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, MD[1], Zach Lease[2], Jordan Richardson[2], Ashley Brown[2] and Ellen O Neill[2]

[1]University of Missouri-Columbia, Columbia, MO and [2]Undergraduate 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 present 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 supratherapeutic 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 (ΔΔQTcF). 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/m^2. 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 ΔΔQTcF (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 ΔΔQTcF (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 ΔΔQTcF ≥10 msec was observed for CTN at any postdose time point; all upper limits of 90% CIs of

https://doi.org/10.1017/S1092852924001937 Published online by Cambridge University Press