View metadata, citation and similar papers at core.ac.uk

brought to you by CORE

provided by Elsevier - Publisher Connector

PND15

ECONOMICAL EVALUATION OF DIFFERENT FORMS OF BETAHISTINE IN PATIENTS WITH VERTIGO

Vorobyev PA[1], Lesnicheva MV[2], Morozova SV[3], Suleymanov SS[4], Sarvilina IV[2], Kupayev VI[2]
[1]Russian Society for Pharmacoeconomics and Outcomes Research, Moscow, Russia, [2]Russian Society for Pharmacoeconomics and Outcomes Research, Moscow, Moscow, Russia, [3]I.M. Sechenov Moscow Medical Academy, Moscow, Moscow, Russia, [4]Russian Society for Pharmacoeconomics and Outcomes Research, Khabarovsk, Khabarovsk, Russia

OBJECTIVES: to perform economic evaluation of three forms of betahistine in patients with vertigo. **METHODS:** an open-labeled prospective multicenter randomized study was performed in 14 out-patient clinics of Russia. The duration of a study was 30 days. Patients with vertigo were treated with three forms of betahistine (Betaserc, Betaver, Vestibo) in combination with any other medications to the discretion of investigator. The effectiveness criteria were proportion of patients with absence of moderate and severe functional disorders (according to International Classification of Functioning, Disability and Health) and increase of patients' quality of life rate compared to the initial one (according to EQ-5D questionnaire). Cost-effectiveness and cost-utility ratios were calculated. **RESULTS:** Betaver group included 70 (33.2%) patients, Betaserc group—71 (33.6%) patients, and Vestibo group—70 (33.2%) patients with moderate vertigo. All patients initially had moderate and severe functional disorders. The proportion of patients without absence of moderate and severe functional disorders up to the end of a study was 54% in Betaver group, 57% in Vestibo group and 69% in Betaserc group. The average difference between initial quality of life rate and the quality of life after the treatment was 19.53, 19.62 and 22.79 (Betaver, Vestibo and Betaserc groups accordingly). Cost of treatment was nearly similar in all groups. The cost-effectiveness ratio according to the criteria "the proportion of patients with absence of moderate and severe functional disorders" was minimal in Betaserc group (8,088.57) compared to Betaver (10,358.17) and Vestibo (8,955.49) groups. The cost-utility ratio according to the criteria "the increase of patients' quality of life rate compared to the initial one" was also minimal in Betaserc group (244.89) compared to Betaver (286.4) and Vestibo (260.17) groups. **CONCLUSIONS:** Betaserc seems to be more clinically and economically effective betahistine compared to another two medications in treatment of patients with vertigo.

PND16

COST SAVING OPPORTUNITY OF POTENTIAL PHARMACIST-INITIATED IV-TO-PO LEVETIRACETAM SWITCHES: A PREDICTION MODEL BASED ON REAL-WORLD DATA

Yeh JY, Garrity LC, Ahrens CL
Cleveland Clinic, Cleveland, OH, USA

OBJECTIVES: Opportunity exists for certain hospitalized patients to appropriately receive oral (PO) levetiracetam given its bioavailability of 100%. Use of intravenous (IV) levetiracetam at our institution had increased and was associated with significant annual cost. This study aimed to evaluate the use of IV levetiracetam, to identify a cost saving opportunity and to project cost savings of potential pharmacist-initiated IV-to-PO levetiracetam switches. The goal was to provide information regarding medication utilization and cost saving opportunities for hospital administration to make informed formulary decisions. **METHODS:** A retrospective medical chart review on 100 randomly selected adult patients receiving at least two doses of IV levetiracetam during hospital stays between July 1, 2008 and November 30, 2008 was conducted. Pre-defined eligibility of IV-to-PO levetiracetam switches, costs, doses and frequencies were obtained for each patient-day. Only levetiracetam costs were considered and presented as 2008 average wholesale prices without further adjustments. Monte Carlo simulation models were created to predict cost savings, and model inputs, parameters and plausible ranges were determined based on real-world data. Three scenarios were hypothesized where switches could have been made with "no delay," "12-hour delay" or "24-hour delay" of pharmacist interventions upon identification of eligibility. Probabilistic sensitivity analysis was performed (2,500 trials) for each scenario. **RESULTS:** Among 729 patient-days (from 99 subjects with one subject excluded as an outlier), 6.6% made IV-to-PO levetiracetam switches and additional 66% were eligible for such switch. With a conservative scenario of 24-hour delay, potential cost savings were estimated as follows: mean $512 (SD $714) per patient or $69.6 (SD $0.4) per patient-day; median $302 (95% CI $20-$1,661) per patient. Of 2,500 estimates, 19.6% could have potential savings of $100–200 per patient, followed by $0-$100 (15.5%), $200-$300 (14.6%) and $300-$400 (9.6%). **CONCLUSIONS:** Pharmacists have potential cost saving opportunities by identification of eligible IV-to-PO levetiracetam switches.

