est VPA concentrations were also higher when concomitantly administered of AVP-825 (22mg sumatriptan) treatment of acute migraine.

METHODS: Retrospective study of 14,122 inpatients identified from the Cerner Health Facts® database between January 1, 2000 and December 31, 2012 who received pharmacological treatment for PD. Controls were matched to cases on age, race, and sex. Multivariable logistic regressions were used to estimate associations between non-ergot DA exposure and the risk of adverse events. Risk estimates were calculated as odd ratios (OR) with 95% confidence intervals (CI). RESULTS: Inpatients were primarily Caucasian (91.2%), men (54.0%), and 80 years of age or older (47.4%) at admission. The majority of patients were levodopa users (87.2%) and antiparkinson mono- therapy was common (71.7%). Relative to levodopa monotherapy, an increased risk of heart failure was observed with non-ergot DA (OR 1.22, CI 1.02-1.50, p = 0.04) and pramipexole monotherapy (OR 1.29, CI 1.00-1.66, p = 0.05). No risk of other cardiovascular events or cerebrovascular events was identified. CONCLUSIONS: Treating PD provides substantial benefits to function, mobility, and survival. It is important to treat PD; therefore, knowledge of cardiovascular and cerebrovascular risks associated with pharmacotherapies is essential to informing treatment decisions.

PND4

SPECIFICITY AND SENSITIVITY OF AQUaporIN 4 ANTIBODY DETECTION TESTS IN PATIENTS WITH NERVOUS SYMPTOMS: A SYSTEMATIC REVIEW AND META-ANALYSIS

Ruiz RJ1, Castañeda-Carbajal O2, Ruiz-Patiño A3, Roselli D1

1Pontificia Universidad Javeriana, Bogota, Colombia. 2Hospital Universitario San Ignacio, Bogota, Colombia. 3Hospital de Clínicas de Santiago, Chile. 4Hospital Universitario Virgen del Rocio, Seville, Spain. OBJECTIVES: Antibodies against water channel protein aquaporin 4 (AQP4) in astrocytes play a role in the etiology and pathophysiology of neuromyelitis optica (NMO). Detection of this immunoglobulin in serum is highly suggestive of this diagnosis. There are several immunoassays currently available, and the antibody with different sensitivities and specificities. We conducted a meta-analysis to determine the overall diagnostic accuracy from these tests. METHODS: We conducted a systematic review in five different electronic databases: PubMed, Embase, The Cochrane Library, Database of Abstracts of Reviews of Effect (DARE) and Lilacs. We included both case control and consecutive enrollment studies that evaluated the performance of the immunoassays in patients with suspected NMO in comparison with the 2006 criteria for diagnosis. Articles were assessed by two different reviewers, who also extracted data. RESULTS: 29 studies for three different immunoassays were included in the meta-analysis. To obtain a summary receiver operating characteristic for the sensitivities and specificity with 95% confidence interval a bivariate random effect model was used. The approximated sensitivity for the cell based assay, the tissue based assay and the ELISA test were 0.77(95% CI 0.68- 0.84), 0.63(95% CI 0.54-0.72) and 0.62(95% CI 0.52-0.72), respectively. The mean specificity for the cell based assay was 0.99 (95% CI 0.98-0.99), tissue based assay 0.99 (95% CI 0.97-0.99) and Elisa test 0.97(95% CI 0.95-0.99). CONCLUSIONS: AQP4 detection in serum with immunoassay is a great tool for the diagnosis of patients with NMO, however, following the clinical course of this disease from other neurological conditions that resemble NMO. Due to differences in test effectiveness, cost-minimization studies would not be appropriate. Since the cost of immunoassays differs, these results will be useful in cost-effectiveness models.

