Fluvoxamine for Children and Adolescents With Obsessive-Compulsive Disorder: A Randomized, Controlled, Multicenter Trial.(Statistical Data Included)

ABSTRACT

Objective: To determine the safety and efficacy of fluvoxamine for the treatment of children and adolescents with obsessive-compulsive disorder (OCD) with a double-blind, placebo-controlled, multicenter study.

Method: Subjects, aged 8 to 17 years, meeting DSM-III-R criteria for OCD were recruited from July 1991 to August 1994. After a 7- to 14-day single-blind, placebo washout/screening period, subjects were randomly assigned to fluvoxamine 50 to 200 mg/day or placebo for 10 weeks. Subjects who had not responded after 6 weeks could discontinue the double-blind phase of the study and enter a long-term, open-label trial of fluvoxamine. Analyses used an intent-to-treat sample with a last-observation-carried-forward method.

Results: Mean Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS) scores with fluvoxamine were significantly lower (p < 0.05) than those with placebo at weeks 1, 2, 3, 4, 6, and 10. Significant (p < 0.05) differences between fluvoxamine and placebo were observed for all secondary outcome measures at all visits. Based on a 25% reduction of CY-BOCS scores, 42% of subjects taking fluvoxamine were responders compared with 26% taking placebo. Forty-six (19 fluvoxamine, 27 placebo) of 120 randomized subjects discontinued early. Adverse events with a placebo-adjusted rate greater than 10% were insomnia and asthenia.


Key Words: fluvoxamine, obsessive-compulsive disorder, psychopharmacology.

Obsessive-compulsive disorder (OCD) is a neuropsychiatric condition that commonly presents during childhood or adolescence (Adams, 1973; Pauls et al., 1995; Rapoport, 1989; Riddle et al., 1990; Swedo et al., 1989). For adults with OCD, a wealth of clinical studies support the efficacy of treatment with medications, specifically, the serotonin reuptake inhibitor clomipramine (DeVeaugh-Geiss et al., 1992) and the selective serotonin reuptake inhibitors (SSRIs) fluvoxamine (Goodman et al., 1989), fluoxetine (Tollefson et al., 1994), sertraline (Greist et al., 1995), and paroxetine (Dunbar et al., 1995), as well as cognitive-behavioral psychotherapies.

Over the past decade, emerging clinical literature supports the efficacy of various treatments for childhood or adolescence (Adams, 1973; Pauls et al., 1995; Rapoport, 1989; Riddle et al., 1990; Swedo et al., 1989). For adults with OCD, a wealth of clinical studies support the efficacy of treatment with medications, specifically, the serotonin reuptake inhibitor clomipramine (DeVeaugh-Geiss et al., 1992) and the selective serotonin reuptake inhibitors (SSRIs) fluvoxamine (Goodman et al., 1989), fluoxetine (Tollefson et al., 1994), sertraline (Greist et al., 1995), and paroxetine (Dunbar et al., 1995), as well as cognitive-behavioral psychotherapies.

The hypothesis was that fluvoxamine was more effective than placebo for the treatment of children and adolescents with OCD. The study, approved by the institutional review board at each site, consisted of three periods: screening, titration, and maintenance. The 7- to 14-day screening period was used to evaluate subjects for suitability, to provide a washout of prior psychotropic medications, and to screen out rapid placebo responders. During this period, subjects who met entry criteria were given single-blind placebo and were evaluated for eligibility by physical examination, laboratory tests, electrocardiogram (EKG), symptom rating scales, and vital signs. At the conclusion of the screening period, baseline evaluations (i.e., symptom severity ratings) were obtained and eligible subjects were randomly assigned to the 10-week, double-blind study drug (baseline, day 1).
Subjects were permitted to withdraw from the study after 6 weeks of double-blind treatment if clinical improvement was considered insufficient and to begin treatment with active drug in a 1-year open-label extension phase. The decision about "insufficient" improvement was made by the investigator based on clinical judgment and input from the subject and parent(s).

Subject Eligibility

Male or female subjects, aged 8 to 17 years, were eligible if they had a DSM-III-R (American Psychiatric Association, 1987) diagnosis of OCD which had been present for more than 6 …

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