PND17

ECONOMIC EVALUATION OF THE IMPACT OF MEMANTINE ON TIME TO NURSING HOME ADMISSION IN THE TREATMENT OF ALZHEIMER'S DISEASE

Lachaine J[1], Beauchemin C[1], Legault M[2], Le Lay A[3]
[1]University of Montreal, Montreal, QC, Canada, [2]Lundbeck Canada Inc., Montreal, QC, Canada, [3]Lundbeck SAS, Paris, France

OBJECTIVES: An observational study recently showed that combining memantine with a cholinesterase inhibitor (ChEI) treatment significantly delayed admission to a nursing home in patients with Alzheimer's disease. The objective of this analysis was to evaluate the economic impact of the concomitant use of memantine and ChEI on time to institutionalization in a Canadian population. **METHODS:** A cost-utility analysis using a Markov model over a 7 years time horizon was performed according to a public third party perspective and a societal perspective. The Markov model includes the following states: non-institutionalized, institutionalized, and deceased. Transition probabilities for institutionalisation were taken from the study by Lopez et al., while transition probabilities for death were taken from Canadian survival tables and adjusted for mortality rates specific to Alzheimer's disease. For the publicly funded health care system perspective, costs of medication (ChEI and ChEI + memantine) as well as the costs of care provided in the community and in nursing homes were considered. For the societal perspective, costs of direct care and supervision provided by caregivers were added. **RESULTS:** From both a societal and a publicly funded health care system perspective, the concomitant use of a ChEI and memantine is a dominant strategy over the use of a ChEI alone. Thus, the costs associated with the use of memantine in combination with a ChEI are lower than those associated with the use of a ChEI alone, and the number of Quality-adjusted-life-years (QALYs) obtained with a ChEI plus memantine is higher than the number of QALYs obtained with a ChEI alone. **CONCLUSIONS:** The results of this economic evaluation indicate that the use of memantine combined with a ChEI to treat Alzheimer's disease is a cost-effective alternative compared to the use of a ChEI alone, both from a health care and societal perspective.

PND18

HEALTH STATUS, RESOURCE UTILIZATION, AND WORK PRODUCTIVITY FOR CAREGIVERS OF ADULTS WITH EPILEPSY: A PROPENSITY SCORE ANALYSIS OF NATIONAL SURVEY DATA

Abouzaid S[1], DiBonaventura MD[2], Forlenza JB[1], Durkin MB[1]
[1]Ortho-McNeil Janssen Scientific Affairs, LLC, Titusville, NJ, USA, [2]KantarHealth, New York, NY, USA

OBJECTIVES: Compare health status, resource utilization, and work productivity between caregivers for an adult with epilepsy and a control group of non-caregivers. **METHODS:** Respondents to the 2009 U.S. National Health and Wellness Survey (NHWS), a self-administered, internet-based questionnaire of adults, who reported providing care for an adult relative with epilepsy, were included in the caregiver group. Propensity score methods were used to construct a 5:1 matched control group from the general NHWS population, excluding caregivers for any other condition, matched on demographics and health characteristics. The caregiver and control groups were compared on health status (SF-12v2 Physical Component Summary (PCS) and Mental Component Summary (MCS) score) and resource use (number of self-reported hospitalizations, ER visits, and physician visits in the past 6 months). Employed caregivers were similarly matched to employed controls from the general NHWS respondents and compared on work productivity using the Work Productivity and Activity Impairment (WPAI) questionnaire. Statistical analyses included chi-square tests, t-tests, and generalized linear models. **RESULTS:** Of the 75,000 NHWS respondents, 222 self-reported caregivers were matched to 1,110 controls ($p > 0.25$ for all included covariates). The caregiver group was 51.8% female with mean (standard deviation) age of 45.2 (15.4) years. Caregivers had lower mean SF-12v2 PCS scores than controls (43.0 vs. 46.3, respectively; $p < 0.0001$) and showed no difference on mean MCS scores (44.8 vs. 46.3, respectively; $p = 0.090$). Caregivers reported significantly ($p < 0.0001$) more ER visits (rate ratio (RR) = the ratio of the caregiver group mean to the control group mean = 4.15), hospitalizations (RR = 6.44), and provider visits (RR = 1.59) than controls. Employed caregivers ($n = 124$) reported significantly ($p \leq 0.0018$) higher rates of absenteeism (RR = 2.66), presenteeism (RR = 2.08), overall work impairment (RR = 2.02), and activity impairment (RR = 1.76) versus controls. **CONCLUSIONS:** Caregivers of adults with epilepsy reported utilizing more health care resources, and had lower work productivity, worse physical health status yet no difference in mental health status versus non-caregivers.

