Semaglutide paired with intensive behavioral therapy showed triple weight loss vs placebo

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A second study of the injectable anti-obesity medication, semaglutide, has confirmed the large weight losses reported in a study earlier this month, establishing the reliability and robustness of this new drug. With

obesity affecting more than 40 percent of American adults, the findings could have a major impact on weight management in primary care and other settings. The study is published today in the *Journal of the American Medical Association*.

The 68-week study was conducted at 41 sites in the United States from August 2018 to April 2020 and was designed to boost total weight loss with semaglutide by combining the medication with a more intensive diet and physical activity program than what was used in the STEP 1 trial, published online February 10th in the *New England Journal of Medicine*. All participants in the new STEP 3 study received 30 sessions of intensive behavioral therapy consisting of diet and physical activity counseling, which was combined with an initial 8-week, 1000-1200 kcal/day meal-replacement diet, consisting of shakes, meal bars, and prepared entrees.

"We wanted to induce a large weight loss with rigorous behavioral therapy and see how much additional weight loss semaglutide could add," said lead author Thomas Wadden, PHD, a professor of psychology in the Department of Psychiatry at the Perelman School of Medicine at the University of Pennsylvania.

The 611 participants in the STEP 3 trial had an average starting weight of 233 pounds with a body mass index of 38 kg/m2. The participants taking semaglutide were given a 2.4 mg dose once weekly. After 68 weeks of treatment, the semaglutide group lost an average of 16 percent of baseline body weight, equal to 37 pounds, compared with 5.7 percent, 14 pounds for those assigned to intensive behavioral therapy combined with placebo. Substantially greater proportions of semaglutide-treated participants (75 percent), compared with placebo (27 percent), achieved weight losses of 10 percent or more of baseline weight.

"These are remarkable weight losses, particularly the one third of

participants who lost 20 percent of baseline weight, a reduction that approaches that achieved with sleeve gastrectomy, a widely used bariatric surgery procedure," Wadden said. "Further study is needed to determine if patients can sustain these substantial losses with long-term use of semaglutide 2.4 mg."

The larger weight losses achieved with semaglutide than with placebo were associated with greater improvements in cardiometabolic risk factors, including changes in waist circumference, systolic blood pressure, hemoglobin A1c, and triglycerides.

"These metabolic benefits and marked improvements in risk factors hold great promise for the prevention and treatment of diabetes and cardiovascular disease," said W. Timothy Garvey, MD, a study co-author and professor of medicine in the Department of Nutrition Sciences at the University of Alabama at Birmingham. "The unprecedented degree of weight loss is also sufficient to prevent and treat other complications of obesity including osteoarthritis, sleep apnea, and non-alcoholic fatty liver disease," he added.

Gastrointestinal side effects were reported by 83 percent of semaglutide participants and included mild-to-moderate nausea and diarrhea that generally improved over time, without the need to discontinue the drug.

Semaglutide is a glucagon-like-peptide 1 (GLP-1) receptor agonist which, at a dose of 1.0 mg once weekly, is approved (as Ozempic) by the U.S. Food and Drug Administration for the management of type 2 diabetes. The higher dose of 2.4 mg, currently being evaluated by the FDA for chronic weight management, appears to affect appetite centers in the brain that control hunger and cravings, leading to a reduction in food and calorie intake. Patients also report feeling full more quickly when eating. The medication is taken once weekly by self-injection under the skin.

"The results with semaglutide appear to be the breakthrough in weight management that health care providers and their patients with obesity have been waiting for," said Wadden. "It's clear that adding semaglutide to intensive behavioral therapy could substantially increase the proportions of patients who lose 10 percent or more of their starting weight, with accompanying improvements in health and mobility."

A question left unanswered by the present study is how much lifestyle counseling is needed with semaglutide to lose an average of approximately 15 percent of baseline weight. Semaglutide-treated participants in the STEP 1 trial lost 14.9 percent of starting weight, with 18 sessions of lifestyle counseling, compared with 2.4 percent for placebo.

"For the placebo-treated participants in STEP 3, the 30 intensive behavioral therapy sessions and meal-replacement diet appeared to increase weight loss by approximately 3 percentage points, as compared with the less intensive lifestyle counseling provided in the STEP 1 trial," Wadden noted. "However, a comparable benefit was not observed in combining rigorous behavioral treatment with semaglutide, suggesting that further study is needed of the optimal program of lifestyle counseling required with semaglutide at the higher dose currently being evaluated."

More information: Thomas A. Wadden et al. Effect of Subcutaneous Semaglutide vs Placebo as an Adjunct to Intensive Behavioral Therapy on Body Weight in Adults With Overweight or Obesity: The STEP 3 Randomized Clinical Trial. *JAMA*. Published online February 24, 2021. DOI: 10.1001/jama.2021.1831

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