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

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

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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

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ΔΔQTcF were <10 msec. The by-time-point analysis showed the maximum least squares mean difference in ΔQTcF (90% CI) between CTN and PBO was 1.64 (−1.40, 4.68) msec at 24 hours postdose. No CTN-treated participants had a QTcF increase of >30 msec; no relevant increases in PR or QRS interval or HR were observed. Four participants had >25% decrease in HR and <50 beats per minute. No abnormal U waves were observed; 1 participant had abnormal T-wave morphology. No serious TEAEs or deaths were reported. The most frequently reported TEAEs with CTN were nausea (24.1%), dizziness (24.1%), and decreased appetite (13.8%).

Conclusions. In this TQT trial, centanafadine, a potential first-in-class NDSRI in development for treatment of ADHD, had no clinically meaningful effect on cardiac repolarization and was generally safe and well tolerated.

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Change in Depressive Symptoms Following Esketamine Initiation among Patients with Treatment-Resistant Depression in a Real-World Setting

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Introduction. Treatment-resistant depression (TRD) is commonly defined as non-response to ≥2 antidepressant treatment courses of adequate doses and durations in the current episode in patients with major depressive disorder (MDD). Esketamine (ESK) nasal spray was approved by the Food and Drug Administration in March 2019 for the treatment of TRD in adults in conjunction with an oral antidepressant (AD). This study assessed changes in depressive symptoms following ESK initiation among patients with TRD in a real-world setting.

Methods. The study was a retrospective longitudinal observational cohort study of adults with TRD who initiated esketamine treatment between March 2019 and June 2022. Data were sourced from the PremiOM™ MDD Dataset (OM1, Boston, MA), a continuously updated cohort of over 440,000 patients with MDD in the United States with linked claims and electronic medical record data. Patients were classified as having TRD if they had ≥1 diagnosis of MDD during the 6 months prior to or on the index date (defined as ESK initiation) and a record of ≥2 unique ADs of adequate dose and duration at any time prior to the index date within the same major depressive episode (MDE; defined as no clean period of ≥180 days without ADs and/or MDD diagnoses). The Patient Health Questionnaire-9 (PHQ-9) was used to measure depressive symptoms. A machine learning model was used to estimate PHQ-9 scores for patients with no documented scores. The latest PHQ-9 score among questionnaires administered in the six months prior to or on the date of first ESK treatment was used as the baseline score. Baseline scores were compared to the latest scores in the 0-3-month and 3-6 month windows after first ESK treatment. A sensitivity analysis excluding the estimated scores was conducted. Marginal models were used to test for differences in post-treatment scores relative to baseline.

Results. The study cohort included 163 patients with a mean age of 49.5 years (standard deviation [SD]=15.4). Most patients were female (58.3%). At baseline, the mean PHQ-9 score was 15.0 (SD=6.7) and 55.8% of patients had either moderately severe or severe depression (PHQ-9 ≥15). Patients experienced statistically significant reductions in PHQ-9 scores of 2.9 points (95% CI: 1.7 to 4.1, p<0.001) in the 0–3-month interval and 4.4 points (95% CI: 3.2 to 5.6, p<0.001) in the 3–6-month interval relative to baseline. The percentage of patients with moderately severe or severe depression (PHQ-9 ≥15) decreased to 34.4% at the 0-3 month interval and 20.9% at the 3-6 month interval. Results were consistent when estimated PHQ-9 scores were excluded.

Conclusions. Among patients with TRD in a real-world setting, PHQ-9 scores significantly decreased in the 6 months following initiation of ESK treatment. Further investigation of longer-term effectiveness of ESK and among key subgroups is warranted.

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Kandinsky Clerambault Syndrome Manifesting as Tinnitus

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Introduction. Tinnitus not heretofore been described as the only manifestation of delusional possession in Kandinsky-Clerambault syndrome. Such a case is presented.

Methods. Case Report: A 70-year-old left handed (pathological) man, eight years prior to presentation, noted gradual onset of decreased hearing and high- pitched constant tinnitus AU made worse with stress. Initially only present in quiet, it intensified, ultimately present in all situations, even with ambient background noise. He believed that the Devil was inside of his head, had been there for many years, and was making his life unbearable by subjecting him to the tinnitus. Other than the tinnitus, the devil did not cause any other symptoms, nor did it communicate with him in any fashion. In an effort to eliminate the Devil-induced tinnitus, he twice attempted suicide through self-strangulation. The tinnitus persisted despite treatment with mirtazapine and lumateperone.

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