Digital Health Technologies in Mental Health Care: Changing Perspectives of Health Care Professionals from 2019 to 2021

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Abstract

Introduction. Demand for digital mental health tools has risen since the start of the COVID-19 pandemic; however, their evolving use in mental health care is not well understood. We surveyed mental health care professionals (HCPs) before and after the onset of the pandemic and assessed how use of and attitudes about digital technology changed.

Methods. We distributed a digital health survey to HCPs in the United States in 2019 (pre-pandemic; N = 141) and in 2021 (during the pandemic; N = 151). Both surveys recorded the respondents' perceived barriers to integrating new digital health technologies and the tools they currently used in their practice.

Results. HCP use of telemedicine increased from 47% of respondents in 2019 to 81% in 2021, as did the use of mHealth sensors (2% vs 10%). Patient comfort with technology remained one of the biggest barriers to implementing new digital tools (40% vs 43%), while difficulty integrating digital tools into clinical practice became less common (40% vs 32%). Data management (19% vs 10%) and patient acceptability (19% vs 13%) were cited less often as barriers in 2021. Respondents' thoughts on what can be most improved by digital technology shifted substantially, with increased access to care rising from 27% of responses in 2019 to 46% in 2021.

Conclusions. The pandemic has changed how HCPs perceive digital health technologies and how they implement these tools in clinical practice. A growing number of HCPs believe increased access to care is the outcome that technology can most improve.

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AXS-05 (DEXTROMETHORPHAN-BUPROPION) Improves Depressive Symptoms and Functioning in Patients With One Prior Treatment Failure: Results From the Evolve Long-Term, Open Label Study

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Abstract

Background. In STAR*D, following non-remission with an SSRI, remission rates for second-line treatments were ~ 25%, regardless of the switch strategy employed. Antidepressants with novel mechanisms may improve outcomes in MDD. AXS-05 (dextromethorphan HBr 45 mg- bupropion HCl 105 mg) is a novel, oral, investigational, NMDA receptor antagonist with multimodal activity. The dextromethorphan component of AXS-05 is an NMDA receptor antagonist and a sigma-1 receptor agonist. The bupropion component of AXS-05 serves primarily to increase the bioavailability of dextromethorphan.

Methods. EVOLVE was an open-label study, in which patients were treated with AXS-05 twice daily for up to 15 months. Subjects had either rolled in after a prior AXS-05 study or were directly enrolled and had a DSM-5 diagnosis of MDD, a MADRS score of ≥25, and had been treated with ≥1 antidepressant in the current major depressive episode (MDE). A total of 186 patients were enrolled. Here we present the results for the directly enrolled patients (n =146).

Results. Mean change in MADRS total score from a baseline of 32.2 were -9.1±7.64, -13.3±8.58, and -20.4±7.79 points at Weeks 1, 2, and 6, respectively ($p < 0.001$ for all). Remission (MADRS ≤10) was achieved by 5.7%, 16.2%, and 46.0% of patients at Weeks 1, 2, and 6, respectively. Improvement in functioning, measured by the SDS, was seen starting at Week 1 ($p < 0.001$). Improvements in MADRS and SDS were sustained at Month 12.

Long-term treatment with AXS-05 was generally well tolerated. The most commonly reported adverse events were COVID-19 infection (8.9%), nausea (8.9%), headache (7.5%), dry mouth (6.2%), insomnia (5.5%), and dizziness (5.5%).

Conclusions. AXS-05 improved depression and functioning in patients who failed one prior antidepressant in the current MDE.

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Metabolic Syndrome in Bipolar Depression with Lumateperone (ITI-007): A Post Hoc Analysis of 2 Randomized, Placebo-Controlled Trials

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Abstract

Introduction. Treatments for bipolar disorder are often associated with increased rates of metabolic syndrome (MetSy). MetSy is defined as meeting 3 of the following 5 criteria: waist circumference >40in (men) or >35in (women), triglycerides ≥150mg/dL, high density lipoprotein cholesterol <40mg/dL (men) or <50mg/dL (women), systolic blood pressure (BP) ≥130mmHg or diastolic BP ≥85mmHg, fasting glucose ≥100mg/dL.

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MetSy elevates the risk of developing type II diabetes, cardiovascular disease, and premature morbidity. Lumateperone (LUMA), a mechanistically novel antipsychotic that simultaneously modulates serotonin, dopamine, and glutamate neurotransmission, is FDA-approved for the treatment of schizophrenia and depressive episodes associated with bipolar I or bipolar II disorder. This distinct pharmacological profile has been associated with favorable tolerability and a low risk of adverse metabolic effects in clinical trials.

