

Sustained Treatment Response With Long-Term Valbenazine in Patients With Tardive Dyskinesia

Christoph U. Correll^{1,2,3}, Jean-Pierre Lindenmayer^{4,5}, Khody Farahmand⁶, Eric Jen⁶, Scott Siegert⁶ and Eduardo Dunayevich⁶

Abstracts

¹Department of Psychiatry, The Zucker Hillside Hospital, Northwell Health; Glen Oaks, NY, USA, ²Departments of Psychiatry and Molecular Medicine, Donald and Barbara Zucker School of Medicine at Hofstra/Northwell; Hempstead, NY, USA, ³Department of Child and Adolescent Psychiatry, Charité Universitätsmedizin Berlin; Berlin, Germany, ⁴Nathan Kline Institute for Psychiatric Research at Manhattan Psychiatric Center; New York, NY, USA, ⁵Department of Psychiatry, NYU Grossman School of Medicine; New York, NY, USA and ⁶Neurocrine Biosciences, Inc.; San Diego, CA, USA

Abstract

Background. Valbenazine is a once-daily VMAT2 inhibitor approved for the treatment of tardive dyskinesia (TD), a persistent and potentially disabling movement disorder associated with prolonged exposure to antipsychotics, antiemetics, and other dopamine receptor blocking agents. The efficacy, safety, and tolerability of valbenazine has been established in several phase 3 trials, including a long-term study (KINECT 4 [NCT02405091]) in which participants received open-label valbenazine (40 or 80 mg) for 48 weeks. Post hoc analyses of KINECT 4 data were conducted to assess patterns of treatment response.

Methods. Data from KINECT 4 treatment completers (participants who reached the Week 48 visit and had the longest duration of treatment) were analyzed post hoc. TD was assessed using the Abnormal Involuntary Movement Scale (AIMS) total score (sum of items 1–7, as rated by the study investigator), the Clinical Global Impression of Change-Tardive Dyskinesia (CGI-TD), and the Patient Global Impression of Change (PGIC). Analyses were conducted at Week 8 (first study visit after the valbenazine dose-optimization period) and Week 48 using the following definitions of response: $\geq 50\%$ and $\geq 70\%$ improvement from baseline in AIMS total score; rating of “much improved” or “very much improved” (score ≤ 2) on the CGI-TD and PGIC.

Results. Of the 167 participants who entered KINECT 4, 103 (62%) were treatment completers and included for analysis. Of these 103 participants, 39% and 86% met the $\geq 50\%$ AIMS response threshold at Weeks 8 and 48, respectively. The percentages of participants who met the highly rigorous AIMS $\geq 70\%$ response threshold at Weeks 8 and 48 were 17% and 52%, respectively. Of the 40 participants with AIMS $\geq 50\%$ total score improvement at Week 8, 95% also met this threshold at Week 48 (“sustained response”). Of the 63 participants with $< 50\%$ AIMS improvement at Week 8, 81% achieved the $\geq 50\%$ response threshold by end of treatment at Week 48. The proportion of participants meeting the threshold for CGI-TD response also increased over time, from 50% at Week 8 to 92% at Week 48. PGIC results were similar, with response rates of 53% and 88% at Weeks 8 and 48, respectively.

Conclusions. Post hoc analyses of data from a 48-week, open-label study of once-daily valbenazine showed that the proportion of participants meeting rigorous treatment response thresholds increased over time. By the end of treatment at Week 48, $> 80\%$ of participants demonstrated robust improvements in TD, as assessed using the AIMS ($\geq 50\%$ improvement), CGI-TD (score ≤ 2), and PGIC (score ≤ 2).

Funding. Neurocrine Biosciences, Inc.

Assessing the Quality of a Telemental Health Training Initiative for Social Work Students to Reduce the Workforce Mental Health Crisis in the Child and Adolescent Population

Kimberly Bailey Dexter, DNP, APRN, PMHNP-BC, RDH, BS¹ and Caroline Sutter, DNP, APRN, FNP-BC²

¹Department of Psychiatry, Division of Child & Adolescent Psychiatry, Virginia Commonwealth University Health Systems, Richmond, VA, USA; Walden University, Minneapolis, MN, USA and ²George Mason University, Fairfax, VA, USA

Abstract

Introduction. Delayed access to mental health services (MHS) has become a crisis in the United States. Children have the highest disproportionate rates of delayed psychiatric services in comparison to adults. There are greater demands for mental health professionals than the workforce can supply. Social workers (SW) have been identified as essential stakeholders for children needing access to mental health services. The shortage of social workers is more profound than nurses, especially in rural and underserved areas. Therefore, the Institute of Medicine (IOM) has recommended all educational institutions incorporate telemental health (TMH) training into interprofessional students' curriculums.

