

A recent epidemiological study, The National Comorbidity Survey of 10,000 adults indicated an adult population prevalence of ADHD of 4.4% (Kessler et al, 2005). A similar figure (4%) was obtained by Faraone and Biederman 2005 in a population survey of 966 adults (Faraone&Biederman, 2005).

Specific clinical characteristics of adults with ADHD, diagnostic issues, and comorbidity of ADHD in adults have been discussed in comparison with those in children.

Weiss G, Hechtman L, Perlman T. Hyperactives as young adults: School, employers and self-rating scales obtained during 10 years follow-up evaluation. *Am J Orthopsychiatry* 1978; 48: 438-445

Faraone SV, Biederman J. What is the prevalence of adult ADHD? Results of a population screen of 966 adults. *J of Att Dis* 2005; 9(2): 384-391

P0282

Treatment with OROS[®]-Methylphenidate in adolescents is associated with an improvement in functioning and quality of life - A post-hoc analysis

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Objectives: To explore changes in daily functioning (C-GAS) and quality of life (ILC) in adolescents (12-18 years) with ADHD treated with OROS[®]-MPH and their parents.

Methods: Post hoc analysis. Open label non-interventional trial in adolescents (ADHD; ICD-10 criteria) treated with flexible dose OROS-MPH for 3 months (42603-ATT-4001). Effectiveness parameter were IOWA Conners' parent rating scale, C-GAS, ILC adolescents and parents at baseline and endpoint, physician's and parents' rating of treatment.

Results: 129 out of 598 patients were adolescents (Ø age 14.2 years; 84.5% male) and 88.4% completed the study. Treatment was discontinued due to adverse events (3.9%), insufficient effectiveness (4.6%), lost to follow up (3.1%). Mean dose of OROS MPH increased from 34.6 mg/day ± 13.4 at baseline to 39.2 mg/day ± 13.4 at endpoint. C-GAS improved from 60.2 ± 14.0 to 72 ± 14.4 (p<0.001). Mean sum score on ILC-adolescents improved from 18.7 ± 3.6 to 20.6 ± 3.7 (p<0.001) and ILC-parents increased from 16.7 ± 3.9 to 19.6 ± 3.8 (p<0.001). Effectivity and tolerability was rated as at least good by >80% of physicians. 80.6% of parents were at least satisfied with therapy. 46 treatment - emergent adverse events were reported in 30 patients. AEs listed overall in ≥2% of patients were insomnia (3.9%), infection (2.3%), headache (2.3%), and nervousness (2.3%).

Conclusion: Transitioning onto OROS[®]-MPH in adolescents was associated with a clinically relevant improvement of QoL and daily functioning. Treatment with OROS MPH was well tolerated.

P0283

Enhancing communication and collaboration with youth-oriented psychopharmacology resources

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Background: Youth and their caretakers exchange information with health providers in order to participate in shared decision-making or to make autonomous treatment choices. Tools supporting these exchanges for psychotropics are not readily available.

Methods: In partnership with the Provincial Centre of Excellence for Child and Youth Mental Health, two pharmacists and a psychiatrist with advanced knowledge in psycho-pharmacotherapeutics designed a psychotropic resource to support the tripartite (i.e. youth, parents/caretakers, health providers) relationship in therapeutic, collaborative, decision-making. The resource promotes a framework for understanding psychotropics, their therapeutic goals, and the methods by which these goals will be reached. Best available evidence for psychotropics and factors influencing uptake of patient-oriented materials informed the content and resource format. Focus groups of youth with mental illnesses, health providers, and stakeholders were conducted during resource development. A graphic designer used focus group feedback to develop layouts and characters. A plain language writer edited the content.

Results: A booklet with a companion passport was chosen. The booklet has several components including frequently asked questions (FAQs), a section on psychotropic medication groups, checklists, appointments, monitoring forms for medications, symptoms, side effects, and functioning, notes pages, and a glossary. The passport, intended for youth, primarily contains monitoring forms (e.g. checklists, medication list, symptoms, side effects, functioning). Clay character photos and colored section schemes enhance visual appeal of the resource.

Conclusion: The goals of the resources are to improve youth and caregiver involvement in psycho-pharmacotherapeutic decision-making and monitoring to enhance collaboration. A qualitative assessment of its impact is planned.

P0284

Efficacy of Pregabalin monotherapy for improving sleep outcomes in patients with fibromyalgia: Results of a 14-week, double-blind, placebo-controlled trial

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Background and Aims: Sleep disturbance is prominent in fibromyalgia (FM). This 14-week, randomized, double-blind, placebo-controlled study, evaluated the effect of pregabalin on pain and sleep-related outcomes in FM.

Methods: Patients meeting ACR (FM) diagnostic criteria were randomized to pregabalin 300, 450, or 600mg/d (BID) or placebo for 14 weeks (A0081077). Primary efficacy parameter: LOCF endpoint mean pain score (MPS). At baseline and endpoint, patients completed the Medical Outcomes Sleep (MOS) Sleep Scale. Mean Sleep Quality scores (11-point numeric ratings) were derived from patient daily diaries.

Results: 745 randomized patients: 95% female, mean age=50 years, baseline MPS: 6.7. Placebo-corrected differences from baseline to endpoint in MPS were: 300mg/d, -0.71 (p=.0009); 450mg/d, -0.98 (p<.0001); 600mg/d, -1.00 (p<.0001). For MOS Sleep Disturbance,

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.

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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.

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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 serindole or olanzapine.

Methods: Results from the first six patients enrolled in a 1y trial of consecutive patients (18-65y; Body Mass Index [BMI] ≤ 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.