APPLICATION OF THE KANO METHODOLOGY FOR EVALUATING MIGRAINE TREATMENT EXPECTATIONS AMONG PATIENTS TREATED BY NEUROLOGISTS IN SPAIN: THE MIGREXX STUDY

Molina J, García-Cabello T, Calvo T

Hospital Universitario San Carlos, Madrid, Spain; *Mercè Sharp & Dohe, SA, Madrid, Spain

OBJECTIVES: To classify the characteristics and properties of the pharmacological treatments among migraine patients treated by neurologists in Spain. Patients are becoming increasingly implicated in treatment decisions. Expectations in relation to therapy largely condition satisfaction with the results obtained. METHODS: Multicenter, cross-sectional study in adult patients with at least one prescription of anti-migraine drugs within the last year. The protocol was approved by the CREC of La Princesa University Hospital (Madrid); Sociodemographic, and clinical characteristics of patients, as well as questions regarding their expectations with regard to migraine treatments and evaluation of the importance of their attributes are documented. Using a treatment expectations questionnaire and applying Kano methodology; sixteen treat-ment attributes were classified as: Must-be, One-dimensional, Attractive, Indifferent, Reverse or Questionable. Patients were required to give informed consent. RESULTS: 68 neurologists included 174 patients diagnosed with migraine (mean age 39 years; 75% women). None of the attributes were considered "Must-be". The attributes considered by most patients to be "One-dimensional" were the absence of long-term adverse effects (55%), side effects from work/study activities (50%), to allow social and family relationship (50%), achievement of symptoms relief (47%) and pain relief (44%). The attributes considered "Attractive" by most patients were: achievement of rapid symptoms and pain relief (54%), and achievement of total disappearance of pain (53%). The attributes that led to a greater dissatisfaction were the occurrence of long-term adverse effects, not to allow work activity or studies and not to achieve pain relief. The three attributes that led to a greater satisfaction were achievement of total disappearance of the symptoms and the pain, and rapid pain relief. CONCLU-SIONS: The expectations regarding a medical treatment significantly influence the satis-faction reached with the outcome of such a treatment. A better knowledge of patient's expectations can lead to a greater satisfaction associated with treatment outcomes.

MODIFIED LAST OBSERVATION CARRIED FORWARD IS A SUPERIOR METHOD OF IMPUTATION

Dutić-Ovčara, R; Lei X; Fanuari, I; Turkulj C

Allergan Inc., Irvine, CA, USA

OBJECTIVE: To compare imputation methods using PREEMPT (Phase III ReSearch Evaluating Migraine Prophylaxis Therapy) clinical data. METHODS: Data were analyzed from two phase 3 studies of onabotulinumtoxinA in chronic migraine (ICH-D II-migraine and ≥ 25 headache days/month). Each study included a 24-week, randomized, double-blind, parallel-group, placebo-controlled phase, followed by a 32-week, open-label onabotulinumtoxinA treatment phase. The prespecified method of imputation of missing data (ie, ≤ 20 days of diary data in a 28-day period) was modified last observation carried forward (mLOCF), which estimated missing data by item-by-item extrapolation of the subject’s most recent count by the subsequent average change rate across treatments. We compared mLOCF with last observation carried forward (LOCF), baseline observation carried forward (BOCF), mLOCF within-treatment (mLOCFw), and observed data (without imputation). Predictions by mLOCF were compared with mLOCF and mLOCFw, and observed data (without imputation). Simulations to predict mLOCF were generated using mLOCF, LOCF, and BOCF. RESULTS: Subject's who were randomized (PREEMPT1: onabotulinumtoxinA [n = 341], placebo [n = 338]; PREEMPT2: onabotulinumtoxinA [n = 347], placebo [n = 358]), 1026 (74%) of the subjects had no missing monthly counts during the double-blind phase (PREEMPT1: onabotulinumtoxinA [n = 341], placebo [n = 338]; PREEMPT2: onabotulinumtoxinA [n = 347], placebo [n = 358]). Each imputation method (mLOCF, LOCF, BOCF, mLOCFw) and observed data generated a similar statistically significant group difference for the primary efficacy endpoint of headache-days counts at Week 24 in PREEMPT2 (P < 0.001). Similar results were observed within PREEMPT1 (P < 0.02). Compared to LOCF and BOCF, mLOCF was superior at predicting known values of headache-day counts in simulations that randomly set observed scores to missing, as demonstrated by least-squares errors of imputed minus actual counts. CONCLUSIONS: PREEMPT treatment differences were similar (and statistically sig-nificant) using each imputation method, likely due to low dropout rates within each treatment group. Compared to LOCF and BOCF, mLOCF was superior at predicting known data.

