Abstracts

patients. Adherent patients had lower rate of depression (4.7% vs. 9.5%, P = 0.019), higher rate of previous DMD use (49.1% vs. 40.0%, P = 0.032), and higher baseline MS-related costs ($4757 vs. $4037, P < 0.001). After adjusting for differences in baseline characteristics, DMD adherent patients had lower occurrence of severe relapse (12.2% vs. 15.0%, P = 0.013) and lower total direct and indirect costs ($14,095 vs. $16,638, P = 0.048). CONCLUSIONS: Over the two-year study period, DMD adherence was associated with significantly fewer severe relapses and lower total medical costs.

PND20

PERCEIVED CAREGIVER BURDEN AND HEALTH RELATED QUALITY OF LIFE IN ALZHEIMER'S CAREGIVERS

Langley PC, Wysong P4, Dilboneeva MD5

University of Minnesota, Minneapolis, MN, USA, 4KantarHealth, Princeton, NJ, USA, 5McGill University, Montreal, QC, Canada

OBJECTIVES: To assess the contribution of the Zarit score, a measure of perceived caregiver burden in Alzheimer’s disease, to health related quality of life (HRQoL) measured using the physical and mental component scores of the SF-12 instrument and SF-6D health utilities. METHODS: A survey of Alzheimer caregivers was undertaken in the US in 2009 (n = 1,079). This survey captured both the characteristics of caregivers and the characteristics of the patient to whom the caregiver gave most attention. At the same time, caregivers were asked to complete the Zarit Burden of caregiver questionnaire and the SF-12 HRQoL instrument. To assess the impact of Zarit scores on HRQoL, linear regression (ordinary least squares) models were specified and estimated for the physical and mental component summary scores of the SF-12 and the health utility scores from the SF-6D. Independent variables included: caregiver and patient characteristics. RESULTS: Average PCS and MCS scores were 47.7 (STD 11.17) and 42.5 (STD 11.93) respectively; utility score was 0.68 (STD 0.13). Zarit scores were distributed with 20.4% of respondents reporting a minimal or no burden, 37.7% a mild to moderate burden, 33.1% moderate to severe burden and 8.8% a severe burden. Overall 16.3% were judged to have mild AD, 53.7% moderate and 30.0% severe. Zarit scores played the key role with their greatest impact on the MCS rather than the PCS dimensions of the SF-12. In the severe AD category the PCS deficit is -5.65 (t = -4.23) compared to a deficit of -17.94 (t = -14.09) for MCS. The corresponding health utility deficit is -0.19 (t = -13.15). Other key variables are caregiver age and gender, patient age and gender and living situation. CONCLUSIONS: Perceived caregiver burden is associated primarily with deficits on the mental component scores of the SF-12 and on SF-6D health utilities.

INTERIM ANALYSIS OF A LARGE ONGOING PHASE IV PROSPECTIVE OBSERVATIONAL COHORT STUDY (MDS ON BOTULINUM TOXIN MOBILITY) OF BOTULINUM TOXIN TYPE A ON HEALTH UTILITY IN PATIENTS RECEIVING TREATMENT FOR APPROVED THERAPEUTIC INDICATIONS IN CANADA

Simonyi S1, Jog M1, Beauspach R2, Miller R4, Bhogal M1, Wein T5

1Allergan Inc., Markham, ON, Canada, 2London Health Sciences Centre, London, ON, Canada, 3Children’s & Women’s Health Centre of B.C, Vancouver, ON, Canada, 4Dalhousie University, Halifax, NS, Canada, 5KantarHealth, Princeton, NJ, USA

OBJECTIVES: Botulinum Toxin Type A (BoNTA) is approved for many therapeutic indications in Canada, including blepharospasm, 7th cranial nerve disorders, cervical dystonia, focal spasticity, cerebral palsy, and hyperhidrosis. Unfortunately, little is known about the impact of treatment on health utility. The objective of the ongoing national MDS Mobility study is to measure the impact of BoNTA on health utility. METHODS: Phase IV prospective observational cohort study in patients receiving BoNTA for approved therapeutic indications in Canada. Physical component scores (PCS), and mental component scores (MCS) are derived from self-reported SF-12c data at baseline, week 4 and subsequent clinic visits. Health utility is then measured using the SF-6D scoring programme. In this interim analysis continuous data were analyzed by student’s t-test and dichotomous data by Chi-square test. RESULTS: To date 917 patients have been enrolled at 40 clinical sites with a 94.5% retention rate. 69.7% of subjects had received ongoing BOTOX® treatment at baseline; 82 were BoNTA-naive. Significant differences were detected in self-reported SF-6D scores between baseline and week 4 in the analysis of continuous (P < 0.05) and dichotomized data (P = 0.0001); and between baseline and week 4 in the analysis of continuous MCS data (P = 0.035). Among BoNTA-naive patients, there was a statistically significant difference in SF-6D scores between baseline and week 4 (P = 0.03 for continuous data; P = 0.018 for dichotomized data). There were no statistical significant changes in the SF-6D scores for patients receiving on-going treatment. CONCLUSIONS: This interim analysis from a large ongoing national study shows that significant improvements in health utility are obtained in patients receiving BoNTA for therapeutic indications. Health utility benefit was most pronounced in BoNTA-naive patients as evidenced by week 4 MCS scores (the expected peak effect window). Further recruitment and long term follow-up and analyses are ongoing.

