Technology in surgery

New no-incision weight-loss surgery

Millions of Americans struggling with severe obesity may in the future have an incision-free option for weight loss. Surgeons are evaluating a procedure called TOGA—for transoral gastroplasty—as part of a multicenter clinical study.

The procedure, which involves passing a stapler down a patient’s throat and stapling the stomach from the inside to form a thumb-sized tube, is part of a trend to use natural orifices to make surgery less invasive and painful. The study is sponsored by Satiety Inc, of Palo Alto, California (www.satietyinc.com), maker of the experimental staplers.

In August 2008, New York-Presbyterian Hospital/Columbia University Medical Center surgeons Daniel Davis, MD, and Marc Bessler, MD, performed the TOGA procedure on the first patient in the New York City area.

“The 25-year old patient is doing very well, she is losing weight, and she is motivated,” Dr Davis told OR Manager in December. He said she has started working out and running and hopes to run a marathon.

No incisions required

Like other obesity procedures, TOGA is designed to alter the anatomy of the stomach to give patients a feeling of fullness after a small meal. But unlike other procedures, the patient has no incisions to recover from. Like other patients after bariatric surgery, patients may still vomit and need to follow a special diet during their recovery period. They also need to make the right food choices for long-term success, as with any other weight-loss surgery. The only postprocedure complaint is a sore throat for a few days from the endoscope, says Dr Davis, who is assistant professor of surgery and co-director of obesity surgery at New York-Presbyterian Hospital/Columbia University Medical Center.

The procedure takes about an hour to perform, and the patient is required by the study protocol to stay in the hospital overnight. The morning after the procedure, the patient undergoes a barium swallow, and x-rays are taken to make sure there are no leaks in the staple line and no injuries to the stomach. These x-rays are used as a baseline for follow-up x-rays for the study.
Qualifications

To qualify for the study and procedure, patients must have a body mass index (BMI) between 35 and 55 and meet criteria set by the hospital’s dieticians and bariatric coordinators. They must also have an endoscopic examination to make sure they don’t have a significant hiatal hernia or other abnormalities of the esophagus or stomach, Dr. Davis notes.

TOGA procedure

With the patient under general anesthesia, the surgeon passes an endoscope through the patient’s mouth into the stomach to take measurements. The surgeon then passes a guidewire into the stomach through the endoscope, removes the endoscope, and passes the stapling device over the guidewire into the stomach to a distance based on the measurements.

With the stapling device in place, the surgeon returns the endoscope to the stomach via a separate channel of the device.

Applying suction, the surgeon draws tissue from the anterior and posterior walls...
of the stomach into the device and fires the first staple cartridge. The surgeon then removes the endoscope and stapling device and gives the device to the nurse to clean and reload with another staple cartridge. Each cartridge is about 4.5 cm long. Usually, just 2 cartridges of the titanium staples are needed, says Dr Davis.

While the nurse reloads the stapling device, the surgeon returns the endoscope to the stomach to examine the staple line and make sure there are no injuries to the stomach. Then the process is repeated to place the second staple cartridge, creating a tube at the entry of the stomach along the lesser curve.

After creating the tube, the surgeon inserts another stapling device called a “restrictor” to narrow the outlet of the bottom of the tube into the stomach to about 1 cm.

The tube collects food, giving the patient a feeling of fullness after a small meal. The tube’s narrowed bottom keeps the food in the tube longer, rather than just letting the food fall into the stomach. Eventually, the stomach acids break the food down, and it slips through the narrow opening into the stomach, and the patient is hungry again, Dr Davis explains.

**Patient follow-up**

Though the TOGA procedure is just starting to be performed in the US, more than 100 have been performed in other countries in the past 2 years. The follow-up on these cases show that the results of the TOGA procedure are as good as for the Lap-Band procedure, and patients are continuing to maintain their weight loss, says Dr Davis.

Follow-up x-rays have found no breakdown of the staple lines, a problem with stomach stapling procedures in the past. The difference with this procedure is that the Satiety staples are placed on the inside of the stomach instead of the outside, and the full thickness of the stomach wall is stapled, not just the top layers, he says.

Presently, 10 sites in the US are performing the TOGA procedure for the study, which will continue until 275 procedures have been performed along with 12-month follow-up. Food and Drug Administration approval of the procedure is probably 2 years away, says Dr Davis.

> —Judith M. Mathias, RN, MA

Learn more about the TOGA procedure and study at www.togaclinicalstudy.com.