Methods. Health insurance claims data from the IBM MarketScan Commercial Database and Multi-State Medicaid Database were analyzed. Individuals aged 18 to 64 with ≥1 inpatient or ≥2 outpatient claims for BD during the year preceding the analysis year (2015-2019) were included, with age- and sex-matched controls. Baseline demographic and clinical characteristics were evaluated. Opioid dispensing during each analysis year was defined as either chronic (coverage for ≥70 days in any 90-day period, or ≥6 prescriptions dispensed during analysis year) or nonchronic (≥1 prescription dispensed, not meeting chronic definition).
Results. BD patients had a higher prevalence of medical and psychiatric comorbidities, including pain diagnoses, vs controls. Among patients with BD in the Commercial database, chronic opioid dispensing decreased from 11% (controls: 3%) in 2015 to 6% (controls: 2%) in 2019, and in the Medicaid database, from 27% (controls: 12%) to 12% (controls: 5%). Among patients with BD in the Commercial database, nonchronic dispensing decreased from 26% (controls: 17%) in 2015 to 20% (controls: 12%) in 2019, and from 32% (controls: 26%) to 25% (controls: 14%) in the Medicaid database.
Conclusion. Between 2015 and 2019, there was a significant decrease in chronic and nonchronic prescription opioid dispensing among BD patients and controls across both the Commercial and Medicaid databases. Despite this finding, it is important to note that both chronic and nonchronic opioid dispensing was consistently higher for BD patients vs controls over time, across both databases.
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A Structured Benefit-Risk Assessment to Evaluate a Combination of Olanzapine and Samidorphan for the Treatment of Schizophrenia and Bipolar I Disorder

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Abstract

Background. A combination of olanzapine and samidorphan (OLZ/SAM) that provides the efficacy of olanzapine while mitigating weight gain was recently approved by the FDA for the treatment of schizophrenia and bipolar I disorder. To improve communication of the OLZ/SAM benefit-risk profile, a structured framework was utilized.
Methods. The Benefit-Risk Action Team framework was used to evaluate OLZ/SAM, with analyses completed for each pivotal study. ENLIGHTEN-1 evaluated antipsychotic efficacy and safety. ENLIGHTEN-2 evaluated the weight profile of OLZ/SAM vs olanzapine. Benefit-risk outcomes were selected based on study outcome parameters, known risks of olanzapine and samidorphan, and public health importance. A subset of opioid antagonist risks was not assessed due to clinical trial exclusions; however, they were factored into the overall evaluation. Risk differences and confidence intervals were analyzed.
Results. In ENLIGHTEN-1, OLZ/SAM had a lower risk of psychiatric discontinuation and nonresponse to treatment compared with placebo; higher risks of hyperprolactinemia, weight gain (≥7%), sedation, and worsening of fasting triglycerides and glucose, and no difference for fasting total and LDL cholesterol, neutropenia, orthostatic hypotension, and movement disorders. In ENLIGHTEN-2, OLZ/SAM had reduced risks of weight gain and waist circumference increase compared to olanzapine along with similar risks of relapse and psychiatric discontinuation and no difference in metabolic worsening, neutropenia, hyperprolactinemia, orthostatic hypotension, sedation, and movement disorders.
Discussion. Based on this assessment, OLZ/SAM has comparable efficacy and a safety profile consistent with olanzapine, with reduced weight gain. A structured approach to assessing the benefit-risk profile of a product facilitates transparent evaluation and communication.
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Development of the MIND-TD Questionnaire as a Screening Tool for Tardive Dyskinesia

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Abstract

Introduction. MIND-TD is a collaboration of healthcare professionals (HCPs) who are committed to raising awareness of tardive dyskinesia (TD), a persistent and potentially disabling movement disorder associated with prolonged exposure to antipsychotics and other dopamine receptor blocking agents. The MIND-TD questionnaire was developed to help HCPs screen for TD and facilitate discussion with patients.
Methods. In August 2020, an expert panel of 13 HCPs (4 psychiatrists, 6 neurologists/movement disorder specialists [MDSs], and 3 advanced practice providers [APPs]) met virtually to discuss potential screening questions for TD. This work was continued by

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