OCTOBER 22, 2015

New Bariatric Procedure Yields Exciting Results

Preliminary Data Strong For Modified Duodenal Switch

By Christina Frangou

A pair of U.S. surgeons has developed a new bariatric procedure, a modified version of a duodenal switch, which may be technically easier to perform and results in weight loss on par with the most effective bariatric operations.

“The weight loss is impressive and, based on historical comparison, greater than vertical sleeve gastrectomy,” reported study author Mitchell Roslin, MD, chief of bariatric surgery at Lenox Hill Hospital, in New York City.

The results are preliminary with no reported follow-up past one year and a low number of patients. Even so, surgeons say the findings are promising: One year after surgery, patients lost, on average, 19 body mass index (BMI) units, or about 84% loss of excess BMI. The weight loss data are based on an analysis of 64 patients who were followed for at least one year after surgery, representing 62% of

the patients eligible for one-year follow-up.

“Certainly, the weight loss results are encouraging,” Dr. Roslin said. “They were obtained in a cohort that had an average BMI of almost 50, with nearly identical data from the two different sites in the study.”

The stomach intestinal pylorus-sparing procedure (SIPS) involves the creation of a 300-cm common channel with a single-anastomosis duodenal enterostomy.

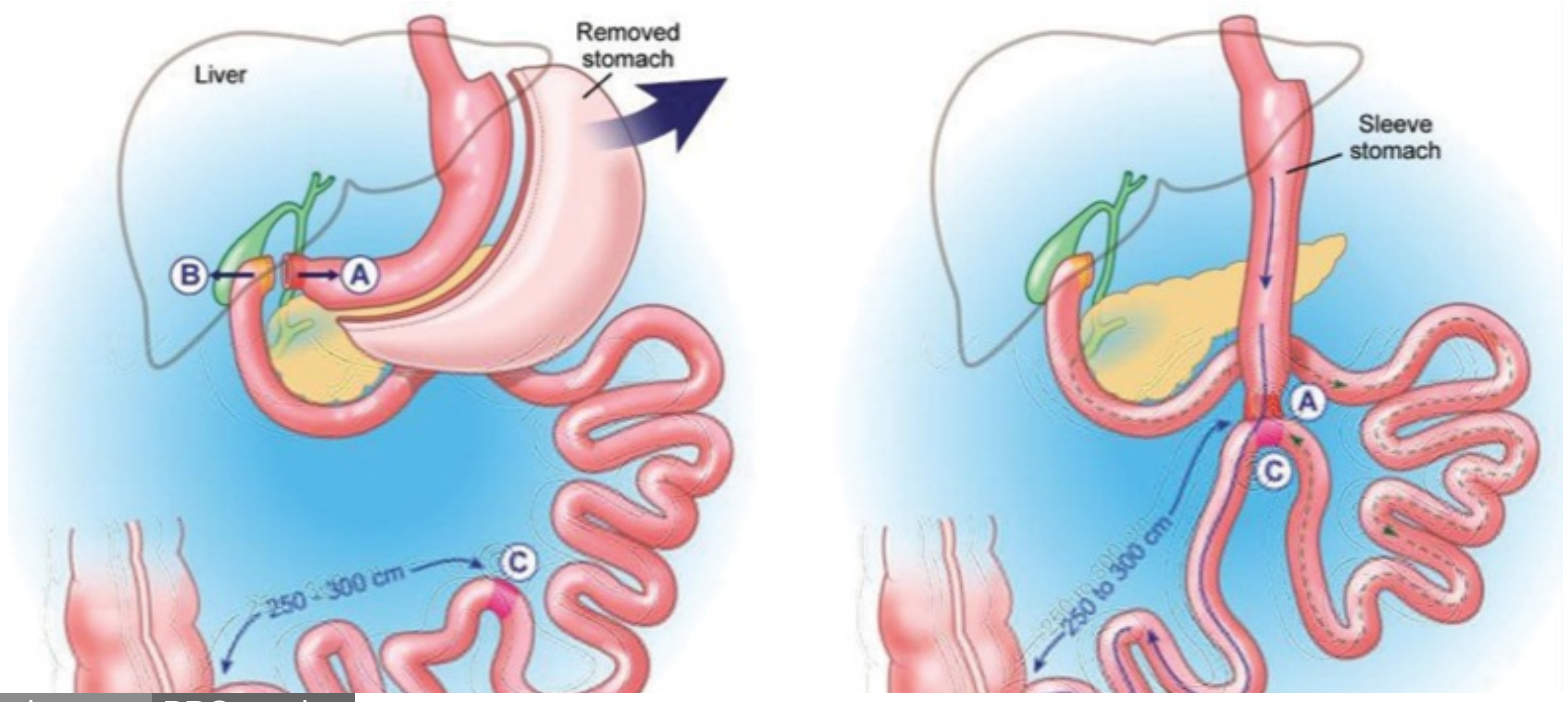
For more than five years, surgeons in Spain have been using a similar procedure known as SADI-S, which involves a single-anastomosis duodenal–ileal bypass with sleeve gastrectomy. In a study published this past winter, they reported that SADI-S is a safe therapeutic option for obese patients with diabetes mellitus, with no incidence of afferent loop syndrome or major complications related to loop reconstruction (Surg Obes Relat Dis 2015 Feb 7. [Epub ahead of print]).

