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

Leona Bessonova, PhD[1], Elizabeth Keane, BA[1], Eric Achtyes, MD, MS[2], Philip D. Harvey, PhD[3], John M. Kane, MD[4], Stephen R. Saklad, PharmD, BCCP[5], Jeffrey Trotter, BS, MBA[6], Amy Claxton, PhD[1], Tiffany Hatfield[1], James McGrory, PhD[1], Wahidullah Noori, PharmD, MS[1], Amy K. O'Sullivan, PhD[1], Joshua E. Biber, PhD[7], Asia Sikora Kessler, PhD[7], Aaron Yarlas, PhD[7] and Dawn I. Velligan, PhD[8]

[1]Alkermes, Inc., Waltham, MA, USA, [2]Division of Psychiatry & Behavioral Medicine, Michigan State University College of Human Medicine, Grand Rapids, MI, USA, [3]University of Miami Miller School of Medicine, Miami, FL, USA, [4]The Zucker Hillside Hospital, Glen Oaks, NY, USA, [5]Pharmacotherapy Division, College of Pharmacy, University of Texas at Austin, San Antonio, TX, USA, [6]Worldwide Clinical Trials, Research Triangle, NC, USA, [7]QualityMetric Incorporated, LLC, Johnston, RI, USA, and [8]University of Texas Health Science Center at San Antonio, San Antonio, TX, USA

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.

Funding. Alkermes, Inc.

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

Andrew J. Cutler, MD[1,2], Katsumi Suzuki, MS[3], Brittney Starling, PharmD[3], Kanan Balakrishnan, PharmD[3], Marina Komaroff, DrPH[3] and Mariacristina Castelli, PhD[3]

[1]SUNY Upstate Medical University, Lakewood Ranch, FL, USA, [2]Neuroscience Education Institute, Carlsbad, CA, USA, and [3]Noven Pharmaceuticals, Inc., Jersey City, NJ, USA

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.

https://doi.org/10.1017/S1092852922000268 Published online by Cambridge University Press

Conclusions. d-ATS was effective in the treatment of ADHD in children and adolescents, meeting its primary endpoint (reported elsewhere) and all secondary endpoints. d-ATS was safe and well-tolerated, with minimal dermal reactions.
Funding. Noven Pharmaceuticals, Inc.

Alliaceous Axilla as a Manifestation of Olfactory Reference Syndrome

Anton S. Lima, MD[1], Jenish V. Patel, MS[2], Tiffany Chang, MD[3] and Alan R. Hirsch, MD[4]

[1]Federal University of Pernambuco, Recife, Brazil, [2]Windsor University School of Medicine, St. Kitts, West Indies, [3]Fudan University Shanghai Medical College, Shanghai, China, and [4]Smell & Taste Treatment and Research Foundation, Chicago, IL, USA

Abstract

Introduction. Olfactory reference syndrome (ORS) is a delusion in which a person believes that he or she exudes a displeasing body aroma that others perceive negatively. The axilla has been reported as a single primary source in only one patient. Furthermore, ORS is rarely reported to be associated with food odor. In these instances, the food is not edible. Delusions of ORS presenting as alliaceous edible food aromas have not heretofore been described.

Case Report. One week after undergoing catheter ablation for atrial fibrillation, this 42-year-old right-handed male experienced a sudden onset of loss of smell and taste. This has persisted on presentation and he described a complete lack of smell, only being able to smell different spices and herbs. Over time, his sense of smell selectively improved such that he was able to smell alliaceous substances, including onion and garlic, as well as a few other aromas. At the same time his smell returned, he noted that his own body exuded a smell of garlic. This occurred especially while weightlifting at the gym. He noticed that the shirts he had worn working out, in the axillary regions, were encumbered with a garlic/onion miasma. He was fearful that this mephitic aroma was being secreted through his armpits, and that others would recognize his tragomaschalia. As a result, he restricted his activities. Over a few months, his smell ability gradually worsened back to the condition he was in after the ablation. Coincident with this, his perception that he was exuding an alliaceous aroma resolved.

Results. Motor examination: Drift testing: mild left pronator drift. Left abductor digiti minimal sign. Olfactory testing prior to the development of ORS: Alcohol Sniff Test (AST): 0 (anosmia). Brief Smell Identification Test (B-SIT): 3 (anosmia). Olfactory testing during ORS: AST: 16 (hyposmia). B-SIT: 9 (hyposmia). Olfactory testing after resolution of ORS: AST: 0 (anosmia).

Discussion. This could be explained by a physiologic axillary odor or malodor, which he could not detect before or after the ORS. During the ORS, the odor may have been misperceived in a dysosmic manner due to his underlying olfactory deficit. Such dysosmia may have then been interpreted as the aroma of an alliaceous vegetable. The intensity of the aroma may have been greatest at the axillary area if compared to the other sources, but due to his underlying hyposmia, he was able to perceive only the axilla as a sole source of the aroma. Besides, psychodynamic preoccupation with bodily physique may have explained his hypersensitivity to minor flaws and his excessive preoccupation with possible harassment from others. He may have consequently misinterpreted individuals' benign observations and attitudes to presume the presence of aroma. In individuals with olfactory deficit, this investigation for the presence of ORS with traditionally unpleasant food aromas or the presence of ORS in those with chemosensory dysfunction is warranted.
Funding. No funding

A Case of Possible Levetiracetam Induced Aseptic Meningitis vs Viral Meningitis

P. Brittany Vickery, PharmD, BCPS, BCPP, J. Kyle Roach, PharmD and Stephen Vickery, PharmD

Wingate University School of Pharmacy, Wingate, NC, USA

Abstract

Introduction. Meningitis causes inflammation of the meninges and when bacteria are not the cause may be considered aseptic. Drug-induced aseptic meningitis (DIAM) can arise from the use of certain medications. The pathophysiology of DIAM is not well understood. Within the antiepileptic medication class, only lamotrigine, carbamazepine, and levetiracetam have been associated with DIAM via documented cases. Common presentation of DIAM involves fever, headache, meningismus, and mental status changes (abnormal consciousness and focal neurological deficits). Other clinical features may include neck stiffness, photophobia, nausea, vomiting, abdominal pain, bone pain, hypotension, edema (facial and optic nerve), rash, and seizures. Case reports of DIAM with varying or limited symptomology exist. Therefore, the presentation alone will not allow for a DIAM diagnosis, prompting further analysis and diagnostic exclusion.

Case. A middle-aged male presented with a 48-hour history of confusion, disorientation, unresponsiveness, and hypersomnolence. Past medical history included hypertension, hyperlipidemia, type-2 diabetes, and seizures. Home medication included chlorthalidone, levetiracetam, lisinopril, metformin, potassium chloride, rosuvastatin with no medication allergies reported. Upon admission, the patient denied fever, headache, nausea, neck pain, vomiting, and rash. Somnolence, dysarthria, and obtundation were noted during the physical evaluation. Hospital medications included home medications along with enoxaparin, correctional dose insulin lispro, and IV lactated ringers. Vitals and labs were unremarkable. On hospital day (HD) 1 the MRI scan was unremarkable, ruling out a demyelinating process. Serology tests (ie, ANA and dsANA) were negative. Neurology was consulted, and a lumbar puncture was performed. On HD-2 AEIM was suspected, prompting levetiracetam discontinuation and lacosamide initiation (50 mg by mouth twice daily). The CSF analysis was notable for pleocytosis (lymphocytic predominance at 96%), elevated protein (100 mg/dL), and slightly elevated glucose (79 mg/dL). The CSF VDRL was negative, ruling out

https://doi.org/10.1017/S1092852922000268 Published online by Cambridge University Press