

Adolescent Psychiatry, Berlin, Germany; ⁵New York Medical College, Department of Psychiatry and Behavioral Sciences, Valhalla, NY, USA; ⁶Teva Branded Pharmaceutical Products R&D, Inc., Global Health Economics and Outcomes Research, West Chester, PA, USA; ⁷Teva Branded Pharmaceutical Products R&D, Inc., Global Medical Affairs, West Chester, PA, USA; ⁸Teva UK Limited, Global Medical Affairs, Harlow, United Kingdom and ⁹Yorker Health, Bridgewater, NJ, USA

Introduction. Healthcare professionals (HCPs) face unique challenges when managing patients with schizophrenia. Educational initiatives targeting common clinical dilemmas encountered by clinicians, such as unfamiliarity with prescribing information for long-acting injectable antipsychotics (LAIs), may assist clinicians when treating patients with schizophrenia.

Methods. Four experts in schizophrenia management used empirical evidence to identify 11 key clinical dilemmas where LAIs may be useful. These experts then developed a heuristic, educational tool (S.C.O.P.E.[™]: Schizophrenia Clinical Outcome Scenarios and Patient-Provider Engagement) based on empirical evidence and expert opinion for clinicians to use when encountering similar scenarios to optimize schizophrenia care. S.C.O.P.E.[™] also includes supportive elements such as an LAI selector.

Results. S.C.O.P.E.[™] is a freely available resource comprising an interactive digital platform providing educational materials for HCPs involved in continued care for patients with schizophrenia. To acquaint HCPs with characteristics of common LAIs used in schizophrenia treatment, S.C.O.P.E.[™] offers a selector that filters LAIs by approved indication(s), initiation regimen, reconstitution, dosing strengths and frequency, injection volumes and routes, and supply and storage information based on approved product labels. The LAI selector does not provide LAI safety and efficacy data, so HCPs should visit individual product websites for this information. Therefore, S.C.O.P.E.[™] will not replace clinical judgment, guidelines, or continuing medical education, and is not a platform for recording patient-level data, nor intended for payer negotiations or access-related questions by HCPs.

Conclusions. S.C.O.P.E.[™] is an educational tool for HCPs to use alongside standard psychiatric evaluations to improve understanding of how to manage common clinical dilemmas when treating patients with schizophrenia, the role of LAIs in schizophrenia management, and the product characteristics of available LAIs.

Funding. Teva Branded Pharmaceutical Products R&D, Inc.

Introducing S.C.O.P.E. : Schizophrenia Clinical Outcome Scenarios and Patient-Provider Engagement An Interactive Digital Platform to Educate on Schizophrenia Care

Christoph U. Correll, MD^{1,2,3,4}, Jose M. Rubio, MD^{1,2,3}, Leslie Citrome, MD, MPH⁵, John M. Kane, MD^{1,2,3}, Marko A. Mychaskiw, PhD⁶, Stephen Thompson, MS⁶, Kelli R. Franzenburg, PhD⁷, Mark Suett, MD⁸ and Sameer Kotak, MS⁹

¹The Zucker Hillside Hospital, Northwell Health, Department of Psychiatry, Glen Oaks, NY, USA; ²Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, Department of Psychiatry and Molecular Medicine, Hempstead, NY, USA; ³Feinstein Institutes for Medical Research, Institute of Behavioral Science, Manhasset, NY, USA; ⁴Charit Universit tsmedizin Berlin, Department of Child and Adolescent Psychiatry, Berlin, Germany; ⁵New York Medical College, Department of Psychiatry and Behavioral Sciences, Valhalla, NY, USA; ⁶Teva Branded Pharmaceutical Products R&D, Inc., Global Health Economics and Outcomes Research, West Chester, PA, USA; ⁷Teva Branded Pharmaceutical Products R&D, Inc., Global Medical Affairs, West Chester, PA, USA; ⁸Teva UK Limited, Global Medical Affairs, Harlow, United Kingdom and ⁹Yorker Health Corp., Glen Rock, NJ, USA

Introduction. Healthcare professionals (HCPs) face unique challenges when managing patients with schizophrenia. Educational initiatives targeting common clinical dilemmas encountered by clinicians, including partial or nonadherence, may alleviate knowledge gaps and clarify the role of long-acting injectable antipsychotic agents (LAIs) in treating this population.

Methods. 4 experts in schizophrenia management used empirical evidence to identify 11 key clinical dilemmas where LAIs may be useful. These experts then developed a heuristic, educational tool (S.C.O.P.E.[™]: Schizophrenia Clinical Outcome Scenarios and Patient-Provider Engagement) based on empirical evidence and expert opinion for clinicians to use when encountering similar scenarios to optimize schizophrenia care.

Results. S.C.O.P.E.[™] is a freely-available resource comprising an interactive digital platform providing educational materials for HCPs involved in continued care for patients with schizophrenia. S.C.O.P.E.[™] provides HCPs with considerations in common clinical scenarios met in inpatient and outpatient settings, as well as questions to consider when patients present to the emergency department. The potential usefulness of LAIs is explored in each scenario. Clinical education videos prepare nurse practitioners, social workers, and case managers to address patient concerns and communicate the benefits of LAI treatment. S.C.O.P.E.[™] will not replace clinical judgment, guidelines, or continuing medical education, and is not a platform for recording patient-level data, nor intended for payer negotiations or access-related questions by HCPs.

Conclusions. S.C.O.P.E.[™] is an educational tool for HCPs to use alongside standard psychiatric evaluations to improve understanding of how to manage common clinical dilemmas when treating patients with schizophrenia and the role of LAIs in schizophrenia management.