Stacy Brethauer, MD, staff surgeon at the Cleveland Clinic Digestive Disease Institute and associate professor of surgery at the Cleveland Clinic Lerner College of Medicine, said there’s growing excitement in the bariatric community about single-anastomosis procedures, although it’s too early for definitive statements about risks and benefits.

“Many of these single-anastomosis procedures are being performed internationally,

and we're hearing more about single-anastomosis procedures at our scientific meetings, especially with international surgeons," Dr. Brethauer said. "Here in the U.S., we don't have any medium- or long-term data yet, but the concept is an intriguing one—you may potentially be offering the metabolic benefit of a duodenal switch without all of the nutritional risks."

At his practice in Lenox Hill, Dr. Roslin shifted from the gastric bypass to sleeve gastrectomy to preserve the pyloric valve during bariatric surgery, believing it helped regulate glucose tolerance after surgery. However, many of his patients required more weight loss than the sleeve could produce. As a result, he added a postpyloric bypass, similar to a duodenal switch but with more intestinal length preserved to prevent diarrhea.



The stomach intestinal pylorus-sparing procedure (SIPS) involves the creation of a 300-cm common channel with a single-anastomosis duodenal enterostomy.

Unlike the classic duodenal switch, SIPS consists of a single anastomosis, a longer common channel and a decreased sleeve gastrectomy (40-44 cm), leaving 3 m of bowel.

Dr. Roslin—who worked with Daniel Cottam, MD, a surgeon at the Bariatric Medicine Institute at Salt Lake Regional Medical Center in Salt Lake City, to develop SIPS—believes the preservation of long length of intestine, along with the ileocecal valve, reduces the risk for malnutrition and diarrhea often associated with the duodenal switch.

“Our goal and philosophy is to stimulate the distal small intestine, but not promote poor absorption and diarrhea,” Dr. Roslin said.

So far, the nutritional follow-up tests on patients show that their levels of vitamins A, D, B1, B12 and serum albumin postoperatively are close to normal. However, blood work was obtained at a variety of dates, and the majority of patients did not have preoperative measurement of micronutrients to allow calculation about the risk for acquired deficit.

To perform SIPS, the surgeon creates a sleeve gastrectomy over a 42-Fr bougie. Once complete, the gastroepiploic vessels are taken down from the end of the sleeve staple line past the pylorus to where perforating vessels from the pancreas enter the duodenum. A passageway is then created for division of the duodenum. The terminal ileus is located and 3 m of small bowel measured. The surgeon attaches the antimesenteric border of the bowel to the end of the proximal duodenum staple line using absorbable sutures. The loop is arranged so the efferent limb descends on the patient's right and the afferent limb ascends on the patient's left. A duodenotomy and enterotomy are made, and the enterotomy closed with running posterior and anterior layers. Finally, the anastomosis is tested intraoperatively for leaks.

