

OBJECTIVES: To evaluate the relative likelihood of severe cutaneous reactions (Steven-Johnson Syndrome, toxic epidermal necrolysis), aseptic meningitis, and organ dysfunction (pancreatitis, hepatotoxicity) associated with antiepileptic drugs (AEDs) in children (aged 2-18 years) as compared to adults (aged 19+) with epilepsy. **METHODS:** This retrospective cohort study analyzed patients in a large nationally representative administrative claims database between 2006 and 2011. The sample consisted of Medicaid, Medicare, and Commercial patients with a diagnosis of epilepsy (ICD-9-CM 345.X) who were continuously enrolled with pharmacy benefits for 6-months and had no prior AEDs fills (new users). Multivariate analysis (logistic regression) was used to follow eligible patients from index date to first adverse event or up to six months after AED initiation. **RESULTS:** The study population included 1,803,871 new users of AEDs. Children comprised 7.9% (N=142,874, female=50.7%, age=12.4 [± 4.7]) and adults 92.1% (N=1,660,997, female=64.6%, age=52.8 [± 17.7]). Compared to adults, children were significantly less likely to experience organ dysfunction (OR=0.228, 95% CI: 0.20-0.26, p<0.0001), but more likely to have severe cutaneous reactions (OR=1.19, 95% CI: 1.14-1.25, p<0.0001) after controlling for potential confounders (gender, region, type of medication). There was no significant age effect on risk of aseptic meningitis. Female adults had a statistically lower likelihood of organ dysfunction compared to males (OR=0.75, 95% CI: 0.72-0.77, p<0.0001), but there was no gender effect for risk of organ dysfunction in children. Females in both groups had a higher likelihood of developing cutaneous reactions compared to males (adults: OR=1.28, 95% CI: 1.25-1.31, p<0.0001; children: OR=1.20, 95% CI: 1.15-1.26, p<0.0001). **CONCLUSIONS:** Adverse effects resulting from treatment with AEDs are an important consideration in evaluating epilepsy treatment options. This study provides new information about the comparative risks of AEDs that can be used to guide optimal prescribing practices for patients with epilepsy.

PND2

COMPARATIVE RISK OF ADVERSE TREATMENT EFFECTS IN PARKINSON'S DISEASE: EVIDENCE FROM A LARGE EMPLOYER POPULATION

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OBJECTIVES: To assess the comparative risk of adverse effects (AEs) across common treatment regimens for Parkinson's disease (PD) in a large, real-world population. **METHODS:** Retrospective analyses were conducted using the MarketScan database, an employer-based source of inpatient, outpatient, and pharmacy claims for >30 million lives. Patients had ≥1 PD diagnosis (ICD-9-CM 332.0) during 2000-2011 and ≥1 of the following anti-PD regimens: levodopa monotherapy (L-dopa), dopamine agonist monotherapy (DA), anticholinergic monotherapy (AC), L-dopa+DA, MAOB-inhibitor monotherapy (MAOB), L-dopa+COMT-inhibitor (L-dopa+COMT), L-dopa+AC, L-dopa+MAOB, or amantadine monotherapy (AMTD). Index groups were assigned based on first regimen exposed to. Patients had ≥6 months pre-index plan enrollment and were followed from index until AE or earliest of new regimen start, disenrollment, or database end. Cox models were estimated for each AE with covariates for index regimen (reference: MAOB), demographics, and pre-index comorbidities and AEs. **RESULTS:** 41,652 patients met the inclusion criteria (mean[SD] age: 73.4[11.0] years, 57.5% male). Index regimen distribution was: L-dopa (n=28,249), DA (n=7,775), AC (n=1,496), L-dopa+DA (n=578), MAOB (n=1,498), L-dopa+COMT (n=343), L-dopa+AC (n=106), L-dopa+MAOB (n=198), AMTD (n=1,409). AC, L-dopa+AC, and AMTD carried increased dyskinesia risk versus MAOB (hazard ratios (HRs) [95% CIs]: 2.1[1.8-2.5], 1.7[1.1-2.7], and 1.9[1.6-2.2], respectively). L-dopa+DA and L-dopa+MAOB had increased risk of orthostatic hypotension (HRs: 2.2[1.4-3.5] and 2.5[1.3-5.0]). L-dopa+DA carried the highest edema risk (HR: 2.1[1.6-2.6]). L-dopa+DA and AMTD had increased risk of hallucinations (HRs: 2.6[1.3-5.1] and 3.0[1.8-4.8]). For 6 of 9 AEs examined, L-dopa+DA had significantly (p<0.05) increased risk versus MAOB; in 4 of these (orthostatic hypotension, edema, nausea, hallucinations), L-dopa+DA carried the highest or second highest HR versus MAOB amongst all regimens examined. **CONCLUSIONS:** Treatments with high dopaminergic levels (L-dopa+DA) generally carried increased AE risk versus MAOB monotherapy. However, other dopamine-containing and non-dopaminergic regimens also carried increased AE risk versus MAOB. These findings highlight practical challenges presented by current PD treatments.

