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The LAP-BAND® weight loss procedure is safe and effective in an expanded group of patients, not just in people who are morbidly obese. This conclusion is reported in a new study published in the scientific journal <u>Obesity</u>. The findings indicate that the procedure may help to intervene before obesity becomes life threatening to patients.

In 2001 the LAP-BAND® adjustable gastric banding system (LAGB) was approved by the FDA as weight loss procedure for patients with a body mass index (BMI) of 40 kg/m2 or higher and for patients with a BMI of at least 35 with an obesity-related condition, such as diabetes or hypertension. (A person with a BMI of 30 or higher is considered obese.) During the procedure, a surgeon makes small incisions in the patient's abdomen and places an adjustable band around the

upper part of the stomach. The newly created upper pouch allows the patient to eat only small amounts of food at a time, and it provides prolonged appetite suppression.

To assess the safety and effectiveness of LAGB in an expanded group of patients, Robert Michaelson, MD, PhD, FACS, of Northwest Weight Loss Surgery in Everett, Washington, and his colleagues recruited 149 individuals with a BMI of 35 to 39.9 without an additional condition, or a BMI of 30 to 34.9 with at least one obesity-related condition.

"Patients in our study had been obese for an average of 17 years," said Dr.

Michaelson. "They tried numerous other weight loss methods and finally reached out for surgical treatment when they were weary of the repetitive failures at maintaining weight loss."

One year after undergoing the procedure, 84.6% of patients achieved at least a 30 percent loss in excess body weight, with an average excess weight loss of 65 percent. A total of 66.4 percent of patients were no longer obese. Obesity-related conditions that were present at the time of surgery improved for many patients, including 64.4 percent of patients who had high cholesterol, 59.6 percent of patients who had hypertension, and 85.7 percent of patients who had diabetes. Patients' quality of life also improved. Most side effects

were mild to moderate and resolved within one month.

The researchers also found that the one year results were maintained or improved at two years, and that each additional 10 percent weight loss at year two was linked with a decrease in triglycerides by 13.7mg/dL, blood sugar levels by 3.5mg/dL, and systolic blood pressure by 3.3mmHg.

"The results of this study convinced the FDA that early intervention in the continuum of obesity is the right thing to do: treat before people go on to develop serious comorbid conditions of obesity," said Dr. Michaelson. He added that this and similar studies prompted the American

Society for Metabolic and Bariatric Surgery to issue a position statement endorsing weight loss surgery for patients with moderate obesity who have failed nonsurgical methods of weight loss. "The next step is to get the private insurers and Medicare, who continue to rely on guidelines established in 1991, to review the incontrovertible literature, take down the barriers to the necessary treatment for this disease, and offer the hope of a cure to 27 million Americans," said Dr. Michaelson.

However, in an accompanying editorial, David Arterburn, MD, MPH, of the Group Health Research Institute in Seattle, and Melinda Maggard, MD, MSH, of the University of California Los Angeles, cautioned that the long-term benefits and

risks of LAGB in lower weight individuals still need to be determined, and that studies in higher weight individuals show weight regain starting at two years. "There are also concerns that serious adverse events are common; including reports of removal rates as high as 50 percent. As the prevalence of severe comorbidities is less in this patient population, the benefits of preventing comorbidities is not known, which will require larger sample sizes to determine," they wrote. "Until longer-term data on the benefits and harms are available, the use of LAGB in patients with BMI of 30 to 35 kg/m2 should be primarily reserved for clinical research studies."

## Weight Loss Surgery Safe and Effective for an Expanded Group of Patients

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