

higher healthcare resource utilization. There remains a need for new treatment options for patients with persistent, prominent, or predominant negative symptoms which specifically improve this historically hard-to-treat and assess symptom domain.

Funding. Sunovion Pharmaceuticals, Inc.

Anticholinergics Should Not Be Used to Treat Tardive Dyskinesia: Insights From an Expert Panel of Psychiatry and Neurology Healthcare Professionals

Nora Vanegas-Arroyave¹, Dawn Vanderhoef², Rachel Manahan² and Samantha Cicero²

¹Department of Neurology, Baylor College of Medicine, Houston, TX, USA and

²Neurocrine Biosciences, Inc., San Diego, CA, USA

Abstract

Introduction. Tardive dyskinesia (TD) is a persistent and often disabling hyperkinetic movement disorder associated with prolonged exposure to dopamine receptor blocking agents (e.g., antipsychotics, antiemetics). The use of anticholinergics for the treatment of movement disorders including TD is a common practice, despite a lack of supportive evidence and the potential to worsen TD. Moreover, there are now FDA-approved medications specifically indicated for TD. Two virtual meetings were held with movement disorder experts from neurology and psychiatry to better understand the real-world use of anticholinergics for TD.

Methods. In November 2020, a panel of eight experts was convened to gather insights on the challenges of differentiating TD from other drug-induced movement disorders (DIMDs) and to discuss appropriate treatments for TD and other DIMDs. A follow-up meeting was held in June 2021 to consolidate these insights. Key recommendations based on the panel discussions are presented.

Results. The panel emphasized that while anticholinergics can help with managing some DIMDs, current evidence indicates that they are not effective in TD and may even worsen symptoms. Therefore, FDA-approved vesicular monoamine transporter 2 (VMAT2) inhibitors like valbenazine were recommended by the panel as first-line TD therapies. The panel noted that TD is often grouped under the term “extrapyramidal symptoms,” which leads to difficulty in differentiating TD from other DIMDs and the inappropriate treatment of TD with anticholinergics. The panel agreed that prophylaxis with anticholinergics is only appropriate in patients at high risk of acute dystonia. However, chronic anticholinergic use should be avoided whenever possible due to potentially serious adverse effects (e.g., cognitive difficulties) and anticholinergic burden, particularly in older patients. The potential for abuse, addiction, and diversion should also be considered when prescribing anticholinergics. Abrupt anticholinergic discontinuation can result in cholinergic rebound, which is

characterized by sleep disturbances, gastrointestinal problems, urinary urgency, and manifestations of DIMDs. Thus, when used appropriately (e.g., for acute dystonia), anticholinergics should be prescribed at minimally effective doses and slowly tapered for successful discontinuation.

Conclusions. These findings align with the current TD treatment guidelines, including the lack of evidence for anticholinergic use and recommended first-line treatment with approved VMAT2 inhibitors. Conclusions from this panel highlight educational needs across HCPs on the phenomenology of DIMDs, the inappropriate use of anticholinergics for TD, TD risks and assessment, and treatment strategies for TD.

Funding. Neurocrine Biosciences, Inc.

Interventions to Reduce the Role Strain of Informal Adult Caregivers of Individuals With Neurocognitive and Mental Disorders

Diana M. Awuah, DNP, APRN, PMHNP-BC, FNP-C

Abstract

Background. The value of the unpaid labor performed by caregivers is estimated to be at least \$306 billion annually, nearly double the combined costs of home health care (\$43 billion) and nursing home care (\$115 billion). However, studies show caregivers are at risk of developing high levels of physical, emotional, and mental strain, which can negatively impact their role, quality of life, and increase medical costs.

Purpose. The project aims to determine if giving informal caregivers non-pharmacological interventions such as self-guided bibliotherapy, stress reduction interventions, and improving health literacy will reduce the role strain of informal adult caregivers and improve their quality of life.

Method. This project employed a mix-method design focusing on the role strain and quality of life of relatives and friends assisting individuals with neurocognitive or mental health disorders. The subjects engaged in weekly self-guided activities for 8 weeks, and responded to survey questions regarding demographics, depression, anxiety, and stress levels. Personal health information (PHI) was not obtained. The subjects were required to answer qualifying questions. A \$5 Amazon gift card was given to participants who completed the project.

Results. Seven people enrolled in the project, but only four participated. All participants were female. Two were African Americans, one Caucasian, and one Hispanic. All four participants completed the pre-test, demographic surveys, and intervention. However, only two completed the post-test survey. One participant completed the pre-test and post-test on the same day at the end of the project.