PND3

INCIDENCE OF ADVERSE TREATMENT EFFECTS IN PARKINSON'S DISEASE: EVIDENCE FROM A LARGE EMPLOYER POPULATION

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OBJECTIVES: To evaluate incidence of adverse effects (AEs) commonly associated with Parkinson's disease (PD) and its treatments in a large, real-world population. **METHODS:** Retrospective analyses were conducted using the MarketScan database, an employer-based sourced of inpatient, outpatient, and pharmacy claims for >30 million lives (2000-2011). Inclusion criteria were ≥1 PD diagnosis (ICD-9-CM 332.0) and ≥30 days exposure to ≥1 of the following regimens: levodopa monotherapy (L-dopa), dopamine agonist monotherapy (DA), anticholinergic monotherapy (AC), L-dopa+DA, MAOB-inhibitor monotherapy (MAOB), L-dopa+COMT-inhibitor (L-dopa+COMT), L-dopa+AC, L-dopa+MAOB, amantadine monotherapy (AMTD). Patients were followed on AEs (defined by ICD-9-CM diagnoses) over all observed regimen exposures. Analyses were descriptive. **RESULTS:** In total, 87,373 patients were identified for inclusion (mean [SD] age 72.8 [10.9] years, 56.8% male). L-dopa was the largest cumulative exposure (80,246 person-years [PYs]), followed by L-dopa+DA (19,871 PYs) and DA

(18,324 PYs). Dyskinesia incidence varied by treatment, ranging from 68/1,000 PYs for L-dopa+MAOB to 492/1,000 PYs for AC. Orthostatic hypotension was higher in 5 of the 6 dopamine-containing regimens (64, 47, 45, 31, 25 per 1,000 PYs for L-dopa+COMT, L-dopa+MAOB, L-dopa, L-dopa+DA, and DA, respectively) versus 2 of the 3 non-dopaminergic regimens (18, 19, 32 per 1,000 PYs for AC, MAOB, and AMTD). Edema incidence was highest during DA (215/1,000 PYs) and L-dopa+DA (192/1,000 PYs) exposures. Somnolence was highest, by far, during DA exposure (201 per 1,000 PYs); L-dopa+DA had the next highest somnolence incidence (115 per 1,000 PYs). Incidence of psychoses was high for all regimens (range: 202/1,000 PYs for L-dopa+MAOB to 3,500/1,000 PYs for AC). Abnormal dreaming/sleep attacks and impulse control disorders were not observed in this population, indicating a lack of coding for these conditions in routine practice. **CONCLUSIONS:** AE incidence during anti-PD treatment exposure varies by specific regimen. Some AEs, such as orthostatic hypotension, appear to be lower in non-dopaminergic monotherapies.

