EPP0561

Who Is Right? Behavioral Problems from the Perspectives of Parents and Children with ADHD symptoms

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Introduction: Diagnosing behavioral problems in children and adolescents, which include conduct symptoms, anxiety, or somatic complaints, is frequently based on subjective perceptions and interviews with family or caregivers. However, current theoreticians and practitioners of systemic theory are increasingly emphasizing that there are multiple subjective narratives about oneself, the world, and one's symptoms. The question is whether these narratives are equivalent, and if not, under what circumstances do they diverge?
Objectives: The study aimed to investigate whether the perception of behavioral problems among young adolescents with ADHD aligns with their parents' perspective, and whether family bonding is a factor in this association.
Methods: The analytic sample comprised about 200 children, aged 10-14 years, and their parents, mostly coming from well-situated families. The data were collected as a part of the NeuroSmog project. The variables were measured by the Child Behaviour Checklist (CBCL), the Youth Self Report (YSR), the Family Adaptation and Cohesion Evaluation Scales (FACES-IV). The structural equation modelling (SEM) to analyse data was used. The models were also stratified by age, sex, and social status.
Results: There is a significant difference between the perspectives of parents and children regarding the level of behavioral problems. Family bonding is associated with behavioral problems among children, but this relationship is only evident from their perspective.
Conclusions: The perception referring to family narratives has the most significant impact on individual functioning.

Disclosure of Interest: None Declared

Depressive Disorders

EPP0564

Long-term safety and frequency of repeat zuranolone treatment in patients with major depressive disorder rolling over from the randomised CORAL Study into the open-label SHORELINE Study

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Introduction: Zuranolone (ZRN) is a positive allosteric modulator of both synaptic and extrasynaptic gamma-aminobutyric acid type A receptors and a neuroactive steroid approved as an oral, once-daily, 14-day treatment course for adults with postpartum depression in the US and under investigation for adults with major depressive disorder (MDD). The randomised, double-blind, placebo-controlled, Phase 3 CORAL Study assessed the efficacy and safety of ZRN 50 mg vs placebo, each co-initiated with an open-label standard-of-care antidepressant (ADT). Patients who completed CORAL could roll over into open-label SHORELINE, which assessed the safety and tolerability of ZRN 50 mg and need for repeat treatment courses in adults with MDD.
Objectives: To assess the safety and tolerability (primary endpoint) and need for repeat ZRN 50 mg treatment courses (secondary endpoint) in adults with MDD who previously enrolled in CORAL.
Methods: CORAL enrolled adults (18–64 years) with MDD and 17-item Hamilton Rating Scale for Depression (HAMD-17) total score ≥24. After completing the 6-week CORAL Study, patients who enrolled in SHORELINE could enter a 46-week observation period to assess the safety and need for 14-day repeat ZRN treatment course(s), with a total of ≤4 repeat treatment courses permitted. Patients were screened every 2 weeks with the 9-item Patient Health Questionnaire, and scores ≥10 prompted a HAMD-17 assessment within 1 week. Patients with HAMD-17 total score ≥20 were eligible for repeat ZRN course(s) ≥8 weeks after completing the prior ZRN treatment course.
Results: Among the 190 patients from CORAL who rolled over into SHORELINE and received ≥1 ZRN treatment course in either study, 133 (70.0%) had received ZRN+ADT and 57 (30.0%) received placebo+ADT in CORAL. Overall, 118 rollover patients received ≥1 open-label ZRN treatment course in SHORELINE. For patients who received ≥1 ZRN treatment course in either study, 76.8% received 1 (54.2%; 103/190) or 2 (22.6%; 43/190) total ZRN treatment courses across both studies in up to 1 year in study. The most common (>5%) treatment-emergent adverse events (TEAEs) during treatment and 14 days following the last ZRN dose were somnolence (16.1% of patients), dizziness (8.5%), headache (8.5%), fatigue (7.6%), sedation (5.9%), and nausea (5.1%); study-period TEAEs (73.7%; 87/118) for the majority of patients were mild/moderate (69.5%; 82/118) in severity and occurred primarily during the treatment period (58.5%; 69/118). No signals for increased suicidal ideation/behaviour were observed.
Conclusions: Safety and tolerability among rollover patients were consistent with previous studies; most of the TEAEs reported by adults with MDD who received ZRN were mild/moderate in severity. Most patients who rolled over from CORAL to SHORELINE received ≤2 total treatment courses in up to 1 year in study.

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