NEUROLOGICAL DISORDERS – Patient-Reported Outcomes Studies

PND19

IMPACT OF MEDICATION ADHERENCE TO DISEASE-MODIFYING DRUGS ON SEVERE RELAPSE, AND DIRECT AND INDIRECT COSTS AMONG EMPLOYEES WITH MULTIPLE SCLEROSIS

Ivanova JI[1], Phillips AL[2], Bergman RE[1], Birnbaum HG[3], Stewart M[4], Meletiche DM[2]
[1]Analysis Group, Inc., New York, NY, USA, [2]EMD Serono, Inc., Rockland, MA, USA, [3]Analysis Group, Inc., Boston, MA, USA, [4]Pfizer Inc, New London, CT, USA

OBJECTIVES: Compare multiple sclerosis (MS) severe relapse rates and total direct and indirect costs over a two-year study period between employees with MS adherent and nonadherent to disease-modifying drugs (DMDs) **METHODS:** Employees with ≥1 MS diagnosis (ICD-9-CM: 340.x) and ≥1 DMD pharmacy claim January 1, 2002–December 31, 2006 were selected from a large US administrative claims database. Patients had continuous coverage ≥6 months before (baseline) and ≥24 months after (study period) their index date (first DMD claim). Adherence was measured using the medication possession ratio (MPR) over the 24-month study period. Patients with MPR ≥80% were classified as adherent (n = 448) and those with MPR < 80% were classified as nonadherent (n = 200). Multivariate analyses adjusting for differences in baseline characteristics were used to compare severe relapse rates (inpatient or emergency department visit with MS diagnosis) and costs in 2007 dollars between DMD adherent and nonadherent patients. Direct medical costs were calculated as reimbursements to providers for medical services and prescription drugs excluding DMDs. Indirect costs included disability and medically-related absenteeism costs. **RESULTS:** DMD adherent patients were on average older (43.5 vs. 41.8 years, $P = 0.015$) and more likely to be male (38.6% vs. 26.0%, $P = 0.002$) compared with nonadherent

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 relapses (12.4% vs. 19.9%, $P = 0.013$) 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[1], Wagner JS[2], DiBonaventura MD[3]
[1]University of Minnesota, Minneapolis, MN, USA, [2]KantarHealth, Princeton, NJ, USA, [3]KantarHealth, New York, NY, USA

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 as measured by 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 care 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. Overall16.3% 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.

PND21

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

Simonyi S[1], Jog M[2], Beauchamp R[3], Miller R[4], Bhogal M[1], Wein T[5]
[1]Allergan Inc., Markham, ON, Canada, [2]London Health Sciences Centre, London, ON, Canada, [3]Children's & Women's Health Centre of B.C, Vancouver, ON, Canada, [4]Dalhousie University, Halifax, NS, Canada, [5]McGill University, Montreal, QC, Canada

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 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-12v2 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 patients returned the week 4 survey and data from 608 individuals were included in the analysis (526 were receiving ongoing BOTOX® treatment at baseline; 82 were BoNTA-naïve). 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 ($p = 0.03$). Among BoNTA-naïve 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.

