Endoluminal Tactics May Cut Bariatric Morbidity

BY DOUG BRUNK
San Diego Bureau

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. "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 presurgical endoluminal therapy arena, 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 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 June 2007.

With the flow of food diverted, GI hormones may change enough to cause the diabetes to reverse itself.

DR. GAGNER

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 of the patients achieved an estimated weight loss of at least 10%, and 10 of the 12 patients lost an estimated 24% of their weight. None of the diabetic patients required 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 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. Obes. Relat. Dis. 2005;1:223). 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.

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

Dr. Schauer disclosed that he is a paid consultant for Bard, Davol, Ethicon Endo-Surgery 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. ■

Bariatric Surgery Scoring System Assesses Patients' Mortality Risk

BY BRUCE JANCIN
Denver Bureau

COLORADO SPRINGS — Development of the first validated risk scoring system in bariatric surgery is anticipated to bring some much-needed accountability to the field, according to speakers at the annual meeting of the American Surgical Association.

The Obesity Surgery Mortality Risk Score (OS-MRS) is an easy-to-use system that effectively stratified risk in its validation study of 4,431 consecutive bariatric surgery patients at four university medical centers, said Dr. Eric J. DeMaria of Duke University, Durham, N.C.: Use of the OS-MRS will provide for a more comprehensive and individualized informed consent process; assist insurance companies and centers-of-excellence programs in their surgeon credentialing efforts; and encourage development of testable surgical risk reduction strategies.

Dr. DeMaria and coworkers developed the OS-MRS while he was at the Medical College of Virginia, Richmond, by analyzing prospectively collected data from 2,075 consecutive patients undergoing gastric bypass surgery. Using multivariate analysis, they identified five independent predictors of 90-day mortality: a body mass index of 50 kg/m^2 or greater, male gender, hypertension, age of at least 45 years, and increased pulmonary embolism risk as indicated by prior thrombosis or pulmonary embolus, right heart failure, obesity hyperventilation, or use of an inferior vena cava filter (Surg. Obes. Relat. Dis. 2007;3:134-40). Diabetes wasn't an independent predictor of mortality risk.

The investigators assigned one point to each of the five preoperative risk factors. Patients with a score of 0-1 were rated class A, lowest risk. A score of 2-3 earned a class B ranking, and 4-5 points conferred class C, high risk.

Ninety-day mortality in the validation study was 0.7%. A total of 25 of the deaths occurred within 30 days after surgery. Pulmonary embolism was the main cause of mortality, accounting for 10 of the 33 postoperative deaths.

Mortality in the 2,166 patients who were class A by the OS-MRS was 0.2%, compared with 1.2% in the 2,140 class B patients and 2.4% in the 125 class C patients. Each of these differences was statistically significant.

A preoperative BMI of at least 50 kg/m^2 was the strongest mortality predictor in the single-center study, with an odds ratio of 3.6. This raises the hypothesis that preoperative weight loss to a BMI below that threshold might markedly reduce postoperative mortality.

"The lack of a valid and predictive risk adjustment score has hampered the interpretation of outcomes in bariatric surgery tremendously over the last decade," said discussant Dr. Michael G. Sarr, professor of surgery and chair of the division of general and GI surgery at the Mayo Clinic, Rochester, Minn. The OS-MRS might have even greater predictive strength if it incorporated weighted scoring of the risk factors, he commented, noting that a scoring system that predicted major morbidity, not just mortality, would also be useful.

Dr. DeMaria said he deliberately avoided using weighted scoring. "It's a clinically useful scoring system primarily due to its simplicity,' he said, adding that a risk score that also predicts postop major morbidity is in the works. ■

Obese Blacks and Hispanics Underestimate Health Risks

BY CAROLYN SACHS
Contributing Writer

HONOLULU — Many overweight black and Hispanic adults' estimates of their obesity-related health problems are more optimistic than are practice-based statistical findings, according to research presented at the annual meeting of the National Medical Association.

Data from a telephone survey "point to an important opportunity for physicians to communicate to their minority patients the serious health consequences associated with excess weight," concluded Dr. Valentine J. Burroughs, chief medical officer of North General Hospital, New York, and colleagues.

The researchers reported that "self-reported rates of obesity-related comorbidities among African-American and Hispanic adults," self-described as overweight, "fall below what would be expected based on clinical data, suggesting a lack of awareness of actual risk."

The study also found that in spite of greater self-reported prevalence of certain risk factors for poor health, "African Americans have a more optimistic view of their overall health and weight status compared to Hispanics."

Information for the study was collected from a telephone survey of 537 black and 526 Hispanic adults; 30.1% of black respondents were male, as were 35.4% of Hispanic respondents. The researchers recruited only candidates who described themselves as being either "slightly" or "very overweight." A higher percentage of Hispanic participants (81.9%) reported themselves as being "slightly overweight," compared with black participants (76.6%). Survey participants' body mass index was calculated from self-reported height and weight.

The obesity-related comorbidities that were most frequently self-reported by black participants were high blood pressure (33.0%), arthritis (20.4%), and high cholesterol (18.4%); Hispanic participants most frequently reported high cholesterol (17.2%), high blood pressure (15.0%), and difficulty sleeping (12.5%).

Survey participants were also asked to rate their overall health. Only 3% of Hispanics rated their health as poor, as did 5% of blacks. On the other hand, 33% of blacks rated their health as either "very good" or "excellent," compared with 23% of Hispanics.

The study was funded by GlaxoSmithKline Consumer Healthcare; all the study authors either consulted for the company or were employed by them. ■