Risks Revealed for Gastric Bypass Complications

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LAS VEGAS — Being male and having a higher than normal preoperative hemoglobin $A_{\rm 1c}$ level were significantly associated with having a major complication following Roux-en-Y gastric bypass surgery, results from an ongoing single-center study showed.

However, the rate of overall complications at 1 year was 15%, which is lower than the 20%-25% that has been reported in the medical literature, Dr. D. Brandon Williams said during a poster session at the annual meeting of the Society of American Gastrointestinal and Endoscopic Surgeons.

"In centers where we have a high volume—we do over 400 of these operations a year—the complication rate is very low, especially the rate of major complications," said Dr. Williams, of the department of surgery at Stanford (Calif.) University.

Between June 5, 2000, and December 5, 2006, 613 patients with a mean age of 43 years and a mean body mass index of 47 kg/m² underwent Roux-en-Y gastric by-



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DR. WILLIAMS

pass surgery at the medical center. In an effort to identify predictors of complications, Dr. Williams and his associates reviewed the medical records for preoperative comorbidities and complications at 12 months postoperatively.

Major complications were defined as anastomotic leak, bleeding, deep vein thrombosis (DVT)/pulmonary embolism (PE), bowel obstruction, myocardial infarction (MI), cerebrovascular accident (CVA), intra-abdominal abscess, and pneumonia. Minor complications were defined as micronutrient deficiency, arrhythmia, wound infection/dehiscence/hernia, and ulcers/strictures.

Dr. Williams reported that 92 patients (15%) experienced 133 complications. Of those, 60 patients had minor complications, and 32 had major complications.

The most common complications included bleeding (28), ulcer/strictures (23), vitamin/nutrient deficiency (15), anasto-



motic leak (12), bowel obstruction (12), wound infection (11), pneumonia (10), DVT/PE (9), abscess (5), MI (3), arrhythmia (3), and CVA (2). There were no mortalities.

Univariate analysis revealed that patients with minor complications were generally older than those with major complications (a mean of 47 vs. 41 years, respectively).

Multivariate analysis revealed that significant predictors of having a major versus a minor complication were being male (OR of 2.1) and having a preoperative he-

moglobin A_{1c} level that was higher than normal (OR of 0.8).

"We actually expected more [factors] would be predictors of complications," Dr. Williams said. "But there are a couple of things that you can use to counsel your patients preoperatively: They might be more likely to have problems if they have uncontrolled diabetes and if they're male."

The researchers also observed a strong association between the rate of major complications and surgeon experience.

For example, 16 major complications were attributed to surgeons who had performed up to 200 gastric bypass operations. That rate dropped to 6 for those who had performed more than 401 procedures.

However, the rate of minor complications remained about the same, regardless of surgeon experience. "This would suggest that there are patient-dependent [risk factors for complications] that you're not going to be able to predict no matter how good [a surgeon] you are," he said.

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Please see accompanying Brief Summary of Prescribing Information.

*Results of a 12-week, placebo-controlled, randomized, double-blind, fixed-dose-treatment trial to assess the efficacy and safety of MIRAPEX vs placebo in the treatment of moderate to severe primary RLS (MIRAPEX n=254; placebo n=85). Measurement parameters included the International Restless Legs Syndrome Rating Scale (IRLS) and the Clinical Global Impressions-Improvement (CGI-I) scale. IRLS is an internationally validated scale that is the standard instrument for evaluation of severity of RLS. Total score ranges from 0 to 40, with 0 being absence of RLS symptoms and 40 the most severe symptoms. CGI-I is widely accepted for measuring improvement in RLS symptoms.

Reference: 1. Data on file, Boehringer Ingelheim Pharmaceuticals, Inc.



Safety:

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