Single Traumatic Injury Lifts Psychopathology Risk

BY DAMIAN McNAMARA

ISTANBUL, TURKEY — Flexibly dosed ziprasidone displayed favorable safety and efficacy in children and adolescents with bipolar I disorder in a double-blind, placebo-controlled, randomized clinical trial.

The study involved 238 bipolar I patients aged 6-17 years in a manic or mixed episode who were randomized 2:1 to ziprasidone (Geodon) at 60-160 mg/day or placebo at 36 U.S. centers. Sixty-five percent of patients in the ziprasidone arm and 58% assigned to placebo completed the 4-week trial, Dr. Robert L. Findling said at the annual congress of the European College of Neuropsychopharmacology.

The primary study end point was change in the Young Mania Rating Scale total score over the course of 4 weeks. The ziprasidone group had a mean 13.8-point drop, significantly greater than the 6.2-point decrease with placebo, according to Dr. Findling, professor of psychiatry and pediatrics at Case Western Reserve University, Cleveland.

The secondary end point was change over time in the Clinical Global Impressions-Severity score: a mean reduction of 1.43 points from baseline in the ziprasidone group, compared with a 0.74-point decrease in controls. The efficacy curves began separating within the first week, while ziprasidone was still being titrated toward a target dose of 60-80 mg/day in children weighing less than 45 kg, or 120-160 mg in those weighing more. The second-generation antipsychotic was given twice daily with food.

Side effects of ziprasidone were similar to those encountered in adult therapy. Sedation occurred in one-third of patients; somnolence in one-quarter; and nausea, fatigue, and dizziness each in 11%-13% of patients.

Weight gain occurred in one patient in each study arm. Prolongation of the QT interval on ECG was noted in a single patient in the ziprasidone arm, whose peak was 478 milliseconds (msec). The mean increase in QT interval in the ziprasidone group at 4 weeks was 8.3 msec, compared with a 2.9 msec decrease in the placebo arm.

This is an important study because of the limited safety and efficacy data available on the use of antipsychotic agents among pediatric patients, along with the documented importance of initiating treatment as early in the disease course as possible to achieve the best possible outcomes, according to the psychiatrist.

The trial was supported by Pfizer Inc., manufacturer of ziprasidone. Dr. Findling disclosed having received research grants and/or serving as a consultant to or on the speakers bureau for Pfizer and roughly a dozen other pharmaceutical companies.

Ziprasidone Appears Safe, Effective in Pediatric Bipolar

BY BRUCE JANCIN

ATLANTA — Parental distress can prolong and worsen a child’s experience after a shared traumatic event, according to a survey of 183 parents who survived the tsunami that struck Southeast Asia in 2004.

The degree of parental exposure to the tsunami did not appear to be a significant factor in the distress experienced by their offspring. However, a parental posttraumatic stress reaction to the event significantly predicted posttraumatic stress disorder (PTSD) in their child at 6 months (odds ratio, 3.89), Dr. Grete Dyb said.

“The first thing a child would do is look to the parent to see if they are scared [and think] if they run, I will run,” Dr. Dyb said at the annual meeting of the International Society for Traumatic Stress Studies.

Children whose parents had a low level of symptoms were resilient even if they had high exposure to an event, Dr. Dyb said.

There were approximately 4,000 Norwegians, including about 1,000 children, on vacation in Southeast Asia on Dec. 26, 2004. The tsunami killed more than 200,000 people, including 58 Norwegians adults and 26 children.

Dr. Dyb and her colleagues interviewed 183 parents about their reactions and experiences, and those of their 319 children and adolescents, 6 months after they returned to Norway. Parents completed the Child Stress Reaction Checklist on behalf of their children. The level of symptoms was rather low in offspring at 6 months, including 22% who were nonsymptomatic, said Dr. Dyb, a researcher at the Norwegian Centre for Violence and Traumatic Studies in Oslo.

Overall, parents reported a low mean level of symptoms, although only 2% said they were nonsymptomatic.

“But we did see a dose-response between objective exposure and subjective response,” Dr. Dyb said. A total of 86 parents and 133 children were in physical danger that day; including 35 parents and 45 children caught by the rushing water. A total 27 parents and 24 children were physically injured. Another 112 parents and 162 children witnessed serious physical injuries in others.

A total of 30 parents and 62 children were separated from their families during the natural disaster.

Child objective exposure also was a predictor of PTSD (OR, 0.79). This factor contributed significantly to PTSD variance in children, Dr. Dyb said.

Sixty percent of respondents were mothers, and 52% of their children and adolescents were girls. The mean age of children was 12 years (range, 6-18 years). The study included siblings in 57% of the cases.

A meeting attendee commented that parents might have hidden their immediate reactions to the disaster to protect their child. Dr. Dyb said that was possible, and added: “Immediate reactions in children were reported by parents, so we worried also about their capacity to report how scared their children were.”

Another attendee suggested interviewing children about their parents’ reactions. “We didn’t ask children about that—that we should have done,” Dr. Dyb said.

Dr. Dyb said she has another study coming out that demonstrates the child’s age plays a role in development of PTSD symptoms. “We had a range of age and development in these children [in the current study]. We thought we had big sample, but we needed more power to look at the age effect.”

Post-Tsunami Parent Stress Predicts Child PTSD Risk

BY DAMIAN McNAMARA

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