PND5

CLASSIFICATION OF NON-HIV LIPODYSTROPHY IN THE US USING ELECTRONIC MEDICAL RECORD (EMR) DATA AND PHYSICIAN NOTES

Ovalle 1, Lang K2, Campion N2, Dhanikar P3, Joseph C4, Garg A5

1University of Michigan, Ann Arbor, MI, USA, 2University of Maryland, Baltimore, MD, USA, 3SeidyNestra, Fort Worth, TX, USA, 4Cleveland Clinic, Cleveland, OH, USA, 5University of Texas Southwestern Medical Center, Dallas, TX, USA. OBJECTIVES: Lipodystrophy syndromes (LD-S) are serious medical conditions characterized by adipose tissue loss and decreased ability to participate in social, family and housework activities. Data on humanistic burden identified as depression, long-term disability, work loss and decreased ability to participate in social, family and housework activities. Five studies reported data on efficacy and safety of small-molecule drugs. Three studies reported overall response rates (ranging from 16-36%) and two studies reported safety outcomes: two studies reported zero adverse events and zero serious adverse events. No data on the economic impact and medical treatment for PD. Controls were matched to cases on age, race, and sex. Multivariable logistic regressions were used to estimate associations between non-ergot dopamine agonists (DAs) and are consistent with the other outcomes of COMPASS, indicating AVP-825 has superior early efficacy compared to oral-SUM.

RESUTLTS: 185 patients treated migraines in both periods, yielding 1531 migraines assessed (765 AVP-825, 766 oral-SUM). The average duration of breath delivery of medication was 3.69 ± 0.64 minutes (10.8 ± 1.07 minutes). The most frequent adverse events were headache (47.5-52%), vomiting (18.0% vs 10.8%; p < 0.05). The percentage of attacks with TMF was significantly greater with AVP-825 vs oral-SUM at all timepoints from 15–90 minutes: 15 minutes (7.2% vs 3.7%; P < 0.01), 30 minutes (18.0% vs 10.8%; P < 0.001), 45 minutes (50.7% vs 21.4%; P < 0.001), 60 minutes (40.9% vs 33.3%; P < 0.01), 90 minutes (52.7% vs 45.6%; P < 0.05). At 2 hours, TMF rates did not differ significantly between treatments (60.6% for AVP-825 vs 56.7% oral-SUM; P = 1). CONCLUSIONS: AVP-825 (22mg sumatriptan) treatment of acute migraine resulted in more rapid achievement of a composite efficacy endpoint, total migraine freedom (TMF), is more rigorous than a composite endpoint, total migraine freedom (TMF), is more rigorous than a composite efficacy endpoint. Additional studies are warranted to confirm the extent of differences in efficacy.
PND1 PAINTED SELF-ASSESSMENTS IN ADVANCED PARKINSON’S DISEASE WITHIN UPDRS AND “OFF” TIME SUBGROUPS: COMPARISON OF IPX066 WITH IMMEDIATE-RELEASE CARBIDOPA-LEVDOPA

Balbina R., Rustay NR, Khanna S, Kelli S, Gupta S

Objective: To measure differences in clinical and HRQoL outcomes relevant for the treatment of PBA. RESULTS: The evidence base for off-label agents used for treatment of PBA is limited, relying on small often uncontrolled studies showing ill-defined treatment effects and little or no safety tracking. DM/Q is the only treatment for PBA that has shown efficacy in well-conducted clinical trials in patients with varied neurological disorders.

PND1 TERIFLUNOMIDE SHOWS CONSISTENT CLINICAL EFFICACY ON SEVERE RELAPSES ACROSS TEMSO AND TOWER: 2 PHASE 3 TRIALS

Leistodel T., Stangel M., MacLeod P., Maurier M., Thangavelu R., Truffinet P., Bozzi S., Delafontaine P., Freedman M.S., Thomas Jefferson University Hospital, Philadelphia, PA, USA; 2Medicinska Hochschule Hannover, Hannover, Germany; 3Austin Health, Heidelberg, Australia; 4Caritas Krankenhaus Bad Mergentheim, Germany; 5St. Luke’s Roosevelt Hospital, New York, NY, USA; 6Genzyme, a Sanofi company, Chilly-Mazarin, France; 7Sanofi, Chilly-Mazarin, France; 8University of Ottawa and the Ottawa Hospital Research Institute, Ottawa, ON, Canada