Nestec (PHF-W) and to extensively hydrolyzed formulas (EHE-Whey or Casein) were reported for the prevention of AD in infants who are not exclusively breastfed. METHODS: Szajewska et al. had previously undertaken a meta-analysis determining the incidence rates and RR of PHF-W compared to cow’s milk formula (CMF) and EHE but details were not for provided for PHF-W vs. EHE. This analysis sheds light on the latter comparisons and extends the analyses to 3-month cycles from birth to 36-months of age. Included were any relevant randomized controlled trials comparing the use of PHF-W with CMF or EHE for the prevention of allergies. The primary outcome of interest were the incidence, cumulative incidence and period prevalence of any allergic manifestations and AD in particular. Of 84 retrieved citations, 15 studies were included for analysis of which 6 studies pertained to PHF-W vs. EHE. All efficacy data were converted into inputs for a spreadsheet decision-analytic eco-nomic model based on 3-month cycles by applying weights derived from the Szajewska et al. meta-analysis and calculating them at 3-month intervals for input into an eco-nomic model. RESULTS: The analysis sample included 557, 559 and 580 patients for PHF-W, EHE-Whey and EHE-Casein, respectively. A RR of 0.75 [0.54, 1.05] at 0–12 months and 0.90 [0.63, 1.02] at 0–36 months was obtained for PHF-W vs. EHE-Whey while a RR of 1.06 [0.74, 1.53] at 0–12 months and 1.13 [0.87, 1.47] at 0–36 months was determined for PHF-W vs. EHE-Casein. All efficacy data were adapted into 3-month indicators. CONCLUSIONS: It appears that the efficacy of PHF-W falls within the range of the other two extensively hydrolyzed formulas.

SENSORY SYSTEMS DISORDERS – Cost Studies

OBJECTIVE: Evaluation of real-life dosing of biologics in plaque psoriasis in Germany and the potential savings by treating patients with ustekinumab instead of using higher doses of TNF-alpha-inhibitors. METHODS: Based on an online survey among 100 dermatologists (DocCheck Medical Services, December 2009) the use of biologics and their dosing distribution for the treatment of plaque psoriasis was evaluated. The proportion of patients receiving maintenance dosages according to label and those receiving a higher dose were evaluated for each biologic separately. A budget impact model was created estimating potential savings by treating patients with ustekinumab according to label (45 mg in patients <100 kg body weight and 90 mg in patients >100 kg body weight) instead of high dose TNF-alpha-inhibitors in terms of annual medication costs. In this model, costs of the current usage pattern of biologics were estimated using German pharmacy prices (source: Lauer-Taxe, version June 1, 2010, most economical pack size). RESULTS: In most cases biologic treatments are used according to the respective labels. In some instances, deviating dosages are used: 14% of adalimumab-treated patients receive an increased dosage of 40 mg every week or 80 mg every 2 weeks and more than 15% of etanercept-treated patients receive 50 mg twice weekly or another deviating dosage as maintenance therapy. 27% of infliximab-treated patients receive maintenance dosages more frequently than every 3 weeks or receive an increased dosage per injection. In Germany, assuming 80% of those high-dose TNF-alpha-inhibitor-treated patients are treated with ustekinumab instead, this would result in savings of approximately €18 million per year. If induction costs of ustekinumab are considered additionally, still €13 million could be saved within one year. CONCLUSION: Using ustekinumab instead of high doses of TNF-alpha-inhibitors for treatment of plaque psoriasis can generate significant savings in medication costs in Germany.

