all 3 pregabalin groups demonstrated significant improvements versus placebo (300, 450, and 600 mg/d, -8.91 [p=.0006]; -10.63 [p<.0001]; and -14.93 [p<.0001], respectively). Similar improvements were seen in Sleep Quality (300, 450, and 600mg/d; 0.42, p=0.0030; 0.48, p=.0006; and 0.68, p<.0001 respectively) and MOS Sleep Adequacy (300, 450 and 600mg/d; 5.86, p=.0324; 7.89, p=.0036, and 11.16, p<.0001 respectively). Endpoint Mean Sleep Quality scores across all 3 treatment groups showed significant improvements (300, 450 and 600mg/d; -0.74, p=.0006, -1.12, and -1.35, both p<.0001 respectively). Most common AEs: dizziness (all pregabalin, 35.8% vs placebo, 7.6%); somnolence (18.0% vs 3.8%). Incidence of AEs appeared to be dose-related; most were mild to moderate.

Conclusions: Pregabalin treatment demonstrated significant improvements in pain and patient reported measures of sleep disturbance, adequacy, and quality.

Study funded by Pfizer, Inc.

P0285

Pregabalin monotherapy for relief of pain associated with fibromyalgia: Durability of pain results of a 14-week, double-blind, placebo-controlled trial

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Background and Aims: Evaluate durability of pregabalin's effect on pain associated with fibromyalgia (FM).

Methods: Randomized, double-blind, placebo-controlled trial with 1-week single-blind placebo run-in. Patients meeting ACR diagnostic criteria were randomized to pregabalin 300, 450, or 600 mg/d (BID) or placebo for 14 weeks (2-week dosage escalation; 12-week fixed-dosage). Pain was assessed with a daily pain diary using an 11-point numeric scale. Primary efficacy parameter was the LOCF endpoint mean pain score (MPS). Sensitivity analyses were assessed using the Duration Adjusted Average Change (DAAC) and a Mixed Model Repeated Measurements (MMRM).

Results: 745 randomized patients: 95% female, mean age=50 years, median FM duration=10 years, baseline MPS=6.7. Placebo-corrected differences in mean change from baseline to endpoint in MPS: 300mg/d, -0.71 (P=0.0009); 450mg/d, -0.98 (P<0.0001); 600mg/d, -1.00 (P<0.0001). Mean differences from placebo at endpoint (adjusted for treatment duration) over the entire treatment period (DAAC): 300mg/d, -.38, P=0.0200; 450mg/d, -.62; P=0.0001 and 600mg/d,-.57 P<0.0001. In the MMRM analysis, all 3 pregabalin treatment groups demonstrated pain relief by Week 1, and every weekly assessment thereafter, with the exception of 300mg/d treatment group at Week 11. Most common AEs: dizziness (all pregabalin, 35.8% vs placebo, 7.6%); somnolence (18.0% vs 3.8%). Most AEs were mild to moderate and resolved with continued treatment.

Conclusions: Pregabalin demonstrated significant reduction in endpoint MPS in FM patients. The DAAC sensitivity analysis confirmed the robustness of this effect. MMRM analyses demonstrated significant pain relief by Week 1 that was maintained throughout pregabalin treatment.

Study funded by Pfizer, Inc.

P0286

Psychosocial characteristics of high utilizing inner city hospital patients

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Background and Aims: A relatively small proportion of patients account for a disproportionate share of healthcare utilization and cost with, on average, 1% of patients responsible for 20-25% of cost, 5% of patients for 40% and 10% for two thirds. These "high-utilizers" frequently suffer from co-morbid medical and psychiatric illnesses, but they are not well characterized in terms of diagnoses, current treatment patterns, or long-term outcomes. We sought to characterize further such patients at a large inner city acute care hospital.

Methods: We applied a validated tool, Patients At Risk for Re-hospitalization, to the entire hospital population and then performed a mixed methods (quantitative/qualitative) study of 100 patients judged to be at high risk (>67%) of re-hospitalization during the ensuing year.

Results: Of over 130,000 patients, 6,000 were identified. These individuals were overwhelmingly non-elderly adults (96% ages 18-64). Most common medical diagnoses were hypertension (49%), asthma (41%), diabetes (33%), and HIV/AIDS (32%). Schizophrenia, bipolar illness, or other psychosis was found in 48%. Over two-thirds had substance abuse diagnoses. Although 56% had made at least one emergency department visit in the past two years, only 37% had seen a primary care provider. Patient interviews revealed high rates of unstable housing, social isolation, and failure to appreciate the severity of health problems.

Conclusion: High utilizers of general health care have very high rates of serious mental illness and substance abuse. Interviews suggest need for improved medical/psychiatric coordination with community outreach. Although such interventions are resource intense, the economic and health benefits may be large.

P0287

Body composition changes during six months of antipsychotic treatment

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Background: For the atypical antipsychotic agents, significant weight gain may occur, hampering compliance and causing adverse health effects. Few studies have investigated body composition changes with detailed methods.

Objective: To describe the effects over six months on body composition in schizophrenic patients randomized to treatment with sertindole or olanzapine.

Methods: Results from the first six patients enrolled in a 1y trial of consecutive patients (18-65y; Body Mass Index [BMI] $\leq$ 35 kg/m2) diagnosed with DSM-IV schizophrenia in the need of a second line antipsychotic agent. Weight, BMI, waist circumference (WC), %bodyfat (%BF) measured by 8-electrode bio-electrical impedance (BIA8) were assessed at each visit.

https://doi.org/10.1016/j.eurpsy.2008.01.1328 Published online by Cambridge University Press