Cholecystectomy and hiatal hernia repair are performed as per the routine of the operating surgeon. Between January 2013 and August 2014, 123 patients underwent SIPS by Drs. Roslin and Cottam at three surgical centers. Of these, 102 were operated on more than a year ago.

The short-term complication profile is consistent with that for other procedures that involve stapling and reconstruction. In this series, there were no anastomotic leaks or perioperative surgical mortality. Two patients (1.6%) were readmitted to the hospital within 30 days of surgery. Two patients complained of constipation and two reported diarrhea. Four had an intraabdominal hematoma, and two developed dysphagia that required esophagogastroduodenoscopy.

In the first month, patients' BMI dropped an average of 5.4 units, or about 20% loss of excess body weight. One year after surgery, the 64 patients for whom data were available lost 84% of excess body weight.

There was a significant difference in operative times between the two operating surgeons, with an average of 147 minutes for Dr. Roslin's patients and an average of 78 minutes for Dr. Cottam's. Dr. Roslin oversews the gastrectomy sleeve staple line and performs a synchronous cholecystectomy, which accounts for the prolonged operative times.

Dr. Brethauer said he recently visited Salt Lake City to learn more about SIPS. He's interested in its potential for patients with very high BMIs and/or large metabolic burden, and as a second-stage operation for patients who have undergone the sleeve gastrectomy but are experiencing inadequate weight loss, weight regain or insufficient comorbidity improvement.

"What got me interested was seeing patients who need that second operation after their sleeve and knowing this certainly would potentially open another option for those patients," Dr. Brethauer said.

However, there are still many unknowns about the long-term consequences of SIPS, he said. Bile and/or acid reflux could be problematic because it can occur with sleeve gastrectomy alone. If patients experience severe gastroesophageal reflux after SIPS, it's unclear what their revision options would be.

“You always have to think about the next step if you needed to revise something,” he continued. “I don’t think anybody has enough experience with this yet to say anything for sure regarding the long-term need for revision, or the best way to revise it if there is a problem.”

He added that surgeons who start performing new procedures must study them carefully, follow their patients, and publish and report their data so that surgeons can make informed decisions about whether to continue with the procedure.

“The biggest challenge is selecting the right patient for the operation, and maintaining good, really close follow-up on the patients because that’s critical if this procedure is to become mainstream.”

Richard M. Peterson, MD, MPH, director of UT Medicine Center for Bariatric and Metabolic Surgery at UT San Antonio, said SIPS could be ideally suited for super-obese patients who need something more than a sleeve or a gastric bypass. “But I need to know long term that the results carry more weight loss than a bypass and are as durable, or close to it, and I need to know the micronutrient problem wouldn’t be an issue.”

Dr. Roslin said he hopes their early results will stimulate discussion among surgeons about whether SIPS is a viable alternative bariatric procedure, particularly for patients who are super morbidly obese or who have weight regain or inadequate weight loss following a vertical sleeve gastrectomy. Patients with super-morbid

obesity, in particular, have been shown to experience inadequate weight loss with vertical sleeve gastrectomy and Roux-en-Y gastric bypass.

Today, biliopancreatic diversion with duodenal switch (BPD-DS) offers the greatest weight loss, best diabetes resolution and lowest recidivism of any studied surgical weight loss procedure, particularly for patients with the greatest amount of weight to lose (Am J Med 2009;122:248-256). Despite this, the popularity of this procedure has been in decline since 2000. In a 2013 study that surveyed members of the International Federation for the Surgery of Obesity and Metabolic Disorders, the proportion of BPD-DS procedures in relation to all bariatric surgeries declined from 6.1% to 4.9% to 2.1% in 2003, 2008 and 2011, respectively (Obes Surg 2013;23:427-436).