disagree that innovation in health care is worthwhile, the tremendous technological success in pharmacological treatment of HIV patients is a case in point. On the other hand, a relatively large number of “me-too” entries in the pharmaceutical market and the diminishing productivity of &D sector call for robust methodologies, which could distinguish high-value, breakthrough products. Sensitivity analyses of cost-effectiveness studies should be made pivotal in decision-making processes in order to ensure efficient diffusion of innovation.

PRM243

SURVEY DESIGN IN THE ASSESSMENT OF THE IMPLEMENTATION OF RISK MINIMISATION MEASURES FOR MEDICINAL PRODUCTS


The introduction of the risk management plan (RMP) has ensured greater proactivity to the pharmacovigilance and post-authorisation benefit risk assessment of human medicinal products. An RMP may include risk minimisation measures (RMM), public health interventions intended to prevent the occurrence, or reduce the impact of adverse drug reactions associated with the exposure to a drug. The new EU legislation on pharmacovigilance explicitly requires the active monitoring of the outcome of RMP, pharmacovigilance units and treatments. Such surveys should be developed following the principles of causality and evidence-based medicine. The survey should be designed in order to assess the degree of risk minimisation foreseen and the impact on the practical implementation of the legislation on the evaluation of the effectiveness of RMM. Surveys addressing the attainment (final outcome indicators) of RMM. Such surveys should be developed following the principles of causality and evidence-based medicine. The survey should be designed in order to assess the degree of risk minimisation foreseen and the impact on the practical implementation of the legislation on the evaluation of the effectiveness of RMM.

PND3

EFFICACY OF FINGOLIMOD IN DELAYING CONFIRMED DISABILITY PROGRESSION IN PATIENTS FAILING PRIOR TREATMENT: A MARKOV MODEL APPLICATION TO ESTIMATE TIME TO DISABILITY HEALTH STATES

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OBJECTIVES: To estimate the efficacy of fingolimod versus placebo on confirmed disability progression (CDP) and on time to severe disability health states in patients with relapsing-remitting multiple sclerosis (RRMS) failing prior treatment. METHODS: Patients in RRMS failing treatment with a disease-modifying therapy were included in the study. Treatments were assessed in a retrospective study conducted in MEDLINE- and EMBASE-indexed publications from 5/2000-1/2013, to December, 2011. A control group of patients without AD was created on a 1:1 ratio, and matched for age, gender and geographic location. The index date was defined as the date of the first AD diagnosis or the first script for AD medication whichever comes first. Prevalence of diseases and treatment exposures in the years preceding the index date were analyzed according to the occurrence of diseases (ICD-9 codes) and medication utilization (AHFS codification) between AD patients and the control group. RESULTS: Data were obtained for a random sample of 34,986 &D group compared to the control group. Furthermore, a greater number of patients used psychotropic drugs (53.5% vs. 35.9%, p<0.001) and anxiolytics, sedatives and hypnotics (70.0% vs. 60.0%, p<0.001) in the control group than in the &D group. CONCLUSIONS: Comorbidities’ frequency was higher in &D patients for several diseases and treatments, particularly for mental disorders-related diagnoses and medications.

DISEASE-SPECIFIC STUDIES

NEUROLOGICAL DISORDERS – Clinical Outcomes Studies

PND1

DISEASE BURDEN IN EPILEPSY ASSOCIATED WITH TUBEROUS SCLEROSIS COMPLEX: SYSTEMATIC REVIEW

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OBJECTIVES: To summarize literature on the burden of epilepsy in tuberous sclerosis complex (TSC), TSC is a genetic disease characterized by behavioral disorders, learning disabilities, autistic features, and neurological manifestations including epilepsy.

METHODS: A systematic search of keywords for TSC and burden of illness was conducted in MEDLINE- and EMBASE-indexed publications from 5/2000-1/2013, and references were reviewed for articles on TSC. The results of the systematic review are reported as a 1:1 ratio, and matched for age, gender and geographic location. The index date was defined as the date of the first AD diagnosis or the first script for AD medication whichever comes first. Prevalence of diseases and treatment exposures in the years preceding the index date were analyzed according to the occurrence of diseases (ICD-9 codes) and medication utilization (AHFS codification) between AD patients and the control group. RESULTS: Data were obtained for a random sample of 34,986 &D group compared to the control group. Furthermore, a greater number of patients used psychotropic drugs (53.5% vs. 35.9%, p<0.001) and anxiolytics, sedatives and hypnotics (70.0% vs. 60.0%, p<0.001) in the control group than in the &D group. CONCLUSIONS: Comorbidities’ frequency was higher in &D patients for several diseases and treatments, particularly for mental disorders-related diagnoses and medications.

