CASE REPORT

Mania may be associated with modafinil in therapeutic doses

**Patient:** Male (17 y/o)

**Medications:** Modafinil (Provigil), methylphenidate (Concerta)

**Comment:** A 17-year old boy, diagnosed with narcolepsy at the age of 14, was first prescribed modafinil (400 mg/day) for 1 year, switched to methylphenidate (40 mg/day) for 2 years, and then returned to modafinil (400 mg/day). The medication was switched due to complaints of irritability and lack of efficacy for treating the sleep attacks. At some point, the subject experienced manic symptoms characterized by increased irritability, flights of fancy and sexual excitation which caused friction with family members, and resulted in a severe fight.

When he off the psychostimulant medication (i.e., modafinil), the patient appeared sad, anhedonic and withdrawn. When the medication was switched back to modafinil (400 mg/day) the manic symptoms reoccurred, and the subject experienced “self-referential thinking” and suspiciousness. A full manic episode developed, which included insomnia, psychomotor agitation and mood-incongruent psychosis. The subject experienced delusions of persecution and visual hallucinations. He was then hospitalized and modafinil was discontinued. His mania required pharmacological treatment that began after written consent had been obtained from the patient and his parents.

According to the authors, this may be the first report of a patient experiencing mania while undergoing treatment with modafinil in therapeutic doses. Although an independent psychiatric disorder cannot be ruled out, the authors suggest that patients receiving modafinil and other psychostimulants for narcolepsy be carefully monitored.

Vorspan F, et al.: Mania in a boy treated with modafinil for narcolepsy. Am J Psychiatry 2005; 162(4):813-814. [Editor’s note: The case report as written is difficult to interpret as to the timing of the manic episodes. My understanding is that the first manic episode was on methylphenidate and the second episode was while on modafinil. — Henrietta L. Leonard, M.D.]

NEWS NOTES

**FDA requests further data on anticonvulsants and suicide**

The New York Times has reported that the Food and Drug Administration (FDA) has requested the manufacturers of epilepsy drugs to reexamine their clinical trial data to determine whether the drugs increase patients’ risk of suicide. The request follows a petition by a personal injury attorney who claims that Pfizer’s anticonvulsant Neurontin (gabapentin) resulted in a number of suicides and suicide attempts among his clients. Pfizer and 13 other manufacturers of epilepsy drugs have six months to analyze the results of their clinical trials. The Update will continue to monitor and report on these developments. [www.nytimes.com]

**Methylphenidate transdermal patch for ADHD: positive clinical data**

Results from two (7-week) clinical trials show that a methylphenidate transdermal system (MTS) was well tolerated in treatment for children with attention-deficit hyperactivity disorder (ADHD). Both studies — a phase 2 study (N=79) and a phase 3 study (N=268) — examined MTS in children aged 6 to 12 years, previously diagnosed with ADHD. MTS (formerly referred to as METHYPATCH) is being developed by Shire Pharmaceuticals Group plc and Noven Pharmaceuticals Inc. According to Shire, the results demonstrate that “MTS has the potential to provide significant benefits for children with ADHD, especially those that have difficulty taking oral medications and those that find a once-a-day patch more appropriate for their lifestyle.” The FDA will review an amendment, which includes the new trial results, to the product’s New Drug Application within 6 months after submission. Further trial results will be released by Shire in May 2005. [www.shire.com]

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