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NEW STUDIES WEIGH IN ON SAFETY AND EFFECTIVENESS OF NEWER BARIATRIC AND METABOLIC PROCEDURE

Sleeve Gastrectomy Demonstrates Weight Loss and Safety **Comparable to More Established Procedures**

SAN DIEGO, CA – JUNE 20, 2012 – Studies from Stanford University, Cleveland Clinic Florida and the Naval Medical Center in San Diego show laparoscopic sleeve gastrectomy, an increasingly popular surgical procedure where the stomach is reduced by 85 percent, is as safe as or safer than laparoscopic gastric bypass or gastric banding. The studies* were presented here at the 29th Annual Meeting of the American Society for Metabolic & Bariatric Surgery (ASMBS).

In one study, Stanford University researchers analyzed safety data from nearly 270,000 metabolic and bariatric surgeries performed between 2007 and 2010. Nearly 16,000 of the procedures were sleeve gastrectomies, which had a 30-day serious complication rate of less than one percent (0.96%), compared to a rate of 1.25 percent for gastric bypass and one-quarter of one percent (0.25%) for gastric banding.

The 30-day mortality rate for sleeve gastrectomy was 0.08 percent, while the rate for gastric bypass was 0.14 percent and 0.03 percent for gastric banding. These mortality and complication rates are lower than those typically associated with gallbladder or hip replacement surgery.^{1,2}

Gastric bypass resulted in the most average weight loss after one year. The average body mass index (BMI) after this procedure dropped by about 40 percent (47.7 to 31.2). Sleeve gastrectomy patients experienced about a 30 percent drop (47.5 to 34.1), while gastric band patients had a 20 percent reduction (45.1 to 37.5).

"In terms of risk and benefit, sleeve gastrectomy sits nicely between gastric bypass and adjustable gastric band," said lead study author John Morton, MD, Associate Professor of Surgery and Director of Bariatric Surgery at Stanford Hospital & Clinics at Stanford University.

This data, along with several other large studies published within the last two years, was recently submitted to the Centers for Medicare & Medicaid Services (CMS), as the agency considers a new national coverage determination for laparoscopic sleeve gastrectomy for its beneficiaries.

Researchers from Cleveland Clinic Florida reviewed safety outcomes of more than 2,400 of their patients who had sleeve gastrectomy, gastric bypass or bariatric and metabolic surgery between 2005 and 2011. This study found sleeve gastrectomy had the lowest complication and reoperation rates of the three procedures.

The rate of a gastrointestinal leak, considered a serious complication, was three-tenths of one percent (0.3%) for sleeve gastrectomy versus four-tenths of one percent (0.4%) for gastric bypass patients. The percentage of procedures requiring reoperations due to complications was 15.3 percent for the gastric band, 7.7 percent for gastric bypass and 1.5 percent for sleeve gastrectomy. On average, patients had a BMI between 44 and 48, were 46 years of age and had at least two obesity-related conditions, such as Type 2 diabetes and high blood pressure.

A third study on sleeve gastrectomy conducted by the Naval Medical Center in San Diego found while gastric bypass patients lost more of their excess weight after the first year, 72.3 percent versus 63.7 percent, there were no statistically significant differences in excess weight loss after two and five years. This study examined 486 patients, half had gastric bypass and half had sleeve gastrectomy.

"Sleeve gastrectomy has proven itself to be a safe and effective option in patients with morbid obesity and this procedure should be considered a primary procedure for weight loss and obesity-related disease improvement and resolution," said Robin Blackstone, MD, President ASMBS.

About Obesity and Metabolic and Bariatric Surgery

Obesity is one of the greatest public health and economic threats facing the United States.³ Approximately 72 million Americans are obese⁴ and, according to the ASMBS, about 18 million have morbid obesity. Obese individuals with a BMI greater than 30 have a 50 to 100 percent increased risk of premature death compared to healthy weight individuals as well as an increased risk of developing more than 40 obesity-related diseases and conditions including Type 2 diabetes, heart disease and cancer.^{5,6} The federal government estimated that in 2008, annual obesity-related health spending reached \$147 billion,⁷ double what it was a decade ago, and projects spending to rise to \$344 billion each year by 2018.⁸

Metabolic/bariatric surgery has been shown to be the most effective and long lasting treatment for morbid obesity and many related conditions and results in significant weight loss. 9,10,11 In the United States, about 200,000 adults have metabolic/bariatric surgery each year. 12 The Agency for Healthcare Research and Quality (AHRQ) reported significant improvements in the safety of metabolic/bariatric surgery due in large part to improved laparoscopic techniques. 13 The risk of death is about 0.1 percent 14 and the overall likelihood of major complications is about 4 percent. 15

About the ASMBS

The ASMBS is the largest organization for bariatric surgeons in the world. It is a non-profit organization that works to advance the art and science of bariatric surgery and is committed to educating medical professionals and the lay public about bariatric surgery as an option for the treatment of morbid obesity, as well as the associated risks and benefits. It encourages its members to investigate and discover new advances in bariatric surgery, while maintaining a steady exchange of experiences and ideas that may lead to improved surgical outcomes for morbidly obese patients. For more information, visit www.asmbs.org.

*PL-102: Laparoscopic Gastric Bypass Versus Laparoscopic Vertical Gastrectomy for Morbid Obesity: 5 Year Results in A Military Institution

Dr. Gordon Wisbach; David M. Lim, DO; William Bertucci, MD; Janos Taller, MD; Robert H. Riffenburgh, PhD, MD; Jack O'Leary, RN

*PL-104: National Comparisons of Bariatric Surgery Safety And Efficacy: Findings from the BOLD Database 2007-2010

Dr. John Morton; Bintu Sherif, Deborah Winegar, PhD; Ninh Nguyen MD, FASMBS; Jaime Ponce, MD, FASMBS; Robin Blackstone, MD, FASMBS

*PL-133: Procedure Related Morbidity Comparing Roux-en-Y Gastric Bypass, Sleeve Gastrectomy And Laparoscopic Adjustable Gastric Band: A Retrospective Long Term Follow Up

Dr. Raul J. Rosenthal; Abraham Fridman, DO; Karan Bath, MD; Andre Teixeira, MD; Samuel Szomstein, MD, FASMBS

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