PND22

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

Gillard PJ[1], Devine B[1], Varon SF[2], Maglinte GA[2], Sullivan S[1]
[1]University of Washington, Department of Pharmacy, Seattle, WA, USA, [2]Allergan, 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-5D (EQ-5D) in chronic migraineurs. **METHODS:** Data from a cross-sectional multi-country study was used. Chronic migraineurs (ICHD-2 diagnosis of migraine and ≥15 headache days/month) completed a series of questions including the HIT-6 (n = 547), MSQ (n = 499), and EQ-5D. Subjects were randomly assigned to training and validation samples of equal size. Correlations between paired EQ-5D 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-5D 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-5D 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-5D score and the mean EQ-5D score estimated using the preferred algorithms. **CONCLUSIONS:** The relationship between the two disease-specific instruments and the EQ-5D are sufficiently robust to use regression equations to estimate EQ-5D 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.

PND23

CONCORDANCE OF SELF-REPORT MEASURES OF DSM-IV-TR, ICD-10, AND RDC INSOMNIA WITH STANDARDIZED CLINICAL ASSESSMENTS IN THE AMERICA INSOMNIA SURVEY (AIS)

Kessler RC[1], Coulouvrat C[2], Lakoma MD[1], Hajak G[3], Roth T[4], Sampson N[1], Shahly V[1], Shillington AC[5], Stephenson JJ[6], Walsh J[7], Zammit G[8]
[1]Harvard Medical School, Boston, MA, USA, [2]Sanofi-Aventis Group, Paris, France, [3]University of Regensburg, Regensburg, Germany, [4]Henry Ford Hospital, Detroit, MI, USA, [5]EPI-Q Inc, Oak Brook, IL, USA, [6]HealthCore, Inc., Wilmington, PA, USA, [7]St. Luke's Hospital, Chesterfield, MO, USA, [8]Clinilabs, Inc., New York, NY, USA

OBJECTIVES: To evaluate the reliability and validity of the Brief Insomnia Questionnaire (BIQ), a fully-structured measure to assess insomnia based on DSM-IV-TR, ICD-10, and RDC criteria. **METHODS:** The AIS is a large (n = 10,094) epidemiological survey of the prevalence and correlates of insomnia in a nationally representative sample of managed health care plan subscribers. Probability sub-samples of AIS respondents over-sampling BIQ cases completed either short-term test-retest interviews (n = 59) or clinical reappraisal interviews (n = 203) to assess BIQ reliability and validity. **RESULTS:** Test-retest correlations were .72–.95 for reports of frequency and .47–.94 for reports of severity of sleep problems (initiation, maintenance, non-restorative sleep), .66–.88 for reports of daytime impairment/distress, and .62 for reported duration. Good individual-level concordance was found between diagnoses based on the BIQ and clinical interviews for meeting criteria in any of the three diagnostic systems, with area under the receiver operating characteristic curve (AUC, a measure of classification accuracy not influenced by disorder prevalence) of .86 for dichotomous classifications. AUC increased to .94 when symptom-level data were added to generate a continuous measure of predicted probability of clinical diagnosis. AUC was lower for dichotomous classifications based on RDC (.68) and ICD-10 (.70) than DSM-IV-TR (.83) criteria, but increased when symptom-level data were added to generate continuous measures of predicted probability of diagnoses (.92–.95). **CONCLUSIONS:** The results demonstrate that the BIQ can be used to obtain accurate estimates of prevalence and correlates of insomnia in the American Insomnia Survey.

PND24

EVALUATING THE IMPACT OF RESTLESS LEGS SYNDROME (RLS) ON NEXT DAY FUNCTIONING

Abraham L[1], Lasch KE[2], Patrick J[3], Piault E[2], Tully SE[2], Treglia M[4]
[1]Pfizer Ltd, Sandwich, UK, [2]Mapi Values, Boston, MA, USA, [3]Pfizer, Inc., New London, CT, USA, [4]Pfizer Inc, New London, CT, USA

OBJECTIVES: Symptoms of Restless Legs Syndrome (RLS) typically worsen in the early evening and nighttime affecting patients' quality and duration of sleep which can have next day sequelae detrimental to daytime performance. The present qualitative research aimed to support the content validity of a new self-reported outcome measure to document the impact of disturbed sleep due to RLS on next day functioning. **METHODS:** An initial conceptual framework was developed based upon a review of the literature. The development of the Restless Legs Syndrome—Next Day Impact (RLS-NDI) questionnaire included: concept elicitation interviews with 20 clinician-confirmed idiopathic RLS patients in the US (aged 35–64); grounded theory data collection and analysis methods; achievement of saturation; and review by clinical and