PND4

FREQUENCY AND ECONOMIC IMPACT OF COMORBID CARDIAC CONDITIONS AMONG HOSPITALIZATIONS OF PATIENTS WITH MULTIPLE SCLEROSIS

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OBJECTIVES: To determine the frequency and economic impact of comorbid cardiac conditions among hospitalizations of patients with a diagnosis of multiple sclerosis (MS). **METHODS:** A retrospective analysis was conducted using the National Inpatient Sample (NIS), Healthcare Cost and Utilization Project, Agency for Healthcare Research and Quality. All hospital discharges with an MS diagnosis (ICD-9 CM 340.xx) from 1/1/2009 to 12/31/2009 were identified. Two cohorts were defined based on the presence or absence of at least one cardiac condition using ICD-9-CM codes: myocardial infarction (410.xx), ischemic disease (411.xx), angina (413.xx), occlusion of cerebral arteries (434.xx), acute cardiovascular disease (436.xx), cerebral ischemia (435.xx), and heart failure (428.xx). Total mean charges were converted to costs using NIS 2009 cost-to-charge ratios. Total costs per discharge were compared between cohorts while controlling for demographics, number of chronic comorbidities, and length of stay (LOS). Descriptive statistics, t tests, and chi square tests were conducted where appropriate, and regression models were employed for cost comparisons. An incremental cost effectiveness ratio (ICER) was calculated for the cost per additional hospital day. **RESULTS:** A total of 27,463 discharges with a diagnosis of MS were identified, and 9.1% (n=2,522) had at least one cardiac comorbidity. The sample was 70% female with a mean age of 53.5 years. MS discharges with a cardiac condition were for patients with a significantly higher mean age (62.5 vs 50.5 years, P<0.0001), more chronic comorbidities (7.8 vs 4.7 conditions, P<0.0001), and a longer LOS (6.4 vs 5.2 days, P<0.0001). The cost of hospitalization was significantly higher for MS discharges with a cardiac comorbidity after controlling for confounders (\$16,752 vs \$10,549, P<0.0001). The incremental cost per hospital day was \$5,375 for discharges with a cardiac condition. **CONCLUSIONS:** Cardiac comorbidities are prevalent among MS discharges and are associated with higher costs than discharges without a cardiac comorbidity.

PND5

ACUTE CARE UTILIZATION IN PATIENTS WITH EPILEPSY ON ANTIEPILEPTIC MONOTHERAPY

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OBJECTIVES: To identify clinical and demographic predictors of urgent health care services utilization in monotherapy-treated patients with epilepsy. **METHODS:** Patients aged 18-64 years with a primary or secondary diagnosis of epilepsy and >1 prescription claim for an antiepileptic drug (AED) pre-index were included. Innovus Invision™ Data Mart insurance claims from January 1, 2007 to September 30, 2010 were retrospectively analyzed. The primary outcome was incidence of seizures defined as an occurrence of an emergency room visit, ambulance service use or hospitalization with a primary or secondary diagnosis of epilepsy during the 1-year follow-up. Predictor variables included AED adherence, general comorbidity, any mental health comorbidity, evidence of a prior seizure, type of epilepsy diagnosis, presence of AED-interacting medications and any bioequivalent AED switch. The covariates included age, gender and geographic region of residence. **RESULTS:** The overall incidence of post-index seizures in the 1-year follow-up for four monotherapy cohorts combined was 5.3% (n=166/3140). The combined cohort analysis demonstrated that pre-index seizures (odds ratio [OR] = 4.28; 95% CI, 2.81-6.53), any mental health comorbidity ([OR] = 3.41; 95% CI, 2.10-5.54), Charlson Comorbidity Index ≥1 ([OR] = 2.88; 95% CI, 1.96-4.24) and monotherapy with levetiracetam ([OR] = 1.54; 95% CI, 1.03-2.31) were significant predictors of seizure recurrence. Among covariates, only geographic region was a significant predictor, with patients residing in the Northeast U.S. having higher odds of post-index seizure ([OR] = 1.92; 95% CI, 1.19-3.10), while controlling for clinical, medication and demographic characteristics. A bioequivalent AED switch, type of epilepsy diagnosis, AED adherence and presence of interacting medications were not significant predictors of seizure recurrence (p>0.05). **CONCLUSIONS:** Results indicate that epilepsy patients with comorbid conditions (both mental and somatic diseases), as well as patients who may have initially been unstable (with previous seizure occurrences) were more likely to experience seizures.