

Endoluminal Options Grow in Bariatric Surgery

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Emerging endoluminal techniques and devices intended for weight loss therapy may reduce the risk of morbidity and mortality associated with current bariatric surgery approaches, according to the research findings of Dr. Philip Schauer and his associates.

The use of endoluminal approaches to avoid any type of abdominal incision and, more importantly, any intra-abdominal dissection "may go a long way to further reduce the morbidity of these operations, making them cheaper and safer," said Dr. Schauer in an interview. "Potentially, they may expand the access for patients. Only 1% of patients with severe obesity are actually getting access to surgery, which is the only known therapy to be effective for a large percentage of patients."

Dr. Schauer, director of advanced laparoscopic and bariatric surgery at the bariatric and metabolic institute of the Cleveland Clinic, and his associates categorized the current endoluminal methods for weight loss therapy as presurgical endoluminal therapy, postsurgical endoluminal revision procedures, and primary procedures (Surg. Endosc. 2007;21:347-56).

In the arena of presurgical endoluminal therapy, Dr. Michel Gagner and his associates pioneered a two-stage operation consisting of a sleeve gastrectomy followed by a Roux-en-Y gastric bypass (RYGB) or a duodenal switch (Obes. Surg. 2003;13:861-4).

"The rationale is that the first-stage operation, sleeve gastrectomy, is comparatively simple (requiring no anastomosis), needs less operative time (1-2 hours), and results in a predictable 40- to 50-kg weight loss," Dr. Schauer and his associates wrote in their review. "Such weight loss reduces the operative risk for the second-stage procedure, which presumably results in more weight loss and greater durability."

Dr. Gagner, professor of surgery and chief of bariatric surgery at Cornell University, New York, and his associates were also the first to publish results of an approach using the placement of endoluminal duodenojejunal tube or plastic sleeve

to the first part of the duodenum proximal to the ampulla of Vater in pigs as a weight-loss strategy (Obes. Surg. 2006;16:620-6). This study, which demonstrated good weight loss in pigs, was the basis for the first human trial reported recently by Dr. Leonardo Rodriguez and his associates at the annual meeting of the American Society for Metabolic and Bariatric Surgery (formerly the American Society for Bariatric Surgery).

In the human trial, 12 patients from Chile and Brazil, including four with diabetes, underwent placement of a 61-cm endoluminal duodenojejunal tube or plastic sleeve that was anchored endoscopically in the duodenum and removed after 12 weeks.

All patients achieved an estimated weight loss of at least 10%, and 10 of the 12 patients lost an estimated 24% of their weight. All of the diabetic patients completed the study without the need for hypoglycemic medications.

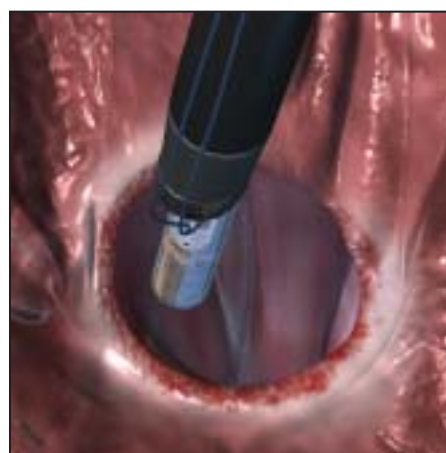
"By diverting the flow of food from the duodenum and the proximal jejunum, we might be able to change some of the GI hormones that may switch the diabetes to reverse itself," Dr. Gagner said in an interview. "I think we will see more and more of that technology being developed, and we'll see variants like different materials, different lengths [of sleeves], et cetera."

Dr. Gagner was not affiliated with the study.

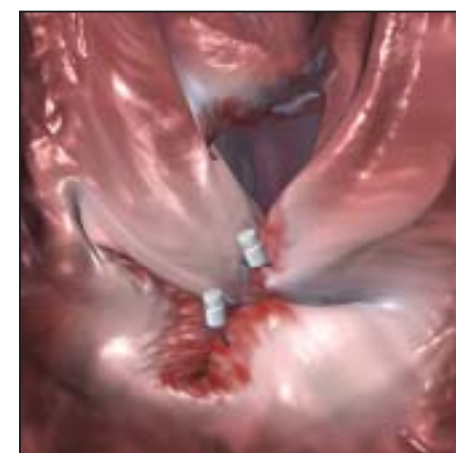
In other studies of presurgical endoluminal therapy, the intragastric balloon developed by BioEnterics Corp. has been used successfully as a first-stage procedure to reduce presurgical weight and perioperative risk in superobese patients, but clinical results are limited.

In the arena of postsurgical endoluminal revision procedures, small studies of C.R. Bard Inc.'s EndoCinch suturing system and endoscopic suturing device have demonstrated promising results.

