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Results. All 41 patients reported a lifetime burden with schizophrenia adversely impacting employment, relationships, emotional health, social activities, and daily tasks. Hospitalization for schizophrenia management was another reported aspect of disease burden. Although most (n=32) patients reported previous medication benefits, side effects affecting physical, emotional/behavioral, and cognitive functioning were reported by all (n=41). Following OLZ/-SAM treatment, 39/41 patients (95%) reported improvements in symptoms including hallucinations, paranoia, depression, sleep, and concentration. Furthermore, patients described improvements in self-esteem, social activities, relationships, and daily activities. Twenty-three patients (56%) reported side effects attributed to OLZ/SAM; lack of energy (n=12 [29%]) and dry mouth (n= 5 [12%]) were most common. Twenty-four (59%) patients were "very satisfied" with OLZ/SAM; most (n=35 [85%]) preferred to continue OLZ/SAM vs switching to another medication. As most substudy patients (n=40; 98%) completed the extension study, satisfied patients may be overrepresented in this analysis.

Conclusion. This qualitative interview approach provided valuable insight into patients' experiences with previous medications and OLZ/SAM. Overall, most patients reported treatment satisfaction and improvements in symptoms, function, and health-related quality of life with OLZ/SAM.

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Disease Prevalence, Comorbid Conditions, and Medication Utilization Among Patients with Schizophrenia in the United States

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Presenting Author: Brittany Roy

Abstract

Objective. Disease prevalence, comorbid conditions, and pharmacological treatments were examined in a large population of US commercial- or Medicaid-insured individuals with schizophrenia.

Methods. This retrospective, cross-sectional claims analysis sourced data from the IBM MarketScan Commercial and Medicare Supplemental Databases and the Multi-state Medicaid Database (01Jan2009 to 30Jun2016). Cases were defined by =1 diagnostic claim (ICD-9-CM/ICD-10-CM) for schizophrenia during the study period. Comorbidities (=1 ICD-9-CM/ICD-10-CM diagnosis code) were grouped according to Clinical Classifications Software (CCS) level 2 categories. For the per-database analysis of comorbidities, schizophrenia cases were matched with controls

by demographic characteristics. Case-control comorbidity comparisons were performed using prevalence rate ratios (PRRs) and 95% CIs. Per-database medication exposure (=1 National Drug Code in outpatients grouped by Redbook classification) was also assessed.

Results. Schizophrenia prevalence was 0.11% and 0.99% in commercially and Medicaid-insured patients, respectively. In both databases, comorbidity prevalence was higher among schizophrenia cases versus controls in approximately =80% of the CCS level 2 categories assessed. Common top categories of comorbidities for schizophrenia cases were mood disorders, anxiety disorders, other connective tissue disease, and diseases of the heart. Comorbidities with the highest case-control PRRs included personality disorders, suicide and intentional self-inflicted injury, and impulse control disorders. Across databases, the most commonly prescribed medications in cases were antipsychotics, antidepressants, and analgesics/antipyretics opiate agonists; the most highly prescribed antipsychotics were risperidone, quetiapine, aripiprazole, and olanzapine.

Conclusions. This large-scale analysis quantifies the high prevalence of medical and psychiatric comorbidity burden in patients with schizophrenia, highlighting the importance of integrated medical and psychiatric care.

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Long-Term Safety and Efficacy of Deutetrabenazine in Younger and Older Patients With Tardive Dyskinesia

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Abstract

Background. Tardive dyskinesia (TD) is an involuntary movement disorder that is more prevalent in older patients. However, there is limited information on TD treatment for this population. In two 12-week pivotal trials (ARM-TD and AIM-TD), TD patients demonstrated significant improvements in Abnormal Involuntary Movement Scale (AIMS) score with deutetrabenazine versus placebo.

Methods. Patients who completed ARM-TD or AIM-TD enrolled in an open-label extension (OLE) study. This post hoc analysis assessed change and percent change from baseline in AIMS score, response rates for ≥50% AIMS improvement, Patient Global Impression of Change (PGIC), Clinical Global

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Impression of Change (CGIC), and safety in younger (<55 years) and older (≥55 years) patients.

