

A New Drug Treatment for Binge-Eating Disorder: What You Need to Know
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Binge eating disorder (BED) is arguably the most prevalent eating disorder in the United States. Despite its high prevalence, it has only recently been recognized as an official psychiatric diagnosis by the DSM-V. There are not currently any Food and Drug Administration (FDA) approved pharmacological treatments for BED. However, an application is currently under review by the FDA to approve the use of the pharmaceutical agent lisdexamfetamine (brand name Vyvanse) in the treatment of BED. If the FDA approves this medication, it would be the first medication ever approved by the FDA for the treatment of BED.

A study recently came out in JAMA Psychiatry examining the effectiveness and safety of lisdexamfetamine in the treatment of BED. Lisdexamfetamine is already approved by the FDA for the treatment of Attention Deficit/Hyperactivity Disorder (ADHD). The medication inhibits reuptake of dopamine (DA) and norepinephrine and elicits the release of monoamine neurotransmitters. Previous research suggests that binge-eating may be related to dysfunction of the DA and norepinephrine systems. It is hypothesized that lisdexamfetamine may help improve these dysfunctions.

The study examined 260 adult (aged 18-55 years old) participants who were diagnosed with moderate to severe BED, as indicated by at least 3 binge-eating (BE) days per week for the 2 weeks prior to the initial study visit. Participants with any comorbid psychiatric condition (including other eating disorders) and certain medical conditions were excluded from the study. The study was conducted at multiple sites and participants were randomly assigned to either a treatment or placebo group. There were 3 treatment groups who each received a different dosage of lisdexamfetamine (30, 50, or 70 mg). The researchers and participants were unaware ("blind") of which condition participants were in. The treatment was administered over 11 weeks (with participants titrating up to their maximum dosage for the first 3 weeks) and each participant remained in the study for 14 weeks.

Results from this study indicate that participants in the 50mg and 70mg treatment groups (but not the 30mg group) significantly decreased their number of BE days per week and frequency of BE episodes from baseline to week 11 when compared with the placebo group. More participants in the treatment groups experienced cessation of BE episodes for a 4-week period, experienced improvements in symptom severity, and decreased their body weight. In terms of safety assessments, 3.1% of participants discontinued lisdexamfetamine due to a treatment emergent adverse event (TEAE), 1.5% had a serious TEAE, and one participant in the 70mg treatment group died due to methamphetamine overdose (which the researchers considered to be unrelated to the study drug). The authors conclude that the safety

profile was generally consistent with studies of lisdexamfetamine in adults with ADHD.

The study had several limitations including a predominantly female, white (non-Hispanic/non-Latino), and overweight or obese sample that excluded participants with comorbid illnesses. Approximately 50% of people with BED also have a comorbid mood disorder and many also have comorbid medical conditions. These people were not represented in this study, which limits the generalization of study results. The study was also limited by a very short follow-up period (3 weeks) so it is impossible to know the long-term effects and safety profile of this medication in this population. The authors also looked at a large number of outcome measures and did not statistically adjust for multiple analyses, which increases the risk of the statistical error of finding significance by chance.

The authors conclude that this study provides preliminary evidence that lisdexamfetamine may be an effective treatment for moderate to severe BED. They suggest a dose-response relationship (increased efficacy with increasing dosage), which is consistent with the findings of ADHD treatment trials. Despite the promising results from this study, it is important to remember that we also have evidence-based effective non-pharmaceutical treatments (such as cognitive-behavioral therapy) for BED. While medications promise patients the “quick fix” that many are looking for, they also come with the risk of side-effects. Lisdexamfetamine is a schedule II controlled substance with a black box warning about the potential for abuse and dependence.

Reference:

McElroy S., Hudson J., Mitchell J., et al. Efficacy and Safety of Lisdexamfetamine for Treatment of Adults with Moderate to Severe Binge-Eating Disorder. A Randomized Clinical Trial. *JAMA Psychiatry*. Published Online 1/14/15