mean number of years since MS diagnosis was 10.16 (SD = 8.23). Most patients were female (78%) and the mean age was 46.09 (SD = 10.78). On average, MFIS scores decreased significantly (BL 12.23 ± 2.2, 12th infusion score 10.97 ± 2.2, p < 0.001) and MOS-Cog scores increased significantly over time (BL 25.8 ± 1.4, 12th infusion score 26.91 ± 1.4, p < 0.001) after controlling for covariates. CONCLUSIONS: MS patients reported improvements in the impact of fatigue and overall cognitive function after one year of natalizumab treatment.

PNP11 IMPROVEMENT IN HEALTH-RELATED QUALITY OF LIFE IN MULTIPLE SCLEROSIS PATIENTS RECEIVING NATALIZUMAB IN THE UNITED STATES

Hou L1, Stephenson J1, Agarwal S2, Rajagopalan K1, Kamar S1

HealthCore, Inc., Wilmington, DE, USA, 1Bogin Udc, Wellesley, MA, USA

OBJECTIVES: To assess the change in general health-related quality of life (HRQoL) of multiple sclerosis (MS) patients after one year of natalizumab treatment. METHODS: MS patients, newly starting natalizumab, were recruited to participate in a longitudinal observational study to assess general health-related quality of life using the SF-12v2 prior to natalizumab initiation and after the 3rd, 6th and 12th infusions. Higher physical component summary scores (PCS) and mental component summary scores (MCS) on the SF-12v2 indicate better HRQoL. Patients were classified in five cohorts based on index dosage: ≤30 mg, >30 mg to ≤60 mg, >60 mg to ≤90 mg, >90 mg, and >139 mg. RESULTS: Data for 192 patients who had completed the baseline through 12th infusion assessments of this ongoing study are reported. The mean age was 46.09 (SD = 10.78) and the majority of patients were female (78%). The mean number of years since MS diagnosis was 10.16e (SD = 8.23). The PCS score improved significantly from baseline (BL 33.30 ± 7.12, 12th infusion 35.91 ± 7.12; p < 0.001); similar improvements were observed in the MCS scores which also improved significantly from baseline (BL 43.12 ± 1.53, 12th infusion 47.95 ± 1.53; p < 0.001). CONCLUSIONS: Patient-reported improvements in general health-related quality of life (HRQoL) can be used to assess the impact of natalizumab treatment on the usual care setting. These results are consistent with results from pivotal clinical trials and document the beneficial impact of natalizumab on HRQoL of MS patients.

PNP32 ANALYSIS OF DULOXETINE UTILIZATION AMONG COMMERCIALLY-INSURED FIBROMYALGIA PATIENTS

Chen SY1, Wu N1, Boulanger L1, Rao P1, Peng Y1, Zhao Y1

1Abt Bio-Pharma Solutions, Inc., Lexington, MA, USA, 2Abt Bio-Pharma Solutions, Inc., Lexington, MA, USA

OBJECTIVES: To assess duloxetine utilization among commercially-insured fibromyalgia patients. METHODS: This study analyzed administrative claims for fibromyalgia patients aged 18–64 who initiated duloxetine in 2006. Initiation was defined as no duloxetine coverage in the prior 90 days, with the first duloxetine prescription dispense date being the “index date.” Patients were excluded if they had less than 30 duloxetine supply days in the 12-months post-index period, or diagnosis of diabetic peripheral neuropathic pain or depression in the 12 months pre-index period. All duloxetine patients were classified in five cohorts based on index dosage: <30 mg, 30 mg, 31–59 mg, 60 mg, and >60 mg. Changes in dosage, average daily dosage (ADD), and adherence to duloxetine (medication possession ratio ≥0.8 as high adherence) were compared across cohorts. Multivariate regression models were performed to examine the association between index dosage and health care costs, controlling for demographics and clinical characteristics. RESULTS: Of 4,869 fibromyalgia patients identified, 4.4% had an index dosage of <30 mg, 22.4% of 30 mg, 5.9% of 31–59 mg, 60.4% of 60 mg, and 7.0% of >60 mg, 28% of total patients experienced any increase in dosage, while 15.9% experienced any decrease. Among those with any dosage change (n = 1,651), patients with an index dosage of 31–59 mg had the shortest duration before any dosage change (89 days), followed by those in the <30 mg, >60 mg, 30 mg, and 60 mg (95, 100, 104, and 159 days, respectively) cohorts. ADD increased with index dosage. Patients with <60 mg index dosage were less likely to be adherent than those in the 60 mg cohort (odds ratios ranged 0.61 to 0.78, all p < 0.05). Patients who had higher total health care costs compared with those in the 60 mg cohort (adjusted difference: $3,747, p < 0.05). CONCLUSIONS: About one-third of duloxetine treated fibromyalgia patients experienced any dosage change. Duloxetine adherence and ADD, and health care costs differ by duloxetine index dosage.