PND4

COMPARING THE EFFICACY OF FIRST AND SECOND GENERATION DISEASE-MODIFYING THERAPIES FOR RELAPSING-REMITTING MULTIPLE SCLEROSIS: A NETWORK META-ANALYSIS

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OBJECTIVES: As the number of available disease-modifying therapies (DMT) for relapsing-remitting multiple sclerosis (RRMS) expands, consideration of all evidence of comparative efficacy of new DMTs is required. The aim of this study was to compare the first generation therapies required to inform clinical care and health policy. This network meta-analysis (NMA) estimates the relative efficacy of DMT in reducing relapses and slowing short-term progression of disability in RRMS.

METHODS: A systematic review of RCTs of interferon beta, glatiramer acetate (first generation DMTs), natalizumab, alemtuzumab, fingolimod, teriflunomide, laquinimod, and BG-12 (second generation DMTs) was conducted with each other or with placebo for the treatment of RRMS. The identified eligible RCTs (n=1461). A random-effects NMA model was used to calculate relative annualized relapse rate (ARR) and hazard ratio (HR) of short-term disability progression. RESULTS: Statistically significant reductions in ARR versus placebo, between 24% - 69% for second generation DMTs and 16% - 33% for first generation DMTs were found. Alemtuzumab, natalizumab, fingolimod, and BG-12 were significantly more efficacious than other DMTs in reducing ARR. There was greater uncertainty associated with DMT efficacy in reducing short-term disability progression. Significant improvements over placebo in reducing short-term disability progression were restricted to second generation DMTs alemtuzumab, natalizumab, fingolimod, laquinimod, BG-12, and teriflunomide (HR: 0.27 – 0.54). No statistically significant improvements in short-term disability progression were exhibited by first generation DMTs and teriflunomide. CONCLUSIONS: The growing number of innovative second generation DMTs offers the potential of therapeutic advances in reducing relapse rates in RRMS, with less efficacy benefits on short-term disability progression. Despite potential advantages, the relative position of second generation DMTs on the RRMS treatment landscape remains to be defined, due to potentially serious side effects, limited long-term safety data and their high cost.

PND5

EFFECTIVENESS OF THE EARLY PSYCHOLOGICAL INTERVENTION ON INSTITUTIONALIZATION OF PATIENTS WITH MILD ALZHEIMER’S DISEASE AND CAREGIVERS’ QUALITY OF LIFE – AN ALISOVA STUDY

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OBJECTIVES: To identify potential determinants of Alzheimer’s disease (AD) by analyzing past medical history in terms of previous diseases or treatments exposure of patients with AD compared to patients without the disease, using the Quebec provoking AD study (QAP) study and the Lumiracoxib in rheumatoid arthritis (RAMQ) study. METHODS: A retrospective study included patients covered by the RAMQ who had at least one diagnosis of AD (ICD-9 code 3310) or have received at least one script for an AD medication (donepezil, rivastigmine, galantamine or memantine) from January, 1995 to December, 2011. A control group of patients without AD was created on a 1:1 ratio and matched for age, gender and geographic location. The index date was defined as the date of the first AD diagnosis or the first script for AD medication whichever comes first. Prevalence of diseases and treatment exposures in the years preceding the index date were analyzed according to the occurrence of diseases (ICD-9 codes) and medication utilization (AHFS codification) between AD patients and the control group. RESULTS: Data were obtained for a random sample of 34,986 &D group compared to the control group. Furthermore, a greater number of patients used psychotropic drugs (53.5% vs. 35.9%, p<0.001) and anxiolytics, sedatives and hypnotics (70.0% vs. 60.0%, p<0.001) in the control group than in the &D group. CONCLUSIONS: Comorbidities’ frequency was higher in &D patients for several diseases and treatments, particularly for mental disorders-related diagnoses and medications.

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OBJECTIVES: To assess the effects of early psychosocial intervention on delaying the incidence of severe disabilities in patients with mild or moderate Alzheimer's disease (AD) and on quality of life (QoL). METHODS: Totally, 240 patient-caregiver dyads were recruited to a pragmatic, controlled, and randomized (1:1:2) clinical trial in 3 hospital districts in Finland between 2002-2006. A primary outcome measure was incidence of severe disabilities (e.g., death of patient or caregiver), defined as an increase in disability measured on the Disability Assessment for Dementia (DAD) and on all other health-related quality of life (HRQLQ). RESULTS: After a mean follow-up of 6.2 years, the primary outcome measure was significantly delayed in the intervention group (P = 0.03), when compared to the control group. CONCLUSIONS: Early psychosocial intervention can improve the long-term outcome of institutionalized severely disabled patients, and of patients with Alzheimer's disease (AD) and other health-related quality of life (HRQLQ).