Dr. Christopher C. Thompson and his associates used the EndoCinch suturing system in eight patients who had undergone RYGB but had regained an average of 24 kg from baseline (Surg. Obe. Relat. Dis. 2005;1:223).



An endoluminal suturing system is moved toward the dilated gastrojejunostomy.



The gastrojejunostomy is reduced in size by the two suture clips.

They placed plications at the rim of the anastomosis, thereby reducing the anastomotic aperture. At 4 months after undergoing the procedure, six of the eight patients had lost an average of 10 kg, and four reported significant improvements in satiety.

In another study, Dr. Michael Schweitzer and his associates used the endoscopic suturing device in four patients who regained weight after RYGB surgery (J. Laparoendosc. Adv. Surg. Tech. A 2004;14:223-6). The study did not include long-term results, but noted that all four patients reported improvements in early weight loss and satiety.

At the annual meeting of the Society of American Gastrointestinal Endoscopic Surgeons in April 2007, Dr. Roberto Fogel of Caracas, Venezuela, reported that an endoluminal vertical gastropasty procedure produced an average excess weight loss of 46% in patients 3 months after surgery. In this procedure, an interrupted suture pattern was used in 31 patients with a mean body mass index (kg/m²) of 38.1. In addition to the weight loss, reductions were achieved in glucose intolerance or type 2 diabetes (from 14 patients to 2), hypertension (from 26 to 11), and dyslipidemia (from 27 to 11).

Such suturing procedures hold particular promise, Dr. Schauer said, because "they emulate gastric restriction, a concept that has been proven over several decades in bariatric surgery."

Dr. Schauer is one of the clinicians participating in the phase III RESTORE (Randomized Evaluation of Endoscopic Suturing Transorally for Anastomotic Outlet Reduction) trial for patients with inade-

quate weight loss following RYGB. The purpose of the trial, which is supported by Bard and Davol Inc., is to evaluate weight loss and other clinical outcomes following application of transoral reduction of a dilated gastrojejunostomy anastomosis in 220 patients who have inadequate weight loss following RYGB. The expected completion date of the trial is July 2008.

The use of endoluminal techniques for the primary treatment of obesity is in its infancy, Dr. Schauer said. One investigational device that has been studied in small trials of patients outside the United States is the transoral gastropasty (TOGa) system, developed by Satiety Inc. In this procedure, an endoscopic stapling device is inserted through the mouth to the stomach to create a small restrictive pouch.

Dr. Schauer called the development of endoluminal techniques for obesity "another potential great leap forward in reducing the risk of these procedures. We already know that going from open procedures to laparoscopic procedures was one of the major factors that propelled bariatric surgery from a very low niche field [15,000 cases per year] across the United States, to 200,000 procedures per year. What really drove that was the reduction in complications and recovery."

Dr. Schauer disclosed that he is a paid consultant for Bard, Davol, Ethicon EndoSurgery Inc., Stryker Endoscopy, Baxter International Inc., W.L. Gore & Associates Inc., and Barosense Inc.

Dr. Gagner disclosed that he is a scientific adviser for GI Dynamics Inc. He has also received research grants from Covidien AG, Olympus America Inc., and Bard.

Increased Physical Activity Can Reduce Visceral Fat in Midlife

NEW ORLEANS — Increased physical activity levels were associated with lower intra-abdominal fat levels in 330 middle-aged women participating in the Study of Women's Health Across the Nation (SWAN), Dr. Sheila Ann Dugan reported at the annual meeting of the American College of Sports Medicine.

In the biracial cohort of women who participated in the ancillary SWAN Diabetes Risk study, a highly statistically significant association was seen between self-reported physical activity, including household and exercise activities, and the level of intra-abdominal fat, Dr. Dugan reported in a poster at the meeting.

The association remained highly significant after adjusting for total percent fat mass, age, ethnicity, hormonal status, educational level, depression score, and parity, and the findings were similar in black and white women, explained Dr. Dugan of Rush University Medical Center, Chicago.

Intra-abdominal fat is a risk factor for diabetes, hypertension, and heart disease, and can be present even in women of normal weight. The study's finding is encouraging because it reinforces the fact that intra-abdominal fat is preventable and modifiable, Dr. Dugan noted in a statement.

Exercising and avoiding overeating can help prevent excess intra-abdominal fat; the American College of Sports Medicine recommends 30-60 minutes of moderate-intensity physical activity per day in healthy adults, according to the statement.

Motivating women to increase their physical activity during their middle years, when visceral fat levels tend to increase due to age-related weight gain and menopause, can positively modify age-related increases in women's intra-abdominal fat and may improve their cardiovascular risk profiles, Dr. Dugan concluded.

—Sharon Worcester