EPIDEMIOLOGY, COSTS AND QUALITY OF LIFE IN PATIENT WITH SEVERE CHRONIC HAND ECZEMA


1University of Milano—Bicocca, Monza, Italy; 2Istituto Dermopatico dell’Immacolata (IDDI)-IRCCS, Roma, Italy; 3DS.E.M, Università di Genova, Genova, Italy; 4Università di Bari, Italy; 5Istituto Dermatologico San Gallo IRCCS, Rima, Italy; 6Università di Verona, Verona, Italy; 7Università Federico II of Naples, Napoli, Italy; 8University of Messina, Messina, Italy; 9University of Sassari, Sassari, Italy; 10University of Perugia, Perugia, Italy; 11University of Padua, Padova, Italy; 12Università di Milano, Milano, Italy; 13CRIF, Federico II University, Naples, Italy; 14CHARTA Foundation, Milano, Italy; 15Università di Modena, Modena, Italy

OBJECTIVES: Some research has shown that Hand Eczema is often work-related, widespread, potentially disabling and costly disease, but misdiagnosed and mistreated. Severe Chronic Hand Eczema (CHE) can be particularly burdensome. We aimed to identify a multidisciplinary, epidemiological and cost-of-illness study is being conducted in 14 Italian dermatological centers. 18 years are being enrolled through a 6-month period. The following data are being collected: socio-demographic, clinical (severity, chronicity and responsiveness to treatment with topical potent corticosteroids) and, among chronic, severe and refractory patients, data on HRQol

META-ANALYSIS OF PARTIALLY HYDROLYZED 100% WHEY FORMULA VERSUS EXTENSIVELY HYDROLYZED FORMULAS IN THE PREVENTION OF ATOPIC DERMATITIS


Pharmida’s Research and Consulting Inc., Ottawa, ON, Canada; 2Pharmida’s Medical University of Warsaw, Warsaw, Poland; 3Helixt Nutrition Institute, Vevey, Switzerland; 4Pharmida’s Research and Consulting Inc., Ottawa, ON, Canada; 5Pharmida’s Europe SAS, Lyon, France

OBJECTIVES: The incidence rates of atopic dermatitis (AD) and relative risks (RR) associated to a brand of partially hydrolyzed 100% whey formula manufactured by

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COST OF ILLNESS IN PATIENTS WITH CHRONIC HAND ECZEMA: RESULTS FROM A MULTI-CENTRE STUDY IN GERMANY

Auguste M1, Diagge T1, Pethomas J1, Keum S1
1University Clinics of Hamburg, Hamburg, Germany; 2University Heidelberg, Heidelberg, Germany

OBJECTIVES: It is assumed broadly that the costs caused by chronic hand eczema (CHE) are significant. However, there is a lack of cost-of-illness studies on CHE. The objective of this study is, therefore, to determine the direct and indirect costs of chronic hand eczema under routine conditions overall and in different treatment stages in Germany.

METHODS: The survey was conducted in 24 outpatient practices and clinical centers. Patients with CHE refractory to topical treatments and insured by statutory health insurances were eligible. Patient characteristics and resource use were directly gathered from patients and physicians. Costs were evaluated from the societal perspective. Four treatment stages were defined: only topical treatments (stage I), additionally photo therapy (II), systemic therapy (III) and inpatient treatment (IV). Bivariate associations between costs and treatment stage were assessed.