LUMA 42-mg monotherapy was evaluated in 2 randomized, double-blind, placebo (PBO)-controlled studies (Study 401 [NCT02600494]; Study 404 [NCT03249376]) in patients with a major depressive episode (MDE) associated with bipolar I or bipolar II disorder. This post hoc pooled analysis of these studies compares rates of MetSy with LUMA 42 mg and PBO in the treatment of bipolar depression.

Methods. The incidence and shift in MetSy were analyzed in data pooled from 2 studies that recruited patients aged 18–75 years with a confirmed diagnosis of bipolar I or bipolar II disorder who were experiencing an MDE (Montgomery-Åsberg Depression Rating Scale [MADRS] Total score ≥20 and Clinical Global Impression Scale-Bipolar Version-Severity [CGI-BP-S] score ≥4). Patients in these studies were randomized 1:1 to LUMA or PBO and treated for 6 weeks.

Results. The safety population comprised 746 patients (LUMA, 372; PBO, 374). Rates of MetSy were similar between groups at baseline (LUMA, 20.7%; PBO, 22.2%) and at the end of treatment (EOT, LUMA, 21.8%; PBO, 23.8%). More LUMA patients (36.4%) compared with PBO patients (30.1%) improved from having MetSy at baseline to no longer meeting MetSy criteria at EOT. The individual criteria that shifted the most from meeting MetSy criteria at baseline to no longer meeting criteria at EOT was BP for LUMA (46.8%) and glucose for PBO (43.2%). The rate of MetSy developed during treatment was similar for LUMA (10.8%) and PBO (10.7%) with approximately half of these patients (LUMA, 43.8%; PBO, 45.2%) shifting due to a change in ≥2 criteria.

Conclusion. In this post hoc analysis of 2 randomized, PBO-controlled trials in patients with a MDE associated with bipolar I or bipolar II disorder, LUMA 42 mg had similar rates of MetSy compared with PBO. These results suggest that LUMA 42 mg is a promising new treatment for bipolar depression with a favorable metabolic profile.

Funding. Intra-Cellular Therapies, Inc.

Efficacy and Safety of Lurasidone in a Younger Population With Bipolar Depression: Pooled Post-hoc Analysis of Two Placebo-controlled Studies

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Abstract

Introduction. Early onset of bipolar disorder is associated with high rates of psychiatric comorbidity (e.g., anxiety disorders, ADHD, PTSD), high rates of recurrence, and marked impairment in functioning and quality of life. The aim of this analysis was to evaluate the efficacy and safety of lurasidone in bipolar depression in youth and young adult patients (10–30 years old).

Methods. Data from two 6-week, double-blind, placebo-controlled studies of lurasidone monotherapy for bipolar I depression were pooled for this analysis. In the 1st study, patients 10–17 years old were evaluated using the Children's Depression Rating Scale–Revised (CDRS-R) and the Clinical Global Impression-Bipolar Severity (CGI-BP-S) depression scale; in the 2nd study, a subgroup of adult patients (18–30 years old) were evaluated by CGI-BP-A, and the MADRS, with the latter being converted to a CDRS-R scores using a validated conversion algorithm.

Results. The safety population consisted of 465 patients (mean age, 17.1 years; mean age of onset, 14.1; mean CDRS-R total score, 60.8). 400 patients (85.7%) completed the study. For lurasidone vs. placebo, LS mean Week 6 change was -21.4 vs. -15.3 for the CDRS-R total score (P<0.0001; ES, 0.46); and -1.6 vs. -1.1 for the CGI-BP-S score (P<0.0001; ES, 0.50). Adverse events (≥5%) on lurasidone vs. placebo were nausea (15.9% vs. 5.2%), headache (15.1% vs. 13.1%), somnolence (7.9% vs. 3.8%), vomiting (5.2% vs. 3.3%), and weight increase (5.2% vs. 2.3%). No clinically meaningful changes were observed in weight, metabolic parameters, or prolactin.

Conclusions. In this post-hoc analysis of two placebo-controlled trials, lurasidone demonstrated clinically meaningful improvement of depressive symptoms in youth and young adults with bipolar depression. Lurasidone was generally safe, well-tolerated, and associated with minimal effects on weight, metabolic parameters, and prolactin.

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Long-Term Safety and Effectiveness of Lurasidone in Adolescents and Young Adults With Schizophrenia: Pooled Post-hoc Analyses of Two 12-month Extension Studies

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