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.

Funding. No Funding

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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Raw scores for GEC, MI, and BRI (sum of 70, 40, and 30 items, respectively) were converted to a T-score (mean=50, standard deviation=10; T-score ≥ 65 considered abnormally elevated) and then to a change from (DB) baseline (CFB) T-score. The mean [±SE] CFB T-score was calculated for the GEC, MI, and BRI by study OLE visit, and the mean last on-study OLE visit was analyzed using a paired t-test.

Results. In the OLE trial, 157 subjects received viloxazine ER (first subject dosed, 24 Jan 2020; data cut, 30 MAR 2021). The mean [±SE (n)] T-score at DB baseline between placebo and viloxazine ER groups was similar for GEC [70.9 ± 0.82 (177) and 71.0 ± 0.77 (173)], MI [73.6 ± 0.86 (178) and 74.0 ± 0.83 (173)], and BRI [63.9 ± 0.85 (177) and 63.6 ± 0.77 (174)]. The CFB T-score decreased across OLE visits in all three measures. At last on-study OLE visit, the mean [±SE (n)] CFB T-score was significantly improved for the GEC [-12.4 ± 1.23 (121); P<0.0001], the MI (-12.6 ± 1.30 (121); P<0.0001], and the BRI [-10.0 ± 1.04 (122); P<0.0001]; median viloxazine ER dose was 400 mg/day.

Conclusions. Following the DB trial, improvement in executive function continued during viloxazine ER treatment in adults throughout the OLE trial, including a significant improvement at subjects' last on-study visit for overall functioning (GEC) and both indices (MI and BRI). Overall, the results suggest adults with ADHD may show improvement in executive function with viloxazine ER treatment.

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Reliability of the Clinician's Tardive Inventory (CTI)

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Abstract

Objectives. Currently utilized clinician-rated symptom scales for tardive dyskinesia (TD) have not kept up with the expanding spectrum of TD phenomenology. The objective of this study was to develop and test the reliability of a new instrument, the CTI.

Methods. A movement disorder neurologist devised the outline of the scale. A steering committee (four neurologists and two psychiatrists) provided revisions until consensus was reached. The resulting instrument assesses frequency of abnormal movements of the eye/eyelid/face, tongue/mouth, jaw, limb/trunk, complex movements (e.g., handwringing, self-caressing), and vocalizations. The CTI rates symptoms from 0–3 with 0 = absent, 1 = infrequent/intermittent or only present with activating maneuvers, 2 = frequent intermittent, brief periods without movements, 3 = constant or nearly constant. Functional impairments including activities of daily living (ADL), social impairment, symptom bother, and harm are rated 0–3 with 0 = patient is unaware or unaffected, 1 = symptoms mildly impact patient, 2 = symptoms moderately impact patient, 3 = symptoms severely impact patient. Following institutional review board approval, the CTI underwent inter-rater and test-retest reliability testing. Videos of patient TD examinations were obtained and reviewed by two movement disorder specialists to confirm the diagnosis of TD by consensus and the adequacy to demonstrate a TD-consistent movement. Vignettes were created to include patients' symptom descriptions and functional, social, or occupational impairments/limitations. Four clinicians rated each video/vignette. Selected videos/vignettes were also subject to an intra-rater retest. Interrater agreement was analyzed via 2-way random-effects interclass correlation (ICC) and test-retest agreement assessment utilizing Kendall's tau-b.

Results. 45 video/vignettes were assessed for interrater reliability, and 16 for test-retest reliability. ICCs for movement frequency were as follows: abnormal eye movement .89; abnormal tongue/mouth movement .91; abnormal jaw movement .89; abnormal limb movement .76; complex movement .87; abnormal vocalization .77; and functional impairments including harm .82; social embarrassment .88; ADLs .83; and symptom bother .92. Retests were conducted on mean (SD) 15 (3) days later with scores ranging from .66–.87.

Conclusions. The CTI is a new instrument with good reliability in assessing TD symptoms and functional impacts. Future validation study is warranted.

Funding. Neurocrine Biosciences

Mental Health Issues for Frontline Hospital Staff During Height of Covid Pandemic 2020

Diego Garces Gross, Yonatan Kaplan, Geoffrey Talis and Cheryl A. Kennedy

Abstract

Introduction. When the SARS-Cov2 virus hit the New York and New Jersey metropolitan area in Spring 2020, hospitals and hospital workers were hit hard with a new unknown pathogen that either killed people or made them very ill. There were large numbers of severely ill patients that strained resources. Hospital workers had extraordinary stress with multiple additional patients, the need to use personal protective equipment (PPE) in short supply, and faced with a pathogen that had no treatments beyond care and support initially.

Methods. We surveyed our hospital workers in late Spring 2020 to identify the main stressors and find out what measures were helpful. An online anonymous survey included questionnaires about sleep, mood, outside stressors, helpful measures, and how

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