RESULTS: A total of 233 CHE patients enrolled in the study. The yearly direct and indirect costs per patient were €1742 (SE: €139) and €386 (€83), respectively. A total of 63.2% of patients were treated only with topical treatments; additionally 15.7% with photo therapy, 11.7% with systemic treatments. A total 9.4% of all patients were admitted to hospitals. The total costs increase with treatment stage IIV (P < 0.001): €1044 (€83), €2107 (€145), €2697 (€461) and €8407 (€991), respectively. Accordingly, costs also correlated with clinical severity. CONCLUSIONS: CHE patients refractory to topical steroids incur marked costs to the society. As expected, biologically treated patients had higher costs but overall severity probably due to the treatment effectiveness. The relationship between costs and severity is complex, probably due to the selected study period and differences in effect between strategies.

THE ECONOMIC COST OF TREATING PATIENTS WITH AGE-RELATED MACULAR DEGENERATION IN SPAIN

Darba J1, Kaskens L2
1Universitat de Barcelona, Barcelona, Spain; 2RCN-Health, Barcelona, Spain

OBJECTIVES: Wet macular degeneration associated with age (wet-AMD) is the leading cause of legal blindness in people over 55. The aim of this study is to determine health care resource utilization and mean costs per patient with wet-AMD.

METHODS: A cross-sectional survey was performed in a hospital setting. Medical costs of patients with wet-AMD. Patient level data was obtained from different public hospitals in Spain and ophthalmologists were surveyed with a semi-structured questionnaire to obtain treatment patterns. Inpatient costs were considered from the perspective of the public health care system. Treatments under study were pegaptanib, verteporfin, ranibizumab and bevacizumab. Although bevacizumab in Spain is not approved for wet-AMD, it was used off-label in the hospital. Direct medical costs considered were drug costs, administration costs, doctors’ visits, nurse time, ophthalmologic time, anesthetics, ambulance hospital care, external consultations and treatment of adverse effects. All costs are referred to 2009. RESULTS: Mean cost per patient treated with wet-AMD represented the following cost for the public health care system: €7290 for pegaptanib, €8106 for verteporfin, €8616 for ranibizumab and €1010 for bevacizumab. We estimated that in Spain only 15% of people in 2009 years have wet-AMD in 2009. CONCLUSIONS: Pharmacological treatments for wet-AMD are photo dynamic therapy with verteporfin, pegaptanib, verteporfin and ranibizumab, with the last one having the highest medical costs. The agog of the population and development of new drugs will probably increase the future economic impact of AMD, which remains a major health care burden.

PREDICTIVE FACTORS OF GLAUCOMA TREATMENT COST IN GERMANY

Lorenz K1, Wolffram C1, Claus V1, Penzlin-Frank C1, Verborgen V1, Pfeiffer N2
1Universitätsmedizin Mainz, Mainz, Germany; 2Alcon Research Ltd., Puurs, Belgium

OBJECTIVES: To describe total costs and factors predicting cost in Germany for glaucoma disease states: ocular hypertension (OHT), and early (EARLY), moderate (MOD) and advanced (ADV) glaucoma. METHODS: A 5-year retrospective analysis collected health care utilization, clinical parameters, treatment used and reasons for treatment change. Disease states defined by the European Glaucoma Society were applied. Costs for health care resources were based upon the German EBM/OPS code for ambulatory visits/procedures, diagnosis-related groups for hospital procedures and the DRG-Liste for medication. Factors predicting cost were tested using stepwise backward multiple linear regression, entry criterion a = 0.2. RESULTS: A total of 154 patients (27 OHT, 43 EARLY, 35 MOD, 49 ADV) were enrolled from 15 centers across 5 German regions. Average age was 67 ± 11 and 57% were female. Number of OHT visits/year was 9.0 ± 7.7, 4.6, 8.7 ± 4.1 and 13.2 ± 8.3 years for OHT, EARLY, MOD and ADV, respectively. Total costs, for patients with OHT, EARLY, MOD or ADV, were €226 ± 117, €432 ± 647, €493 ± 385, and €808 ± 877, respectively. Most costs were due to medication (€212 ± 99, €217 ± 130, €243 ± 161, €340 ± 193) and hospital interventions (€32 ± 101, €115 ± 538, €134 ± 285, €367 ±