

Clinical Management of Patients with Schizophrenia Treated with Long-Acting Injectable Antipsychotics and Telepsychiatry Use During COVID-19 Pandemic

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Abstract

Background. The COVID-19 pandemic substantially impacted care of patients with schizophrenia treated with long-acting injectable antipsychotics (LAIs). This study examined how clinics adapted operations to maintain a standard of care for these patients after pandemic onset.

Methods. Online surveys were completed in October–November 2020 by one principal investigator (PI) or PI-appointed designee at 35 clinics participating in OASIS (NCT03919994). Items concerned pandemic impacts on clinic operations, particularly telepsychiatry, and on the care of patients with schizophrenia treated with LAIs.

Results. All 35 clinics reported using telepsychiatry; 20 (57%) implemented telepsychiatry after pandemic onset. Telepsychiatry visits increased from 12%–15% to 45%–69% across outpatient visit types after pandemic onset; frequency of no-show and/or canceled telepsychiatry visits decreased by approximately one-third. Nearly half of clinics increased the frequency of telepsychiatry visits for patients with schizophrenia treated with LAIs. Approximately one-third of participants each reported switching patients treated with LAIs to longer injection interval LAIs or to oral antipsychotics. The most common system/clinic- and patient-related barrier for telepsychiatry visits was lower reimbursement rate and access to technology/reliable internet, respectively. Almost all participants (94%) were satisfied with telepsychiatry for maintaining care of patients with schizophrenia treated with LAIs; most predicted a hybrid of telepsychiatry and office visits post-pandemic.

Conclusions. Changes made by clinics after pandemic onset were viewed by almost all participants as satisfactory for maintaining a standard of care for patients with schizophrenia treated with LAIs. Most participants predicted continuing telepsychiatry to

support patient care post-pandemic; equitable access to telepsychiatry will be important in this regard.

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d-Amphetamine Transdermal System in Treatment of Children and Adolescents with ADHD: Secondary Endpoint Results from a Phase 2 Trial

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Abstract

Background. Amphetamines are a first-line treatment for ADHD. The dextroamphetamine transdermal system (d-ATS) was developed as an alternative to oral amphetamine formulations. A randomized controlled trial of d-ATS in children and adolescents with ADHD was conducted, and its primary and key secondary endpoints were met. Here, we report secondary endpoints of the study, further assessing the efficacy and safety of d-ATS.

Methods. This study comprised a 5-week, open-label dose optimization period (DOP) followed by a 2-week, randomized, crossover double-blind treatment period (DBP). All eligible patients received d-ATS 5 mg/9 h and were evaluated weekly for a possible dose increase to 10 mg/9 h, 15 mg/9 h, and 20 mg/9 h. Once reached, the optimal dose was maintained for the DOP and utilized during the DBP. Secondary objectives for this study included assessment of efficacy via Permanent Product Measure of Performance-Attempted and -Correct (PERMP-A, PERMP-C), ADHD-RS-IV, Conners Parent Rating Scale Revised Short Form (CPRS-R:S), and Clinical Global Impression (CGI) scores in a laboratory classroom setting. Efficacy was analyzed using a mixed-model repeated-measures (MMRM) approach. Safety assessments included treatment-emergent adverse events (TEAEs) and dermal safety.

Results. In total, 110 patients were enrolled in the DOP, and 106 patients were randomized in the DBP. Patients receiving d-ATS demonstrated significant improvement vs placebo in PERMP-A and -C scores in the DBP consistently from 2 to 12 hours post-dose ($P < .001$ for all timepoints). ADHD-RS-IV total scores improved during the DOP and improved further during the DBP, with a least-squares mean (95% CI) difference for d-ATS vs placebo of -13.1 ($-16.2, -10.0$; $P < .001$). Significant differences between placebo and d-ATS in the DBP were also observed for the CPRS-R:S and CGI scales ($P < .001$). Most TEAEs were mild or moderate, with 3 TEAEs (abdominal pain, irritated mood, and appetite loss) leading to study discontinuation in the DOP and none in the DBP. No patients were discontinued due to dermal reactions in either phase.