Funding. Teva Branded Pharmaceutical Products R&D, Inc.

Efficacy and Safety of Lamotrigine in Pediatric Mood Disorders: Patients' Perspective

Sultana Jahan, MD¹, Zach Lease², Jordan Richardson², Ashley Brown² and Ellen O'Neill²

¹University of Missouri-Columbia, Columbia, MO and ²Undergraduate student, University of Missouri-Columbia, Columbia, MO

Background. Data gathered from previous studies has demonstrated the efficacy and safety of lamotrigine in the adult psychiatric population; however, it has not been well studied in children and adolescents with mood disorders (Watanabe & Hongo, 2017).

Objective. The objective of this study is to understand patients' perspective of Lamotrigine efficacy and safety when prescribed for children and adolescents with mood disorders.

Methods. A proposal was approved by the University of Missouri-Columbia Internal Review Board to conduct this study. To answer a questionnaire, 20 patients were randomly selected who were taking lamotrigine for mood disorder. All 20 patients were seen in person at the University of Missouri Child and Adolescent Psychiatry Out-patient Clinic. A consent form was reviewed and signed by their respective legal guardian. The questionnaire consisted of yes or no, and free-response questions. Each participant was asked a series of questions about their symptoms before and after lamotrigine, whether or not the medication was helpful, and whether or not they experienced any side effects. Additional details were also obtained, including dosage, the length of their prescription, and any concomitant medications. Demographic information, including age, race, gender, and grade, was also obtained.

Results. Among the participants, 65% were females and 35% were male patients who agreed to take the questionnaire. Fifty percent of the patients were between the ages of 16 and 18, 35% were between the ages of 11 and 15 and, 15% were between the ages of 8 and 10. Seventy percent were Caucasian, 10% were African American, and 20% identified as belonging to another race. 35% of the patients were prescribed lamotrigine for less than a year, and 65% were prescribed lamotrigine for over a year. 30% of patients take 25-50mg daily, 25% take between 51-100mg daily, 40% take 101-200mg daily, and 5% take more than 200mg daily. Before lamotrigine was prescribed to the 20 patients in this study, collective reported symptoms included: anger, aggression, mood swings, irritability, depression, anxiety, and self-harm. Eighty percent of patients claimed lamotrigine improved their symptoms after taking the medication. Most improvement was claimed by patients with mood swings followed by patients with anger,

aggression, and irritable mood. Seventy percent of patients reported no side effects with the medication. 10% of patients reported increased appetite, 5% reported rash, 5% GI issue, and other 10% reported various side effects, including fatigue, myalgia, and restlessness.

Conclusion. According to patients reports, this study provides data that lamotrigine may be effective in pediatric mood disorders and shows minimal adverse effects. Further larger clinical studies are needed to conclude the safety and efficacy of Lamotrigine in the treatment of pediatric mood disorder.

Funding. No Funding

A Thorough QT Study Using C-QTc to Evaluate the Effects of Centanafadine on Cardiac Repolarization

Susan E. Shoaf, PhD, Osman Turkoglu, MD, Xiaofeng Wang, PhD and Jennifer Repella Gordon, MS

Otsuka Pharmaceutical Development & Commercialization, Inc., Rockville, MD

Introduction. Centanafadine (CTN) is a potential first-in-class norepinephrine/dopamine/serotonin triple reuptake inhibitor (NDSRI) in development for treatment of attention-deficit/hyperactivity disorder (ADHD). The effect of CTN on cardiac repolarization from a thorough QT (TQT) trial is reported.

Methods. In this double-blind, placebo (PBO)- and active-controlled, 3-period crossover TQT trial, healthy adults (18-65 years) were randomized to dosing sequences including CTN (800 mg suprathreshold dose: 4 x 100 mg tablets in the morning and 5 hours later), CTN PBO (4 PBO tablets in the morning and 5 hours later), and active control moxifloxacin (400 mg + CTN PBO in the morning and CTN PBO 5 hours later). Morning doses were separated by 72 hours. Plasma was collected and data were extracted from continuously recorded ECGs for 24 hours following dosing. Effects on ECG parameters (QT interval with Fridericia correction factor [QTcF], PR and QRS intervals, and T- and U-wave morphology), and heart rate (HR) were assessed. The primary analysis was C-QTc, the relationship between drug concentration and PBO-corrected change from baseline in QTcF ($\Delta\Delta\text{QTcF}$). Categorical analyses of ECG parameters were conducted for changes in QTcF, PR, and QRS intervals and in HR.

Results. Of 30 participants enrolled, 56.7% were male and 86.7% were White. Mean (SD) age was 37.6 (14.5) years; mean (SD) BMI was 26.4 (3.4) kg/m². The slope (90% CI) of the C-QTc relationship for CTN was -0.001 (-0.003 , 0.00002) msec/[ng/mL] and not significant. The predicted $\Delta\Delta\text{QTcF}$ (90% CI) at the geometric mean C_{max} of CTN 800 mg was -2.72 (-6.92 , 1.48) msec. A significant slope (90% CI) of the C-QTc relationship for moxifloxacin (0.004 [0.002 , 0.006] msec/[ng/mL]) and a predicted $\Delta\Delta\text{QTcF}$ (90% CI) at the geometric mean C_{max} of moxifloxacin 400 mg above 5 msec (11.75 [8.25 , 15.24]) confirmed assay sensitivity. No $\Delta\Delta\text{QTcF} \geq 10$ msec was observed for CTN at any postdose time point; all upper limits of 90% CIs of