PNP33 PREDICTORS OF PAIN MEDICATION SELECTION AMONG PATIENTS DIAGNOSED WITH FIBROMYALGIA

Zhao Y1, Chen SY1, Boulanger L1, Nagar S1, Fraser K1, Wu N1

1El Lily Company, Indianapolis, IN, USA, 2Abt Bio-Pharma Solutions, Inc, Lexington, MA, USA

OBJECTIVES: Multiple pharmacologic therapies have been recommended for managing fibromyalgia. However, the factors associated with each treatment initiation have not been well established. This study assessed demographic and clinical predictors of duloxetine versus other pain medications dispensed among patients with fibromyalgia. METHODS: Employing a retrospective cohort design and data from commercial insurance, this study examined predictors of treatment among fibromyalgia patients who were 18 to 64 years old and initiated duloxetine versus selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs), venlafaxine, gabapentin, pregabalin, the ampa or non-NMDA glutamates between January 1, 2007 and December 31, 2008. Treatment initiation was defined as no access to the same medication over the previous 90 days, and the most recent initiation date was set as the index date. All patients selected had at least 1 fibromyalgia diagnosis (ICD-9-CM: 729.1) in the 12 months prior to initiation of each study therapy. Multiple logistic regression models were estimated to assess predictors of initiating duloxetine versus each of the other fibromyalgia therapies. RESULTS: Commercially insured fibromyalgia patients (n = 117,305) were on average 48 years of age, and 76% were females. Common fibromyalgia-related comorbidities were low back pain (35%), osteoarthritis (17%), and diabetes (12%). After controlling for demographic and clinical characteristics, those 35+ years of age, females, and patients who received SSRIs, TCAs, venlafaxine, gabapentin, or pregabalin over the 1-year pre-index period were generally more likely to initiate duloxetine than the other study medications. Other predictors of duloxetine initiation included higher prescription copayment and history of rheumatoid arthritis, osteoporosis, and sleep disturbance. CONCLUSIONS: These findings indicate that age, cost sharing, presence of selected comorbidities, and prior use of certain medications to treat pain were significant predictors of duloxetine initiation among working age, commercially insured fibromyalgia patients.

PNP34 UTILIZATION, PRICE, AND EXPENDITURE TRENDS FOR ANTI-MIGRAINE DRUGS IN THE US MEDICAID PROGRAM FROM 1991 THROUGH 2008

Chiu CH1, Wu J1, Wilgie P2, Lin AC1

1University of Cincinnati, Cincinnati, OH, USA, 2University of Cincinnati, Cincinnati, OH, USA

OBJECTIVES: Medications are critical for preventing and controlling migraine headaches. The objectives of this project are to describe anti-migraine drug (AD) utilization, price and reimbursement trends, and to compare market share competitions between Egots and serotonin 5-HT1 receptor agonists (tripatims). METHODS: Study drugs included ergot derivatives and triptams. A retrospective, descriptive time-series analysis was conducted for this study. The data source is the national Medicaid pharmacy claim database from CMS. The quarterly prescription numbers and reimbursement amounts were calculated from 1st quarter 1991 to 4th quarter 2008. The