

Clinical trial examines safety, effectiveness of drug to treat binge eating disorder

January 14 2015

At some doses, the medication lisdexamfetamine dimesylate, a drug approved to treat attention-deficit/hyperactivity disorder, was effective compared with placebo in decreasing binge-eating (BE) days in patients with binge-eating disorder (BED), a public health problem associated symptoms of mental illness and obesity and for which there are no approved medications, according to a study published online by *JAMA Psychiatry*.

BED is characterized by recurrent episodes of excessive food consumption accompanied by a sense of loss of control and psychological distress. Cognitive behavioral therapy, as well as psychotherapy, can reduce BE behavior but implementation of these treatments has not been widespread. Consequently, many patients with BED are undertreated despite having functional impairments and difficulties in their social and personal lives. The U.S. Food and Drug Administration has not approved pharmacologic treatments for BED, according to background information in the study.

Susan L. McElroy, M.D., of the Research Institute, Lindner Center of HOPE, Mason, Ohio, and coauthors compared lisdexamfetamine with placebo in adults with moderate to severe BED in a <u>randomized clinical trial</u> from May 2011 through January 2012. The study included 259 and 255 adults with BED in safety and intention-to-treat analyses, respectively. The medication was administered in dosages of 30, 50 or 70 mg/day or placebo.



BE days per week decreased in the 50-mg/d and 70 mg/d treatment groups but not in the 30 mg/d treatment group compared with the placebo group, according to the study results. Results also indicate the percentage of patients who achieved four-week BE cessation was lower with the placebo group (21.3 percent) compared with the 50-mg/d (42.2 percent) and 70-mg/d (50 percent) treatment groups.

"In the primary analysis of this study of adults with moderate to severe BED, lisdexamfetamine dimesylate treatment with 50 and 70 mg/d, but not 30 mg/d, demonstrated a significant decrease (compared with placebo) in weekly BE days per week at week 11. Similarly, BE episodes decreased in the 50- and 70-mg/d treatment groups. The one-week BE episode response status was improved in the 50- and 70-mg/d treatment groups, and a greater proportion of participants achieved four-week cessation of BE episodes and global improvement of symptom severity with all lisdexamfetamine dosages. ... Confirmation of these findings in ongoing clinical trials may results in improved pharmacologic treatment for moderate to severe BED," the study concludes.

More information: *JAMA Psychiatry*. Published online January 14, 2015. DOI: 10.1001/jamapsychiatry.2014.2162

Provided by The JAMA Network Journals

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