CONCLUSIONS: GA was found to reduce relapses and clinical progression compared with placebo, and clinical progression in comparison with interferons. Serious adverse events were comparable with previous and our data. The quantitative methods demonstrated that the benefits of GA outweigh the risks but the results differ substantially depending on the quantitative risk-benefit model used.

PN4

A META-ANALYSIS OF THE DURATION OF CLINICAL EFFECT OF ONABOTULINUMTOXINA IN CERVICAL DYSTONIA

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OBJECTIVES: Cervical dystonia is a disabling, painful condition involving involuntary movement and posturing of the head and neck. Botulinum toxin injections are the standard of care in the symptomatic management of this condition, but need to be re-administered regularly to maintain a stable improvement. The duration of clinical effect and postural activity of need to be determined in order to determine the product used and can impact annualized drug and health care utilization costs.

METHODS: A literature search was undertaken to identify prospective or retrospective studies reporting duration of effect of onabotulinumtoxina (BOTOX®). A formal meta-analysis was conducted using Comprehensive Meta-Analysis Version 2. Both a fixed effects and random effects model were performed. The quality of each identified journal article was evaluated using the Chao & Bero Quality scoring instrument by two separate investigators. Differences in scores were resolved through conference. Subgroup analyses were performed on several moderating variables such as study quality and dose of onabotulinumtoxina. RESULTS: Of the identified potential journal articles, 13 studies met the inclusion criteria and were used for the meta-analysis. The duration of effect of onabotulinumtoxina in cervical dystonia was found to be 13.7 weeks (95% CI 13.4 – 13.9 weeks) for the fixed effects model and 13.6 weeks (95% CI 13.1 – 13.8 weeks) for the random effects model. A meta-regression found that the higher the quality score, the shorter the duration of effect. Another meta-regression found that doses of onabotulinumtoxina greater than 200U generally resulted in a longer duration of effect. CONCLUSIONS: Assessing the annual probability of patients transitioning between stages of the Expanded Disability Status Scale (EDSS). Comparisons between patient groups included time to disability greater or equal to (≥) EDSS 4 and EDSS 6, time from EDSS 4 to disability ≥ EDSS 6 and mean EDSS score over time. RESULTS: Median time to EDSS ≥ 4 and EDSS ≥ 6 was 5.5 [4.5, 7.5] and 9.0 [7.0, 12.0] years in SOT patients compared with 10 [8.5, 12.0] and 18.5 [16.0, 22.5] years in non-SOT patients. Median time from EDSS 4 to disability greater than EDSS 6 was 3.4 [1.8, 5.4] years in SOT compared with 5.3 [3.5, 8.0] years in non-SOT patients. Mean EDSS scores at 2, 5 and 10 years post-onset were estimated at 1.05, 2.55 and 3.21 for SO and 1.95, 2.13 and 1.07 for non-SOT, respectively. CONCLUSIONS: The analysis suggests that RRMS patients who experience relapse and MRI activity despite previous treatment with a DMT face faster progression to severe disability states. The analysis highlights the importance of effective treatment options for these patients.

PN5

EFFICACY AND SAFETY OF IMMUNO-REGULATORY DRUGS, INTERFERONS ETA AND GLATIRAMER IN CLINICALLY-REMITTING MULTIPLE SCLEROSIS

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OBJECTIVES: To assess the relative efficacy and safety of high (HD) and low dose (LD) beta interferons (IFN-β1a and IFN-β1b) and glatiramer treatments in relapsing-remitting multiple sclerosis. METHODS: Systematic review of literature. A bibliographic search was carried out to identify primary studies on MEDLINE and EMBASE until February 2011. Other databases consulted were: Cochrane library, Centre for Reviews and Dissemination, EMBASE, ISI Web of Knowledge e INHATA. Inclusion criteria: 1) head to head randomized clinical trials, 2) patients with relapsing-remitting multiple sclerosis, and 3) Outcomes: relapse rate, proportion of relapse-free patients. RESULTS: Based on the published literature, the duration of effect of onabotulinumtoxina was 13-14 weeks. This suggests that, in general, patients with cervical dystonia treated with onabotulinumtoxina should require approximately 4 treatments per year. A dose-effect for duration was also identified.

PN6

OUTCOMES OF ANTIETILEPTIC DRUGS USES AT DOSES ABOVE THE RECOMMENDED RANGE AMONG CHILDREN WITH STRUCTURAL-METABOLIC EPILEPSY IN MALAYSIA

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OBJECTIVES: To assess the rate and clinical outcomes of using antiepileptic drugs (AEDs) at doses above the recommended range (DARR) in pediatric outpatients with structural-metabolic epilepsy. METHODS: Patients were followed-up retrospectively for one year since the first visit. Inclusion criteria were age ≥ 2 years; a diagnosis of structural-metabolic epilepsy, AEDs treatment; and three or more visits during the first year from the referral time. Exclusion criteria were epilepsy surgery within the first year from the referral time, and patients not satisfied inclusion criteria. During the period from January to June 2010, the required data were extracted from medical records. Assessment of AEDs doses was based on the recommended drug doses that are mentioned in “Pediatric Protocols for Malaysian Children”. RESULTS: Of 120 followed-up patients, 62 were exposed to AEDs at DARR. In term of visits, 32 (56.8%) visits out of 563 demonstrated DARR. There was no association between the uses of AEDs at DARR with age, gender, race, child development, and seizure type. However, the uses of AEDs at DARR are significantly higher in polytherapy than monotherapy visits (Chi-square, p<0.001). Visits included DARR led to higher seizure frequency than visits without DARR (Mann-Whitney, P=0.001). Ultimately, only patients who weren’t exposed to AEDs at DARR showed a significant improvement in their seizure control at the last follow-up visit compared with the baseline (Wilcoxon, P=0.001). CONCLUSIONS: The low frequency of DARR indicates the knowledgeable and awareness of the in charger pediatric neurologist about consequences of exceeding average effective doses. In term of better seizure control, uses of AEDs at DARR shows no benefit over using these agents at recommended doses.

PND

THE ROLE OF SPONTANEOUS EVENTS DATABASES FOR BENEFIT-RISK ANALYSIS

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OBJECTIVES: Vertigo is a crippling and stressful symptom. It involves the illusion of movement that manifests itself with an impression of spinning. It is often accompanied by neurovegetative signs, but the patient remains conscious during the attack. Vertigo, often recurrent and sometimes persistent, can strongly alter the quality of life of patients, to the point of preventing the performance of the majority of daily activities. It increases the risk of falling and depression or anxiety. Describe the initial care of patients with vertigo by general practitioners in France. METHODS: A total of 1400 general practitioners practicing in France were contacted, then questioned. RESULTS: The prevalence of consultations for vertigo and, this being any type of vertigo, is 5.57%.

PND

THE ROLE OF SPONTANEOUS EVENTS DATABASES FOR BENEFIT-RISK ANALYSIS

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OBJECTIVES: We used the World Health Organisation database (Vigibase) to evaluate the contribution of a global spontaneous adverse event (AE) database for an analysis of benefit-risk for Glatiramer acetate (GA) in multiple sclerosis. METHODS: Vigibase is a passive surveillance system that in 2011 contained over 6 million reports of spontaneous AEs suspected of being linked to health care products from regulatory authorities in nearly 90 countries. GA, interferon beta-1a, interferon...