Results. This analysis included 119 younger and 218 older patients enrolled in the OLE. Data presented at Week 145 (mean \pm SE): total deutetrabenazine dose was 39.4 \pm 1.39mg/day and 39.5 \pm 1.04mg/day in younger and older patients, respectively. Changes from baseline in AIMS score were -6.7 ± 0.62 and -6.5 ± 0.47 , respectively (percent changes of $-61.4\%\pm4.10\%$ and $-54.6\%\pm3.01\%$). The majority of younger and older patients achieved treatment success per CGIC (67% and 76%) and PGIC (64% and 63%) and achieved \geq 50% AIMS response (76% and 62%). Deutetrabenazine was generally well tolerated in both groups. Exposure-adjusted incidence rates (incidence/patient-years) were <0.01 and 0.02 for akathisia, 0.07 (both) for somnolence and sedation, 0.04 and 0.11 for parkinson-like events, and 0.06 and 0.09 for depression in younger and older patients, respectively.

Conclusions. Deutetrabenazine treatment was associated with sustained improvements in AIMS score and was well tolerated in both younger and older TD patients.

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Analysis of Treatment Goals for Patients with Schizophrenia: A US Survey of Psychiatrists, Patients with SCZ and Caregivers

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Presenting Author: Maxine Chen

Abstract

Objectives. Objectives for this survey are to determine similarities or differences in treatment goals reported by psychiatrists, patients with schizophrenia (SCZ) and caregivers in the US, as well as whether goals differed by patients currently on an oral antipsychotic (OAP) or long-acting injectable (LAI), and whether goals differed by age.

Methods. This was a real-world, cross-sectional survey of US psychiatrists, patients =18 years old diagnosed with SCZ, and caregivers. Data was collected using the Disease Specific Programme (DSP) methodology. Psychiatrists (n=120) completed detailed record forms for next 8 outpatients and 2 inpatients matching inclusion criteria. The same patients and their caregivers, if present, were invited by their psychiatrist to voluntarily complete a separate survey.

Results. Responses on treatment goals were collected from psychiatrists for all patients included in the analysis (n=1161), patients (n= 542) and caregivers (n=130). Among 3 top goals,

psychiatrists, patients and caregivers concurred that "decrease in disease symptoms" is most important (63%, 64%, 68% respectively). For psychiatrists and caregivers, second was "decrease in hospitalization for relapse" (41%, and 38% respectively), whereas for patients, it was "thinking clearly" (47%). Of the 3 least important goals, psychiatrists, patients and caregivers agreed with "sexual problems" (59%, 43%, 44%, respectively) and "weight gain" (38%, 44%, 38%, respectively).

When asked which goals were met by current medication, patients responded "decrease in disease symptoms" (68%) and "thinking clearly" (39%). However, caregivers responded "thinking clearly" (30%) was not met by current medication. Caregivers most important goals, "decrease in disease symptom" (70%) and "decrease in hospitalization for relapse" (41%), were met. Additional analyses of patients on OAPs and LAIs, did not show differences in goals. However, "decrease in disease symptoms" was numerically more important for patients on LAIs vs OAPs according to psychiatrists (68% vs 62%) and caregivers (77% vs 70% respectively). Caregivers responded "decrease in hospitalization for relapse" was met for 63% patients currently on an LAI and 35% OAP. No major differences in treatment goals were observed by patient age (18–35 vs 36–65 vs >65 years).

Discussion. There is consensus among US psychiatrists, patients and caregivers on the most important treatment goal "decrease in disease symptoms", regardless of patients' current medication or age. For patients, "thinking more clearly" was second, compared with "decrease in hospitalization due to relapse", for psychiatrists and caregivers. All agreed that least important treatment goals, related to AEs, were "weight gain" and "sexual problems". More caregivers agreed "decrease in hospitalization for relapse" was met by patients on LAIs vs OAPs. These findings may help with discussions between psychiatrists, patients and caregivers.

Funding. Lundbeck LLC and Otsuka Pharmaceutical Development & Commercialization, Inc.

Safety and Tolerability of Aripiprazole Lauroxil 2-Month Formulation With 1-Day Initiation for Treatment of Schizophrenia in the ALPINE Study

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Abstract

Objective. Evaluate safety and tolerability of an aripiprazole lauroxil (AL) 2-month regimen using 1-day initiation in patients hospitalized for acute exacerbation of schizophrenia and transitioned to outpatient care.