Target Population. The delays in MHS are directly related to the shortage of mental health professionals especially for nursing but it is more apparent in social work. The United States Health Resource and Service Administration (HRSA) have projected there is a greater demand for mental health clinicians than the workforce is able to supply. *Social workers* are essential providers for navigating our nation's mental health system. They can also train to become licensed mental health therapists. HRSA predicts by 2025 the demand for SWs will be 157,760. However, the estimated supply will be 147,500 resulting in a shortage of approximately 10,260 social workers. *Children* have the greatest risk for lack of access amongst mental health patients in the U.S. An estimated 13–20 % of children in the United States have a diagnosable mental illness. Twenty-one percent of that amount are children who reside in rural or underserved areas. Strikingly, only 7% of children living in rural or underserved areas will receive a mental health appointment.

Purpose. The purpose of the George Mason University initiative was to develop a telemental health training model that would be incorporated into social work students' curriculum and meet the IOMs' recommendation. The GMU Population Health Center Initiative sought to identify how SW students, trained as TMH providers could be the resolution to the workforce shortage crisis.

Methods. This project design was a quality improvement initiative to assess social work students' perception of the telemental health training. The CTiBS framework was used to determine the level of competency SW students achieved upon completion of the TMH training. The Activity Theory was used as the methodological framework to assess social work students' readiness of change, engagement, and TMH technology.

Results. After reviewing quantitative data, 70% participants (n=7) declared novice competency. The remaining 30% (n=3) affirmed proficiency (SD= 0.46, V=0.21). Sixty percent (n=6) participants declared they would consider becoming TMH providers. Sixty percent (n=6) of the trainees stated they were satisfied with the training and would consider providing TMH services upon graduation (SD= 0.49, V=0.24). Ninety percent (n=9) of trainees stated they could successfully conduct a TMH visit and would consider working in rural and underserved areas (SD= 0.30, V=0.09). One hundred percent (n=10) of the participants stated the TMH training was a beneficial skill for their profession.

Conclusion. One hundred percent of the participants found TMH training beneficial and ninety percent would use it to conduct visits for children upon graduation. The workforce crisis will not improve unless the IOM recommendations are adapted by educational institutions. A telemental health-prepared labor force will help to reduce the rates of mental health disparities in children.

Funding. No Funding

Increasing Awareness of Naloxone-Induced Noncardiogenic Pulmonary and Peripheral Edema

Kimberly D. Conley, RN, CFRN, CEN¹,
Dana Murphy-Parker, MS, PMHNP-BC, CARN-AP, FIAAN²
and Virginia M. Conley, PhD, PMHNP-C, FNP-BC, FAANP³

¹Frontier Nursing University, PMHNP Student, Lexington, KY, USA, ²University of Colorado, Clinical Faculty, Denver, CO, USA and ³Flowstate Health, LLC, Des Moines, IA, USA

Abstract

Introduction. Naloxone use has increased in recent years in response to the nation's opioid crisis. Once only available to health care professionals, it is now obtainable by prescription for persons at risk for substance overdose and their families. Increasing its availability is seen by some as an "over-the-counter solution" to the opioid problem. However, while naloxone has been viewed as relatively safe, with a low side effect profile when appropriately dosed and monitored, it is not without safety concerns that may go unrecognized or misattributed to other causes.

Methods. Here we present a case study of a 41-year-old female who presented to our medication-assisted treatment (MAT) clinic complaining of sudden onset weight gain, shortness of breath, upper and lower extremity peripheral edema, tachycardia, insomnia, and nocturnal enuresis. These symptoms made it difficult for her to work at her housekeeping job, resulting in missed workdays. She had seen a primary care provider for her symptoms and been prescribed a rescue inhaler for her shortness of breath. This patient had previously been treated for opioid use disorder with buprenorphine/naloxone and experienced similar symptoms, which disappeared when she relapsed on opioids. However, symptoms reappeared upon resuming her prescribed treatment.

Results. The patient was identified as experiencing side effects to naloxone, causing noncardiogenic edema. Her MAT medication was switched to buprenorphine. Within two weeks her heart rate had returned to normal, she had lost weight, and she no longer had nocturnal enuresis or needed the rescue inhaler. Her peripheral edema resolved so she was able to walk better and resume work. At the same time, buprenorphine continued to relieve her cravings.

There is a dearth of information related to naloxone-induced edema. Our patient had not received a formal evaluation of pulmonary edema, but her pulmonary and cardiac symptoms were consistent with that diagnosis. Although pulmonary edema is mentioned in the product literature, peripheral edema is not. A literature search indicates that the number of case studies on naloxone-induced pulmonary edema have increased since 2018, but only one other case of naloxone-induced peripheral edema was discovered.

Conclusions/Importance. Naloxone is used in a variety of settings by differing types of health care providers. As the number of persons treated with naloxone increases, there will likely be a corresponding increase in incidences of pulmonary and/or