Abstract

Introduction. Tardive dyskinesia (TD) is a persistent and potentially disabling movement disorder associated with exposure to antipsychotics and other dopamine receptor blocking agents. Effective and comprehensive treatment of TD requires reducing patients' abnormal involuntary movements without disrupting their psychiatric stability. This can be especially challenging when patients have complex psychiatric conditions (e.g., >1 psychiatric diagnosis) and are taking multiple medications. Valbenazine, a highly potent and selective vesicular monoamine transporter 2 (VMAT2) inhibitor, is approved for the once-daily treatment of TD. This post hoc analysis of two long-term studies (KINECT 3, KINECT 4) was conducted to evaluate changes in psychiatric status and clinician- and patient-reported treatment success in study participants who received valbenazine (40 or 80 mg) for 48 weeks.

Methods. Data from KINECT 3 and KINECT 4 were pooled and analyzed in participants categorized by their primary psychiatric diagnosis: schizophrenia/schizoaffective disorder ("SCHZ") or mood disorder ("MD"). Concomitant medications needed for managing these and other psychiatric or medical conditions were allowed. Treatment success was defined as achieving a rating of "much improved" or "very much improved" at Week 48, as assessed using the Clinical Global Impression of Change-Tardive Dyskinesia (CGI-TD) and Patient Global Impression of Change (PGIC). Psychiatric stability was monitored using the following scales: Positive and Negative Syndrome Scale (PANSS) and Calgary Depression Scale for Schizophrenia (CDSS) in the SCHZ subgroup; Young Mania Rating Scale (YMRS) and Montgomery-Åsberg Depression Rating Scale (MADRS) in the MD subgroup. Suicidal ideation/behavior was monitored using the Columbia-Suicide Severity Rating Scale.

Results. More than 75% of study participants in the SCHZ subgroup achieved treatment success with valbenazine, based on clinician assessment (CGI-TD, 79.7%) and patient self-report (PGIC, 78.0%). Mean changes from baseline to Week 48 for PANSS scores (positive symptoms [-0.7], negative symptoms [-0.6], general psychopathology [-1.9], total [-3.2]) and CDSS total score (-0.5) indicated maintenance of psychiatric stability in the SCHZ subgroup. Similar treatment success rates were found in the MD subgroup for both CGI-TD (77.6%) and PGIC (84.5%), with mean changes from baseline in YMRS total score (-1.0) and MADRS total score (+0.3) indicating psychiatric stability was maintained. No emergence of suicidal ideation/behavior was observed during the studies.

Conclusions. Pooled analyses from two 48-week studies indicate that long-term treatment of TD with once-daily valbenazine resulted in substantial clinician- and patient-reported global improvements in TD, while psychiatric stability was maintained regardless of primary psychiatric condition.

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Conducting Women's Groups in the Inpatient Unit: Empowering a High-Risk Population by Preventing Unplanned Pregnancies

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Abstract

Introduction. Women with mental illness are 5x more likely to experience an unplanned pregnancy due to lower rates of effective contraception use; they also experience higher rates of adverse pregnancy outcomes. Education about women's reproductive health and family planning are not routinely offered in inpatient mental health and addiction treatment settings.

Methods. Weekly women's groups on the inpatient psychiatry unit were led by psychiatry residents who were trained and provided a script. Groups focused on structured contraception education followed by an open-discussion format.

Data collected included the percentage of women with history of contraception use, child protective service involvement, unplanned pregnancies, abortions, and percentage of women who found the group helpful. Special care was taken to discuss contraception as a tool for empowering women to make their own decisions about their contraceptive needs.

Results. Thirteen sessions were conducted, and attendance among women on the inpatient unit was 42%. Out of the 32 patients who participated, 100% found the group beneficial and responded they would share information they learned with women outside the group. 26.4% self-identified as using contraception, 50% had unplanned pregnancy, 23.6% have had an abortion, and 26.4% have had child protective services involvement.

Dissemination of contraceptive information in these women's groups effectively led women to consider options that were available to them and seek contraceptive methods that were appropriate to their situation. Women reported they gained a better understanding of the medical, emotional, and financial implications of unplanned pregnancies. The groups were conducted in an open-discussion format that allowed women to participate in shared experiences; in many cases, the discussions were therapeutic. Feedback from patients and unit staff was positive. Many patients requested further groups to discuss issues women face, such as domestic violence and experiences as a mother.

Conclusions. Conducting women's groups on the inpatient unit is critical in view of the poor access to healthcare that vulnerable women who seek inpatient psychiatric care experience. The groups on the inpatient unit are unique because it is often the only time these women have an opportunity for crucial, gender-specific preventative healthcare. These groups should further

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lead to appropriate referral and follow-up with primary care or women's clinic providers.