PND21

MAPPING FROM DISEASE-SPECIFIC MEASURES TO HEALTH-STATE UTILITY VALUES IN CHRONIC MIGRANEURS

Gillard PJ1, Denton B1, Varon SP2, Plagnol GA3, Sullivan S1

1University of Washington, Department of Pharmacy, Seattle, WA, USA, 2Allergan, Inc, Irvine, CA, USA

OBJECTIVES: To develop algorithms that convert disease-specific quality-of-life scores for the Headache Impact Test (HIT-6) and the Migraine Specific Quality of Life, v. 2.1 (MSQ) Questionnaire to health-state utility values derived from the EuroQol-SD (EQ-SD) in chronic migraineurs. METHODS: Data from a cross-sectional multi-country study was used. Chronic migraineurs (ICHD-2 diagnosis of migraine and 215 headache days/month) completed a series of questions including the HIT-6 and EQ-5D. MSQ subjects were randomized into a training and validation samples of equal size. Correlations between paired EQ-SD index scores and both HIT-6 scores and MSQ domain scores (Role-Restrictive [RR], Role-Preventative [RP], and Emotional-Function [EF]) were examined using Spearman correlation coefficients. Regression models were constructed to predict EQ-SD utility values from the HIT-6 scores or the MSQ domain scores. Preferred algorithms were validated using the validation samples. RESULTS: Correlations between the EQ-SD index score and the HIT-6 and MSQ dimension scores were statistically significant (P < 0.001) with correlation coefficients of -0.33 (HIT-6), 0.44 (MSQ-RR), 0.46 (MSQ-RP), and 0.30 (MSQ-EF). The preferred HIT-6 algorithm was a non-linear model which contained a quadratic term for HIT-6, and explained 34% of the variance in the training sample. The preferred MSQ algorithm was a linear model with covariates representing each domain, and explained 43% of the variance in the training sample. Both models also included covariates for age, gender, employment status, headache medication use, and comorbidities. In the validation analyses, no statistically significant difference was observed between the mean observed EQ-SD score and the mean EQ-SD score estimated using the preferred algorithms. CONCLUSIONS: The relationship between the two disease-specific instruments and the EQ-SD are sufficiently robust to use regression equations to estimate EQ-SD utility values. These preferred models may be useful in estimating health-state utilities in trials of CM patients where no preference-based measure is present.
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 meaning, comprehensiveness, and to identify any necessary revisions to the items and conceptual framework. RESULTS: Two out of the nine items were generated from patient quotes obtained during the concept elicitation 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 dullness, dizziness), 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 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-NDSI 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

Burk PD1, White MK2, Castelli-Haley J3, Rendas-Baum R4
1Teva Neuroscience, Kansas City, MO, USA, 2QualityMetric Incorporated, Lincoln, RI, USA, 3QualityMetric Health Outcomes Solutions, Lincoln, RI, USA

OBJECTIVES: The 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-DC) 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 to evaluate the content validity of the SCOPA-DC 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 themes that specifically addressed the study objectives. The original SCOPA-DC 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-DC 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-DC, 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-DC 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-DC.

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

Brin CL1, Maglinte GA2, Rendas-Baum R3, DeRosa M1, Yang M4, Varon SF5
1University of Georgia, Athens, GA, USA, 2Allergan, Inc, Irvine, CA, USA

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, ≥1 per month). Variable demographic characteristics among the three MSQ groups were compared using Chi-square and ANOVA. Multivariate linear regression was used to identify factors (e.g., demographic) associated with MSQ scores. RESULTS: A total of 3,194 eligible respondents were categorized as having CM (n = 582), HEM (n = 635), or LEM (n = 1,977). The CM group had the lowest mean MSQ score (32.8, 95% CI: 31.8–33.8) compared with HEM (35.3, 95% CI: 34.4–36.2) and LEM (37.0, 95% CI: 36.0–38.0). Migraineurs were mostly female (83.5%) with a mean ((± standard deviation) age of 48.3 ± 24.1. Internal consistency for the MSQ was good (Cronbach’s α = 0.88). Significant differences (p < 0.01) were observed for the three MSQ groups. Linear regression models demonstrated that independent variables associated with lower MSQ scores included younger age, female gender, and higher frequency of headache. CONCLUSIONS: The MSQ is valid and reliable in migraineurs and provides a practical and informative instrument for the evaluation of overall quality of life of PD patients in cross-cultural studies.

PD2N1

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

Rendas-Baum R1, Maglinte GA2, DeRosa M1, Yang M4, Varon SF5
1Allergan, Inc, Irvine, CA, USA, 2QualityMetric Incorporated, Lincoln, RI, USA

OBJECTIVES: The 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-Preventive (RR), 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. 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 (fed up or frustrated; p = 0.037). Item 12 also presented non-uniform DIF related to a language variable (p = 0.010). CONCLUSIONS: Among Chronic Migraineurs, the MSQ provides a valid and reliable measure of RR, RF, and EF, yielding domain scores that can be reliably compared across languages and countries.

PD2N2

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

Jenkinson C1, Fitzpatrick R3, Findley L1, Churchill DM2, Hughes RA

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 = 0.83, Italy = 0.87, Japan = 0.79 and Spain = 0.73) and scaling assumptions of the instrument in the USA, Canada, Spain, Italy 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

Naithani K1, Armstrong E2, Skirpnek G3
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 PDQ-4 (r = −0.28 to −0.47), MIDAS (r = −0.42 to −0.58), and HUT (r = −0.55 to −0.71). Known groups validity indicated significant differences (p < 0.0001) in the hypothesized direction between CM, HEM, and LEM for RF (F = 58.74), RR (F = 91.78), and EF (F = 153.38). CONCLUSIONS: The MSQ is a reliable and valid questionnaire that can differentiate the functional impact between CM, HEM, and LEM.