

# Cost-Effectiveness of Bariatric Surgery Assessed

BY DOUG BRUNK

NEW ORLEANS — Although not cost-saving, bariatric surgery appears to be a good value for the money, the results from a large single-center study showed.

“The long-term cost-effectiveness of bariatric surgery will largely depend on the natural history and extent of late postsurgical complications and costs,”

Dr. William H. Herman said at the annual scientific sessions of the American Diabetes Association.

To gain a better understanding of the cost-effectiveness of bariatric surgery in a managed care population, Dr. Herman and his associates studied 221 patients who underwent Roux-en-Y procedures in a Southeastern Michigan HMO between May 1, 2001, and June 30, 2005. Patients were asked to complete the EQ-

5D, a standardized tool used to measure health-related quality of life before, and 1 year after, bariatric surgery.

The patients' mean age was 42 years, 88% were female, and the mean body mass index before surgery was 52 kg/m<sup>2</sup>, reported Dr. Herman, director of the Michigan Diabetes Research and Training Center at the University of Michigan, Ann Arbor. At baseline, 49% had hypertension, 36% had diabetes, and 49% had obstructive sleep apnea.



then rose to about \$600 per month 1 year after surgery.

“In the 6 months before bariatric surgery, there was some ramp-up in outpatient pharmacy costs and, not unexpectedly, an increase in clinic costs and diagnostic and laboratory testing likely related to the pre-operative period,” Dr. Herman said. “Following bariatric surgery there was a dramatic reduction in outpatient pharmacy costs but some increase in inpatient costs,”

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DR. HERMAN

which seemed to increase the year following surgery,” he added.

The surgery itself cost about \$12,000, with a slightly lower cost for the laparoscopic procedure.

When the researchers prospectively assessed presurgical quality of life, they found that the average health utility scores improved by 0.14 1 year after surgery.

In analyses that took a lifetime time horizon, adopted a payer perspective, and discounted costs and health utilities at 3% per year, the cost-utility ratio for bariatric surgery was about \$15,000 per quality-adjusted life year gained.

Dr. Herman also reported that bariatric surgery was more cost effective in older patients, more obese patients, and nondiabetic patients, and when performed laparoscopically.

Dr. Herman disclosed that he serves as an adviser to Johnson & Johnson and Sanofi-Aventis, and as a consultant to Amylin Pharmaceuticals Inc. ■

## PLAVIX

(clopidogrel bisulfate) tablet, film coated

clinical trials are listed below regardless of relationship to PLAVIX. In general, the incidence of these events was similar to that in patients receiving aspirin (in CAPRIE) or placebo + aspirin (in the other clinical trials).

Body as a whole: Allergic reaction, necrosis ischemic. *Cardiovascular disorders:* Edema generalized. *Gastrointestinal system disorders:* Peptic, gastric or duodenal ulcer, gastritis, gastric ulcer perforated, gastritis hemorrhagic, upper GI ulcer hemorrhagic. *Liver and Biliary system disorders:* Bilirubinemia, hepatitis infectious, liver fatty. *Platelet, bleeding and clotting disorders:* hemarthrosis, hematuria, hemoptysis, hemorrhage intracranial, hemorrhage retroperitoneal, hemorrhage of operative wound, ocular hemorrhage, pulmonary hemorrhage, purpura allergic, thrombocytopenia. *Red blood cell disorders:* Anemia aplastic, anemia hypochromic. *Reproductive disorders, female:* Menorrhagia. *Respiratory system disorders:* Hemothorax. *Skin and appendage disorders:* Bullous eruption, rash erythematous, rash maculopapular, urticaria. *Urinary system disorders:* Abnormal renal function, acute renal failure. *White cell and reticuloendothelial system disorders:* Agranulocytosis, granulocytopenia, leukemia, leukopenia, neutropenia.

### Postmarketing Experience

The following events have been reported spontaneously from worldwide post-marketing experience:

