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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Abstract

Introduction. Tardive dyskinesia (TD) is a persistent and potentially disabling movement disorder associated with exposure to antipsychotics and other dopamine receptor blocking agents. Effective and comprehensive treatment of TD requires reducing patients' abnormal involuntary movements without disrupting their psychiatric stability. This can be especially challenging when patients have complex psychiatric conditions (e.g., >1 psychiatric diagnosis) and are taking multiple medications. Valbenazine, a highly potent and selective vesicular monoamine transporter 2 (VMAT2) inhibitor, is approved for the once-daily treatment of TD. This post hoc analysis of two long-term studies (KINECT 3, KINECT 4) was conducted to evaluate changes in psychiatric status and clinician- and patient-reported treatment success in study participants who received valbenazine (40 or 80 mg) for 48 weeks.

Methods. Data from KINECT 3 and KINECT 4 were pooled and analyzed in participants categorized by their primary psychiatric diagnosis: schizophrenia/schizoaffective disorder ("SCHZ") or mood disorder ("MD"). Concomitant medications needed for managing these and other psychiatric or medical conditions were allowed. Treatment success was defined as achieving a rating of "much improved" or "very much improved" at Week 48, as assessed using the Clinical Global Impression of Change-Tardive Dyskinesia (CGI-TD) and Patient Global Impression of Change (PGIC). Psychiatric stability was monitored using the following scales: Positive and Negative Syndrome Scale (PANSS) and Calgary Depression Scale for Schizophrenia (CDSS) in the SCHZ subgroup; Young Mania Rating Scale (YMRS) and Montgomery-Åsberg Depression Rating Scale (MADRS) in the MD subgroup. Suicidal ideation/behavior was monitored using the Columbia-Suicide Severity Rating Scale.

Results. More than 75% of study participants in the SCHZ subgroup achieved treatment success with valbenazine, based on clinician assessment (CGI-TD, 79.7%) and patient self-report (PGIC, 78.0%). Mean changes from baseline to Week 48 for PANSS scores (positive symptoms [-0.7], negative symptoms [-0.6], general psychopathology [-1.9], total [-3.2]) and CDSS total score (-0.5) indicated maintenance of psychiatric stability in the SCHZ subgroup. Similar treatment success rates were found in the MD subgroup for both CGI-TD (77.6%) and PGIC (84.5%), with mean changes from baseline in YMRS total score (-1.0) and MADRS total score (+0.3) indicating psychiatric stability was maintained. No emergence of suicidal ideation/behavior was observed during the studies.

Conclusions. Pooled analyses from two 48-week studies indicate that long-term treatment of TD with once-daily valbenazine resulted in substantial clinician- and patient-reported global improvements in TD, while psychiatric stability was maintained regardless of primary psychiatric condition.

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Conducting Women's Groups in the Inpatient Unit: Empowering a High-Risk Population by Preventing Unplanned Pregnancies

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Abstract

Introduction. Women with mental illness are 5x more likely to experience an unplanned pregnancy due to lower rates of effective contraception use; they also experience higher rates of adverse pregnancy outcomes. Education about women's reproductive health and family planning are not routinely offered in inpatient mental health and addiction treatment settings.

Methods. Weekly women's groups on the inpatient psychiatry unit were led by psychiatry residents who were trained and provided a script. Groups focused on structured contraception education followed by an open-discussion format.

Data collected included the percentage of women with history of contraception use, child protective service involvement, unplanned pregnancies, abortions, and percentage of women who found the group helpful. Special care was taken to discuss contraception as a tool for empowering women to make their own decisions about their contraceptive needs.

Results. Thirteen sessions were conducted, and attendance among women on the inpatient unit was 42%. Out of the 32 patients who participated, 100% found the group beneficial and responded they would share information they learned with women outside the group. 26.4% self-identified as using contraception, 50% had unplanned pregnancy, 23.6% have had an abortion, and 26.4% have had child protective services involvement.

Dissemination of contraceptive information in these women's groups effectively led women to consider options that were available to them and seek contraceptive methods that were appropriate to their situation. Women reported they gained a better understanding of the medical, emotional, and financial implications of unplanned pregnancies. The groups were conducted in an open-discussion format that allowed women to participate in shared experiences; in many cases, the discussions were therapeutic. Feedback from patients and unit staff was positive. Many patients requested further groups to discuss issues women face, such as domestic violence and experiences as a mother.

Conclusions. Conducting women's groups on the inpatient unit is critical in view of the poor access to healthcare that vulnerable women who seek inpatient psychiatric care experience. The groups on the inpatient unit are unique because it is often the only time these women have an opportunity for crucial, gender-specific preventative healthcare. These groups should further

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