

Early data from clinical trial indicates safety and efficacy of new weight loss procedure

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Findings from the early phase of a clinical trial led by Johns Hopkins investigators indicates that a new, minimally invasive weight loss treatment known as bariatric arterial embolization is safe and effective in sustaining weight loss in severely obese people.

The data, although preliminary, show the procedure seems to initiate weight loss, dramatic hunger reduction and lower levels of ghrelin, one of the main hormones involved in controlling hunger. The results will be presented at the Society of Interventional Radiology's 2016 Annual Scientific Meeting in Vancouver, British Columbia, on Sunday, April 3.

"Obesity is a highly prevalent, detrimental and costly disease in the U.S. and abroad," says [Clifford Weiss](#), M.D., associate professor of radiology and radiological science and director of [interventional radiology](#) research at the Johns Hopkins University School of Medicine. "The interventions currently available to treat this condition are behavioral modifications, diet and exercise, medications, and invasive surgery. We're excited about the possibility of adding bariatric arterial embolization as another tool for health care providers to offer patients in the effort to curb this epidemic."

Johns Hopkins researchers, along with former Johns Hopkins faculty member Aravind Arepally, designed the Bariatric Embolization of Arteries for the Treatment of Obesity (BEAT Obesity) pilot clinical trial. The trial included a multidisciplinary team of weight loss physicians, physiologists, hormone specialists, gastroenterologists,

registered dietitians, psychologists and surgeons. As part of this trial, Weiss and his team enrolled seven mostly female participants (six women) ages 31 to 59 who were severely obese but otherwise healthy. Participants had a body mass index (BMI) ranging from 40 to 50, far above the obesity threshold level of a BMI of 30. Participants were enrolled at the Johns Hopkins Weight Management Center. Investigators tracked the subjects' weight loss, ghrelin levels, hunger and satiety assessments, and adverse events at one, three and six months.

Each participant was educated on ways to implement critical lifestyle and diet changes before and after the procedure. Participants then underwent a bariatric arterial embolization, an image-guided procedure that involves the injection of microscopic beads through a small catheter inserted in a tiny nick in the skin of the groin or wrist. The beads are targeted to a portion of the stomach known as the fundus, which produces the vast majority of the body's ghrelin. The beads decrease blood flow, limiting the secretion of ghrelin, thereby minimizing hunger and initiating weight loss, researchers hypothesize.

In these seven patients, bariatric embolization was safe, with no major adverse events reported. All patients demonstrated weight loss and dramatic hunger reduction levels after the procedure. Ghrelin levels also trended down.

Following bariatric arterial embolization, participants had an average excess weight loss of 5.9 percent, 9.5 percent and 13.3 percent at one, three and six months, respectively. Excess [weight loss](#) is the percentage of pounds lost above the patient's ideal body weight.

Participants reported an average 81 percent, 59 percent and 26 percent decrease in hunger/appetite score at two weeks, one month and three months, respectively. Appetite and satiety questionnaires assessed a participant's perceived sensation of hunger throughout the day. They

were completed for six consecutive days prior to the procedure and for six consecutive days prior to each follow-up visit. Participants also had an average 17.5 percent decrease in ghrelin levels at three months.

"These early results demonstrate that bariatric arterial embolization is safe and appears to be effective in helping patients lose a significant amount of weight in the short and intermediate term," says Weiss.

"Compared to a surgical gastric bypass procedure, bariatric arterial embolization is significantly less invasive and has a much shorter recovery time."

Weiss cautions this research is still in its early stages. Now that the safety of this procedure has been demonstrated, he says, more clinical trials are needed to evaluate larger numbers of patients to determine the treatment's efficacy and durability over time. Additional research will also have to be done to explore the potential cost savings of this procedure. Weiss says there is not enough data to determine this yet.

"As this study expands and includes more patients both at Johns Hopkins, and now at Mount Sinai Health System in New York, we will be able to gain more insight into the effectiveness of bariatric arterial embolization and the role interventional radiology can play in the critical battle against obesity," says Weiss.

Public health research estimates there are approximately 2.1 billion obese people in the world. Obesity is known to cause an array of complications, such as diabetes, cancer, hypertension and stroke, among other life-threatening conditions. Health care costs related to obesity are estimated at \$300 billion in America and Canada alone.

Provided by Johns Hopkins University School of Medicine

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