Ongoing efforts will be put forth to increase group attendance, to incorporate participation from unit staff, and to build this group into a resident curriculum for group therapy.

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Effects of Viloxazine ER (Qelbree®) on Weight and Height Trajectories: Interim Results From a Long-term, Open-Label Extension Trial in Pediatric ADHD

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Abstract

Introduction. Stimulant medications and the norepinephrine reuptake inhibitor, atomoxetine, contain warnings regarding potential for slowing of growth (weight and height) in children and recommend monitoring of growth when using these medications for pediatric ADHD. Viloxazine ER (viloxazine extended-release capsules; Qelbree®), is a nonstimulant medication, FDA-approved for ADHD in adults and children (≥6 years of age). Viloxazine ER has pharmacologic differences from other approved ADHD medications and might not affect growth in the same manner as other therapies. A safety analysis was conducted to determine viloxazine ER effects on growth and weight trajectories in pediatric ADHD patients with long-term use.

Methods. Data were evaluated from five DBPC, phase 2 and 3 clinical trials and an ongoing long-term, open-label extension (OLE) trial (NCT02736656). Viloxazine ER doses during the trials ranged from 100–400 mg/day (age 6–11 yrs) or 100–600 mg/day (age 12–17 yrs). Height and weight were evaluated pre-treatment in both DB and OLE every 3 months during the OLE, and converted into percentile values and corresponding z-scores using Centers for Disease Control (CDC) normal growth curves to evaluate growth trajectories. The incidence of weight- and growth-related adverse events (AEs) terms were also evaluated.

Results. At the time of data cut (31 July 2019), 1097 subjects had received at least one dose of viloxazine ER in the OLE (66% male, mean (SD) age 10.8 (3.06), 59% age 6–11, mean (SD) BMI 18.8 (3.42) kg/m^2, height 146.7 (17.46) cm, weight 42.1 (16.01) kg. During the OLE, mean (SE) z-scores for height and weight were between -1 and 1 for all timepoints, indicating growth measures within a normal range compared with expected values. Similar results were observed when weight and height were analyzed by sex and by age categories. Growth data were available for 338 subjects at 12 months. Among these subjects, the mean (SD) change from baseline in weight-for-age z-score was -0.2 (0.5) and height-for-age z-score was -0.14 (1.1). Adverse events relevant to weight and growth in the DB trials (incidence ≥ 1%) included (viloxazine ER [100–600 mg/day] n=1117 vs. placebo n=487): decreased appetite (8.1% vs. 0.8%), nausea (5.1% vs. 2.7%), vomiting (4.7% vs. 1.4%), weight increase (0.4% vs. 1.2%) and weight decrease (1.3% vs. 0.4%), and increased appetite (0.2% vs. 1.2%). During the OLE weight-and growth-related AEs reported for ≥ 1% of subjects were: decreased appetite 5.8%, vomiting 2.7%, nausea 2.4%, weight decreased 2.3%, and weight increased 2.0%.

Conclusions. Over time, pediatric subjects taking viloxazine ER, on average, maintained normal weight and height relative to the CDC's child growth charts. However, because Qelbree may affect weight, it is recommended that healthcare providers check patient weight before starting and while using viloxazine ER.

Funding. Supernus Pharmaceuticals, Inc.

Impact of Viloxazine Extended-Release Capsules (Qelbree®) on Executive Function in Adults With ADHD During an Open-Label Extension Study

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Abstract

Introduction. Executive function deficits (EFDs) are associated with attention-deficit/hyperactivity disorder (ADHD). Viloxazine ER (viloxazine extended-release capsules; Qelbree®) is a novel, nonstimulant, FDA-approved treatment for ADHD in persons ≥6 years of age. In a Phase 3, double-blind (DB), placebo-controlled trial in adults (NCT04016779), viloxazine ER-treated subjects exhibited significant improvement in both ADHD core symptoms (inattention and hyperactivity/impulsivity) compared to placebo. In addition, improvement in EFDs was observed in subjects using the Behavior Rating Inventory of Executive Function – Adult Version (BRIEF-A, Self-report), a 75-item scale that assesses aspects of executive function (Metacognition Index [MI]) and problems with self-regulation (Behavioral Regulation Index [BRI]) and overall functioning (Global Executive Composite [GEC]). At Week 6 in DB trial, a statistically significant greater reduction (improvement) was observed in viloxazine ER-treated subjects compared to placebo in the GEC and MI, but not in the BRI. Here, preliminary results of further BRIEF-A assessments in adults during an ongoing open-label extension (OLE) safety trial (NCT04143217) are presented.

Methods. Subjects complete the BRIEF-A at baseline and at Week 6 in the DB trial, and at Week 4 and every 8 weeks thereafter in the OLE trial. Subjects rate each BRIEF-A item on a 3-point scale (1=Never, 2=Sometimes, or 3=Often) based on the last month.

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