- *Body as a whole:*
  - hypersensitivity reactions, anaphylactoid reactions, serum sickness
- *Central and Peripheral Nervous System disorders:*
  - confusion, hallucinations, taste disorders
- *Hepato-biliary disorders:*
  - abnormal liver function test, hepatitis (non-infectious), acute liver failure
- *Platelet, Bleeding and Clotting disorders:*
  - cases of bleeding with fatal outcome (especially intracranial, gastrointestinal and retroperitoneal hemorrhage)
  - thrombotic thrombocytopenic purpura (TTP) – some cases with fatal outcome – (see **WARNINGS**)
  - agranulocytosis, aplastic anemia/pancytopenia
  - conjunctival, ocular and retinal bleeding
- *Respiratory, thoracic and mediastinal disorders:*
  - bronchospasm, interstitial pneumonitis
- *Skin and subcutaneous tissue disorders:*
  - angioedema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, lichen planus
- *Renal and urinary disorders:*
  - glomerulopathy, increased creatinine levels
- *Vascular disorders:*
  - vasculitis, hypotension
- *Gastrointestinal disorders:*
  - colitis (including ulcerative or lymphocytic colitis), pancreatitis, stomatitis
- *Musculoskeletal, connective tissue and bone disorders:*
  - myalgia

### OVERDOSAGE

Overdose following clopidogrel administration may lead to prolonged bleeding time and subsequent bleeding complications. A single oral dose of clopidogrel at 1500 or 2000 mg/kg was lethal to mice and to rats and at 3000 mg/kg to baboons. Symptoms of acute toxicity were vomiting (in baboons), prostration, difficult breathing, and gastrointestinal hemorrhage in all species.

### Recommendations About Specific Treatment

Based on biological plausibility, platelet transfusion may be appropriate to reverse the pharmacological effects of PLAVIX if quick reversal is required.

### DOSAGE AND ADMINISTRATION

#### Recent MI, Recent Stroke, or Established Peripheral Arterial Disease

The recommended daily dose of PLAVIX is 75 mg once daily.

#### Acute Coronary Syndrome

For patients with non-ST-segment elevation acute coronary syndrome (unstable angina/non-Q-wave MI), PLAVIX should be initiated with a single 300-mg loading dose and then continued at 75 mg once daily. Aspirin (75 mg–325 mg once daily) should be initiated and continued in combination with PLAVIX. In CURE, most patients with Acute Coronary Syndrome also received heparin acutely (see **CLINICAL STUDIES** in the full prescribing information).

For patients with ST-segment elevation acute myocardial infarction, the recommended dose of PLAVIX is 75 mg once daily, administered in combination with aspirin, with or without thrombolytics. PLAVIX may be initiated with or without a loading dose (300 mg was used in CLARITY; see **CLINICAL STUDIES** in the full prescribing information).

#### Pharmacogenetics

CYP2C19 poor metabolizer status is associated with diminished response to clopidogrel. The optimal dose regimen for poor metabolizers has yet to be determined. (See **CLINICAL PHARMACOLOGY: Pharmacogenetics** in the full prescribing information.)

No dosage adjustment is necessary for elderly patients or patients with renal disease. (See **CLINICAL PHARMACOLOGY: Special Populations** in the full prescribing information.)

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## High Bariatric Surgeon Volume Predicts Low Adverse Event Rate

GRAPEVINE, TEX. — Even for experienced bariatric surgeons operating at recognized centers of excellence, the adverse event rate for Roux-en-Y gastric bypass declines by 10% for every additional 10 cases performed annually.

In a large national study, the inverse relationship between surgeon volume and adverse events was continuous. There was no suggestion of any specific volume cut-point that defined a surgeon as an expert, Dr. Mark D. Smith said at the annual meeting of the American Society for Metabolic and Bariatric Surgery.

Dr. Smith, a bariatric surgeon in Portland, Ore., reported on 3,409 patients who underwent an initial Roux-en-Y gastric bypass with 31 surgeons at 10 centers of excellence participating in the National Institute of Diabetes and Digestive and Kidney Diseases-sponsored, prospective Longitudinal Assessment of Bariatric Surgery-1 (LABS-1) study.

Of the 31 surgeons, 15 averaged fewer than 50 of the procedures per year, 9 performed 50-99 annually, and 7 did 100

or more. Both national bariatric surgery centers of excellence programs require that surgeons perform a minimum of 50 cases per year for accreditation.

The primary, composite 30-day adverse event end point comprised death, venous thromboembolism, reintervention, or hospitalization for the full 30 days. It occurred in 4.0% of patients whose surgeons performed at least 50 Roux-en-Y gastric bypasses annually and 9.1% of patients of lesser-volume surgeons. After adjustment for patients' operative risk, the relative risk of adverse events was 2.2-fold greater with surgeons who averaged fewer than 50 cases per year than with those who did more.

After more detailed analysis, it was apparent that the inverse relationship between surgeon volume and adverse outcomes was continuous, and that for every 10 cases performed annually, the risk of adverse events decreased by 10%. The effect of surgeon volume was greater in higher-risk patients, Dr. Smith said.

—Bruce Jancin