when CBT was assessed against SEGP, WMD was -12.2 (p=0.024) at 4 months, indicating that CBT (individualized therapy) demonstrated significantly better reduction in fatigue compared to SEGP (group therapy). CONCLUSIONS: Overall results demonstrated that CBT was significantly superior in alleviating fatigue compared to no therapy, RT, and SEGP. CBT appears to be promising, acceptable and clinically beneficial approach that could potentially benefit patients with MS fatigue in future. Thus, further research is warranted to determine which aspects of CBT are most effective and the optimal delivery of CBT for MS fatigue.

PND3

RELAPSES REQUIRING INTRAVENOUS STEROIDS AND MULTIPLE SCLEROSIS-RELATED HOSPITALIZATIONS: FINDINGS FROM THE PHASE 3 DEFINE AND CONFIRM STUDIES

METHODS: The intent-to-treat population comprised 1,234 and 1,417 patients, respectively, in DEFINE and CONFIRM studies included relapses requiring intravenous steroid therapy and MS-related hospitalizations. RESULTS: The intent-to-treat populations of the DEFINE and CONFIRM studies comprised 1,234 and 1,417 patients, respectively. In DEFINE, the adjusted annualized rate of relapses requiring intravenous steroid therapy was 32% (BID; 0.68 [0.42–1.09]) and 50% (TID; 0.50 [0.30–0.85]) vs placebo (p=0.0098). In CONFIRM, the adjusted annualized rate of relapses requiring intravenous steroid therapy was 45% (TID; 0.55 [0.34–0.88]) vs placebo (p=0.0001). Relative reductions in DEFINE and CONFIRM in relapse rate were 35% (BID; 0.65 [0.41–1.04]) and 45% (TID; 0.55 [0.34–0.88]) vs placebo (p=0.0125); relative reductions in DEFINE and CONFIRM in relapse rate were 35% (BID; 0.65 [0.41–1.04]) and 45% (TID; 0.55 [0.34–0.88]) vs placebo (p=0.0125). CONCLUSIONS: These findings further support the potential efficacy results for the primary and secondary clinical endpoints in DEFINE and CONFIRM, and also suggest potential health economic benefits of BG-12 treatment for relapsing MS.

PND4

CAPSAICIN 8% PATCH MONOTHERAPY FOR TREATMENT OF POST-HERPETIC NEURALGIA: INTEGRATED ANALYSIS OF PHASE III STUDIES

OBJECTIVES: To evaluate the clinical effectiveness of capsaicin 8% patch monotherapy in the treatment of post-herpetic neuralgia (PHN) using an integrated analysis of individual patient data from Phase III studies. METHODS: Data from four double-blind randomized controlled trials of patches containing either capsaicin 8% monotherapy (PND4) or capsaicin w/CTRL. Study subjects did not have coexistent neuropathic pain medication (either opioid, anticonvulsant, or antidepressant) during study period and received a 60-minute patch application. The primary endpoint was percentage change in numeric pain rating scale (NPRS) “average pain for the past 24 hours” score between Baseline and Weeks 2-8; secondary endpoint following treatment. The proportion of subjects achieving a 30% decrease in their “average pain” NPRS scores from Baseline to Weeks 2-8 ("Responders") was also analysed. The primary endpoint was analysed with a general linear model with subject baseline characteristics and study site allocation entered as fixed effects and trial subgroup entered as a random effect. Statistical significance for all tests was p=0.05. RESULTS: A total of 533 subjects received capsaicin monotherapy; 55% received QTZ. QTZ and CTRL subgroups had near-identical baseline characteristics for gender (48% male), age (70.2 years); PHN duration (3.7 years); baseline “average” pain (5.0), and treatment area size (321cm2). The adjusted estimated marginal mean percentage change in pain from Baseline to Week 8 was -36.9% (95% CI: -40.9 to -32.0) for QTZ and -27.3 (-32.0 to -22.7) for CTRL (p=0.001). Baseline to Week 12 percentage change similarly favoured QTZ (p=0.001). In addition, 48% of QTZ subjects were responders (40% of controls (p=0.007). The adjusted odds-ratio for treatment response was 1.66 (95% CI: 1.15 to 2.40) in favour of QTZ. CONCLUSIONS: Capsaicin 8% patch monotherapy is a clinically effective treatment option for post-herpetic neuralgia when compared to low-dose active comparator.

