

A balloon in a pill leads to weight loss

August 8 2016, by Lauren Rosenblatt, Pittsburgh Post-Gazette

After trying countless exercise and weight-loss programs, Sherry Vukman tried a new strategy to shed some pounds - swallowing a balloon.

Vukman, 53, of Wilkins, Pa., was part of a nationwide clinical trial to test the Obalon balloon system, which is designed to help people with a body mass index between 30 and 40 to lose weight. They have a BMI high enough to be considered obese but not high enough to qualify for bariatric surgery - a group that has an "unmet need," said George Eid, one of the researchers and the assistant chair of the Bariatric and Metabolic Institute at Allegheny Health Network.

The clinical trial launched in 2015 at 15 sites around the nation and included more 300 patients. The participant swallows a pill that contains a balloon. Once in the stomach, the physician inflates the balloon with a nitrogen-based gas, allowing it to take up space in the stomach, which makes patient feel fuller faster. Over time usually three <u>balloons</u> are placed in the stomach. Combined with diet and exercise counseling, the system is meant to kick-start weight loss.

"Once you see results, you get encouraged to do more," Eid said at a press briefing Wednesday. "When people gain weight, they get into a vicious cycle. The intervention is to break that cycle."

On average, participants lost about 7 percent of their total body weight. Those in the control group, who received a sugar pill along with diet and exercise counseling, lost about 4 percent. Participants also showed



improved blood pressure and lowered their cholesterol levels.

At the Pittsburgh site, the 24 total participants lost an average of 25 pounds. Vukman, who received the pill with the balloon, lost 50 pounds.

Vukman signed up for the clinical trial about the time she had started a new job as an IT administrator, and the stress of the adjustment was causing her to overeat, she said.

Weighing in at 210 pounds, she had the first balloon put in her stomach in May 2015. Over the next nine weeks, she had two more balloons put in. Initially, she was worried about how restrictive they would be, but she said she only noticed them when she slept and was still able to do "everything she wanted."

She did feel their presence after one indulgent meal though, when she got caught up in conversation and finished off her salad. That night, she said, "I felt like I ate a big turkey dinner." The experience made her realize the importance of portion control.

Vukman has kept off most of the weight since the balloons were removed last October. She still focuses on her eating habits and is now conscious of what foods she eats, avoiding sugary drinks and maintaining a consistent three meals a day.

"I was surprised. I thought once the balloons were removed I would suddenly be starving," she said.

Lisa Matrich, past president of the Pittsburgh Academy for Nutrition and Dietetics, the professional organization of registered dietitians and others, said in a phone interview that he balloon can curb the feelings of deprivation that often accompany dieting, and can make the process of losing weight less daunting for many.



But, although the balloon system is a good place to start, it can be hard to change lifelong habits with just six months. "During that first six months when they have the balloon, that's the window of opportunity to change behaviors. It's not a magic balloon. It doesn't do it for you. You can find ways to eat around it," she said.

A healthy BMI is below 25, and those with a BMI above 30 are obese. This puts them at an increased risk for cardiovascular disease, hypertension and diabetes.

Eid said the gas-filled balloon poses no significant complications but that there is a risk for nausea, vomiting or abdominal cramping. In rare cases, the balloon may lead to bowel obstruction and require surgery. He said people could have the treatment as many times as they like if they continue to have a BMI above 30, whether for health or cosmetic reasons.

The Obalon balloon system has not been approved by the U.S. Food and Drug Administration, but Eid believes it will be within the next year. It has been approved in several other countries, including Europe, but the company's website has pop-ups stating the product is not intended for U.S. audiences.

There are similar balloons that the FDA approved in August 2015 that are filled with fluid rather than gas. Although Allegheny Health Network also offers a fluid-filled option, Eid said the gas-filled balloons lead to fewer gastrointestinal side effects. Others say the fluid-filled balloons are more effective.

In August, Magee-Womens Hospital of UPMC began offering the ORBERA Intragastric Balloon. The balloon is placed in the stomach through the mouth and then filled with saline. Anita Couroculas, chief of the Section of Minimally Invasive Bariatric and General Surgery, said in



an email that she anticipates these balloons are more effective than those filled with gas and that most people will lose between 20 and 40 pounds.

None of these balloon procedures are covered by insurance.

For Vukman, though, the Obalon balloon was her "Cinderella story." This summer, more than six months after the trial, she said she felt better doing physical activities like biking and kayaking because she has less weight to carry around. Her biggest motivation to maintain healthy behaviors, she said, is her 13-year-old daughter, Hannah.

"I want to make sure I'm healthy enough to be around and to be able to do things with her," she said. "I do have a better outlook on myself. I was always worried about being the overweight, frumpy mother."

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Citation: A balloon in a pill leads to weight loss (2016, August 8) retrieved 6 May 2024 from https://medicalxpress.com/news/2016-08-balloon-pill-weight-loss.html

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