OBJECTIVES: Teriflunomide is a once-daily oral immunomodulator approved for relapsing-remitting MS. Here we report the key efficacy, safety, and post hoc analyses from the randomized, placebo-controlled phase 3 trials TEMSO (NCT0134563) and TOWER (NCT01751881). METHODS: In TEMSO/TOWER, a total of 108/169 patients with relapsing MS were randomized (1:1:1) to once-daily teriflunomide 14 mg, teriflunomide 7 mg, or placebo. Treatment duration was 108 weeks (TEMSO) or variable, based on time of enrollment (TOWER, 48–152 weeks, ending 48 weeks after last randomization). Primary and key secondary endpoints were annualized relapse rate (ARR) and disability progression confirmed for 12 weeks. Results: Temsol observed significant improvements in the global impression of change (GIC) favoring teriflunomide vs. placebo for 5 severe relapse outcomes: (A) relapses with sequelae defined by the Expanded Disability Status Scale (EDSS) increase ≥4 points 30 days postrelapse; (B) relapses with investigator-defined sequelae; (C) severe relapses by Panitch definition; (D) relapses leading to hospitalization; and (E) relapses requiring intravenous corticosteroids. RESULTS: Teriflunomide 14 mg significantly reduced both ARR and disability progression vs placebo. Teriflunomide 7 mg significantly reduced ARR but not disability progression. Teriflunomide 14 mg significantly reduced annualized rates of severe relapse outcome compared with placebo (-1.92% vs. 0.0011)/36.6% (P 0.0021); (D) 52.6% (P < 0.0001)/53.5% (P = 0.0004); (E) 25.4% (P = 0.0015)/33.6% (P = 0.0515); and (F) 33.7% (0.0003)/35.7% (P < 0.0002). Teriflunomide 14 mg was associated with a longer time interval between EDSS 5.0 or SPMS worsening and delayed EDSS 7.0 or SPMS worsening for all EDSS definitions, although not significantly in all definitions. Both teriflunomide dosages showed similar safety profiles across the 2 studies. CONCLUSIONS: Teriflunomide 14 mg has shown consistent and significant positive effects on ARR and disability progression in 2 phase 3 trials in relapsing-remitting MS. Additional studies are needed to conclude safety profiles, economic usefulness and tolerance of teriflunomide.

PND2 ESTIMATION OF TIME TO REACH RRMS EDSS HEALTH STATES ≥ 7.0 OR SPMS FOR DELAYED-RELEASE DIMETHYL FUMARATE

Wallach K, Liu Z, Berling M, Malone B.1, Alvizo Veja, CA, USA

OBJECTIVES: To estimate the time to reach a 7.0 or SPMS on the EDSS for RRMS patients and understand how this time varies by age. METHODS: Data were obtained from a randomized, double-blind, placebo-controlled Phase 2b study in RRMS patients (NCT01619402). Patients received daily oral delayed-release dimethyl fumarate (Dimyfumarate; DMF) or placebo for 2 years. Time to reach 7.0 or SPMS was estimated based on a Markov model. The model considered time spent in each EDSS state as well as the rate of transition from one EDSS state to another state. The model was calibrated with clinical trial data and validated against clinical trial data. RESULTS: The median time to reach 7.0 or SPMS was 5.0 years (95% CI: 4.3-6) for untreated patients. The median time to reach 7.0 or SPMS was 3.25 years (95% CI: 2.8-4) for patients treated with DMF. CONCLUSIONS: DMF was associated with a reduced time to reach 7.0 or SPMS compared to placebo. DMF is a safe and effective treatment for RRMS patients who are at risk of progressing to 7.0 or SPMS.

PND3 "NUMBER NEEDED TO TREAT" ANALYSIS TO ASSESS THE COMPARATIVE EFFICACY OF THERAPIES FROM TERIFLUNOMIDE AND DIMETHYL FUMARATE STUDIES IN RELAPSING MULTIPLE SCLEROSIS

Leistodel T., Montanell X, Miller AE, Dive-Pouletty C, Freedman M.S.1, Thomas Jefferson University Hospital, Philadelphia, PA, USA; 2Vall d’Hebron University Hospital, Barcelona, Spain; 3Toyo School of Medicine, Nihon University, Tokyo, Japan; 4Caritas Krankenhaus Bad Mergentheim, Germany; 5St. Luke’s Roosevelt Hospital, New York, NY, USA; 6Genzyme, a Sanofi company, Chilly-Mazarin, France; 7Sanofi, Chilly-Mazarin, France; 8University of Ottawa and the Ottawa Hospital Research Institute, Ottawa, ON, Canada

OBJECTIVES: Teriflunomide and dimethyl fumarate (DMF) oral therapies for relapsing-remitting MS have demonstrated efficacy in clinical trials on magnetic