Descriptive statistics were employed for the data analysis due to the small sample size. A non-parametric 2-independent sample test was used because of the small sample size. The test did not show any statistical significance between the variables in the pre- and post-test DASS-21 after the intervention. Subjects reported the project intervention was “helpful.” Another participant said she could not fully engage in the interventions because of family obligations. Still, she enjoyed the resources, such as the weekly NAMI family support group meetings given by the SI. The pre-test DASS-21 mean score for N=3 was 26 and standard deviation was 15.62.

Discussion. The current COVID-19 has led to an increase in mental health issues. Because of the overwhelming increase in mental health cases, many individuals with mental health problems are being turned away. The decrease in the availability of mental health providers has led to an increased need for informal caregivers. However, studies show stress from caregiving can negatively affect the health of caregivers and result in loss of work productivity. However, specialized support for caregivers is frequently limited. Brown et al. (2016) said nonpharmacological self-help interventions such as bibliotherapy, stress-reduction techniques, and health literacy training could improve caregivers’ health. Therefore, lawmakers and healthcare professionals need to come up with interventions to help caregivers.

Funding. No Funding

AI-Based Adherence Prediction for Patients: Leveraging a Mobile Application to Improve Clinical Trials

Dooti Roy¹, Zheng Zhu¹, Lei Guan², Shaolei Feng², Kristen Daniels¹ and Michael Sand¹

¹Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, USA and ²AiCure, LLC, New York, NY, USA

Abstract

Introduction. Medication nonadherence is a public health concern and can impact clinical trial data quality. Traditional compliance collection (pill counts, diaries) can be unreliable in central nervous system trials. As such, strategies such as adherence technologies may play a key role in trial outcomes. AiCure, a computer vision-assisted dosing mobile application (app), collects dosing data and connects patients to sites for dosing support. Phone-based computer vision algorithms confirm dosing and transfer videos for artificial intelligence and human review. Boehringer Ingelheim is partnering with AiCure on pilot trials using AiCure adherence data to improve patient retention and clinical trial data quality. Here we report initial findings.

Methods. This pilot used data from two Phase II trials on the efficacy and safety of BI 409306 in people with schizophrenia (NCT03351244) or Attenuated Psychosis Syndrome (NCT03230097). The AiCure mobile app alerted participants to dosing protocols. The dose event was visually confirmed, providing sites a real-time view of

adherence and allowing for targeted outreach and intervention. Adherence data from the first 2 weeks generated quantitative, machine-learning models to predict the individual adherence over the trial. Predictive modeling explored different monitoring periods (7-, 10-, and 14-day) and adherence cutoff points (0.8, 0.7, 0.6).

Results. Initial AiCure assessment identified 43% of participants in NCT03351244 as $\leq 80\%$ compliant (definition of compliance $> 80\%$ compliant). Variance in adherence rates between electronic case report forms (eCRF; 78%) and AiCure (26%) data was also observed in the highly compliant/adherent group in NCT03230097. Using the first 2 weeks of adherence data (both studies combined), a participant’s adherence predicted their average adherence for the remainder of the trial. Observation of a participant’s adherence for the latest 4 weeks predicted the probability of premature dropout from the trial. There were further correlations of lower predicted adherence with actual disposition-based dropouts.

The early adherence predictive model (0.6 adherence cutoff) identified 22%, 20%, and 19% of patients for trial NCT03351244 (total n=235) as high-risk patients (low-adherence prediction) across 7-, 10-, and 14-day monitoring periods, respectively. Of those high-risk patients, 81%, 90%, and 96%, respectively, were truly nonadherent based on actual adherence data. The 14-day monitoring period model provided the lowest false omission rate, indicative of a better performing model.

Conclusions. AiCure data provided insights into patient behavior and adherence patterns which would not be available via CRF. Predictive models developed with AiCure adherence data can identify and predict future poor adherers. This creates opportunities to plan interventions and mitigation strategies to improve patient adherence during trials, thereby providing test drugs the best opportunity at proving efficacy.

Funding. Boehringer Ingelheim International GmbH (NCT03351244/1289-0049 and NCT03230097/1289-0032)

Patient and Staff Attitudes Toward Clothing Restrictions on a Pediatric Psychiatric Unit

Scott C. Schmidt, DNP

The Stratford Clinic, Greenwood Village, CO, USA

Abstract

Introduction. Pediatric psychiatric inpatients are among the most vulnerable individuals in society. While the use of seclusion and restraint is well chronicled in the field of research in this population, there is limited literature describing the effects, meaning, and attitudes of mandating the wear of clothing in hospital settings. This research explores the phenomenon of the practice of mandatory wear of hospital-issued clothing and its meaning to patients and the awareness and attitudes of this practice among staff caring for this population. This research aims to improve understanding of the experiences of patients regarding this practice at a large, urban hospital providing care for children using a mixed methods design. A qualitative, descriptive phenomenological analysis was conducted through individual interviews with