PND7

A MIXED TREATMENT COMPARISON OF GABAPENTIN ENACARBIL, PRAZIPOLEXE, ROPINIRELOE AND ROTIGOTINE IN MODERATE-TO-SEVERE RESTLESS LEGS SYNDROME (RLS)

OBJECTIVES: To compare, in the absence of head-to-head trials, the clinical benefit of gabapentin enacarbil, levodopa, praziproxile, ropinirole, and rotigotine in the treatment of moderate-to-severe restless legs syndrome (RLS). A mixed treatment comparison (MTC) was performed using the Bayesian approach in the software WinBUGS. A systematic literature review was first conducted to identify RLS trials published over the past ten years through search on MEDLINE, EMBASE, Cochrane, clinicaltrials.gov and more. Twenty-six RLS trials were identified, with seven remaining after data exclusion. A sensitivity analysis was performed on the full set of twenty-eight trials to validate the results of the primary analysis. RESULTS: The indirect comparison was established among four active treatments (gabapentin enacarbil, praziproxile, ropinirole, rotigotine) and placebo, due to the lack of latest clinical evidence on levodopa. Analysis on the primary endpoints indicates that rotigotine is most likely to lead to the greatest reduction in RLS score from baseline for 12 weeks, with 74.7% at the 12-week follow-up. CONCLUSIONS: Rotigotine’s comparative therapeutic benefit is also observed in RLS responders rate and in five out of six items of the RLS-6 scale.}

PND6

COMBINING RCT AND OBSERVATIONAL DATA IN A MIXED TREATMENT COMPARISON OF DISEASE-MODIFYING-THERAPIES FOR MULTIPLE SCLEROSIS

OBJECTIVES: To compare the relative effectiveness of DMTS within a mixed treatment comparison (MTC) framework, and explores the contribution of real-world evidence from observational studies to the evidence-base. METHODS: Sixteen randomized controlled trials (RCTs) and four observational studies incorporating nine DMTS were identified and compared across a number of quality criteria. The Bayesian MTC model was fitted in WinBUGS, for the outcome Annualised Relapse Rate (ARR). Alternative methods of combining data from RCT and observational studies were also considered. RESULTS: The main conclusions from this study are that dual therapy is superior to monotherapy; monotherapy is inferior to dual therapy. CONCLUSIONS: RCTs and observational studies can contribute complementary evidence on important comparative effectiveness questions.

PND2

OFF-LABEL USE OF ANTI-EPILEPTIC DRUGS AND ITS COSTS – A DRUG UTILIZATION STUDY IN PORTUGAL

OBJECTIVES: This study aimed to analyse the pattern of prescription and use of antiepileptic drugs (AEDs), being its main focus the characterization of off-label use and its costs. METHODS: Cross sectional survey, carried out from Sept. 2009 to Feb. 2010 in 20 pharmacies of Lisbon Region. Inclusion criteria: pharmacy users with a prescription including at least 1 AED (all medicines listed under the Anaesthesiological Therapeutic Chemical code N03-Antiepileptics, having epilepsy in the SPC as main indication). Information was collected by interview, conducted by trained pharmacist. Data processing was performed by cross-checking the official price of each medicine single unit, at the time of the study, with data on posology reported by each patient. Aggregate annual expenditures were calculated based on that information. RESULTS: Data from 543 patients were analysed; 95.9% were females, age range 2-91 years (mean: 50.9). The main consumed AEDs were valproic acid (18.0%), pregabalin (16.2%), topiramate (15.7%) and carbamazepine (14.7%). The first prescriber was in 36.1% of the cases a neurologist and in 31.9% a psychiatrist. Epilepsy was the indication in 29.5% of the patients. Off-label use was found in 33.1% of the sample. Among the off-label sample, topiramate (11.4%), clonazepam (7.2%), carbamazepine (6.7%) and gabapentin (30.9%) were the anticonvulsants most widely used off-label. Clonazepam (85.7%) and topiramate (59.0%) had most of their uses in off-label indications. Psychiatrists (59.2%) and neurologists (28.2%) were the prescribers in the majority of the off-label cases. The main off-label indications were depression (51.4%) and mood stabilization (19.4%). Total costs with AEDs were 210,851.57€ in which 48,424.04€ (23.0%) represents an off-label cost. CONCLUSIONS: Approximately 1/3 of the sample used AEDs in off-label indication.