nonpharmacological prescription digital therapeutic delivered through a video game interface for the treatment of ADHD.
Objective. The objective is to summarize the data from a clinical trial in support of FDA clearance using AKL-T01 adjunctively in children currently taking stimulant medication for ADHD.
Methods. The STARS-Adjunct Trial was a multicenter, 12-week, open-label study of AKL-T01 in 206 children aged 8 to 14 years with a confirmed diagnosis of primarily inattentive or combined-type ADHD. The study included two cohorts: (1) subjects currently treated with ADHD medication (n=130) and (2) subjects not on any ADHD medication (n=76). Subjects had an ADHD Impairment Rating Scale (IRS) score ≥3 at baseline, and both cohorts used AKL-T01 for approximately 25 minutes per day, 5 days per week, over two 4-week treatment periods separated by a 4-week treatment pause.
Results. AKL-T01 significantly improved (lowered) ADHD-related impairment as measured with the IRS (clinician rated) after the first 4-week treatment in both cohorts ($P < 0.001$). Results show that effects persist during a 4-week treatment pause and further improve with a second 4-week treatment period. A majority of parents and children indicated a perceived improvement in ability to pay attention after the trial. Most common device-related adverse events were decreased frustration tolerance, headache, and irritability which ranged from mild to moderate. No serious adverse events were reported.
Conclusions. This study adds to and extends the clinical evidence base for AKL-T01, a video game-based treatment for improving attentional functioning in 8–12-year-old children with ADHD. Continued evaluation of the effects of AKL-T01 on other important aspects of functioning, like academic and social functioning, health utilization, and health outcomes, would continue to add to the evidence base that the effects observed in this and previous studies have substantial clinical and functional impact.
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Impact of Cariprazine on Weight and Blood Pressure in Bipolar I Depression: A Real-World Study Using Electronic Medical Records

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Abstract

Introduction. Patients with a severe mental illness such as bipolar I disorder (BP-I) have a higher prevalence of obesity and related metabolic comorbidities than the general population. This study evaluated the impact of cariprazine on weight and blood pressure in patients with BP-I depression using electronic medical records (EMRs) from a nationally representative database.
Methods. Analyses were based on data from EMRs in the Symphony Health's Integrated Dataverse® from March 2015 to October 2018. Patients ≥18 years of age with ≥2 cariprazine fills (first dispensing=index date) and clinical activity for ≥12 months pre-index (baseline) and ≥1 month post-index were included. Patients also had a diagnosis of BP-I depression at their most recent episode prior to cariprazine initiation. The on-treatment period spanned from the index date to the earliest of cariprazine discontinuation, a switch to another atypical or long-acting injectable antipsychotic, end of clinical activity, or end of data. Metabolic outcomes of interest were weight and blood pressure (systolic and diastolic). For each outcome, patients were required to have ≥1 measurement in both the baseline and on-treatment periods. Linear trajectories during those periods were estimated using mixed-effects models; 95% confidence intervals (CIs) were calculated using non-parametric bootstrap procedures.
Results. In total, 1702 patients who met study eligibility criteria had ≥1 weight measurement recorded in the baseline and on-treatment periods; of these patients, 178 had bipolar I depression as their most recent episode. Patients gained an average of 2.43 kg/year during the baseline period and 0.60 (95% CI: -1.97, 3.70) kg/year during the on-treatment period. Analyses of blood pressure change (n=179) showed that cariprazine had neutral effects over the on-treatment period. Patients' systolic blood pressure increased at 1.12 mmHg/year during baseline and decreased at -0.63 (95% CI: -3.59, 2.25) mmHg/year during the on-treatment period. For diastolic blood pressure, increases of 0.25 mmHg/year during baseline and 0.44 (95% CI: -1.65, 2.16) mmHg/year during the on-treatment period were observed.
Conclusions. Although patient weight was increasing prior to cariprazine initiation, a neutral weight trajectory was seen with long-term cariprazine treatment among those with a most recent BP-I depression episode. Cariprazine also had minimal impact on systolic or diastolic blood pressure. Overall, these findings are consistent with prior short- and long-term studies showing that cariprazine has a neutral weight and metabolic profile.
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Treatment Success and Psychiatric Stability in Adults With Tardive Dyskinesia: Post Hoc Analyses of Two Long-Term Valbenazine Studies

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