ASMBS American Society for Metabolic & Bariatric Surgery

ASMBS STATEMENT ON JAMA STUDY ON LAGB

January 23, 2008

News headlines around the world read "*Obesity Surgery Can Cure Diabetes*" after the first randomized controlled study of the effect of Laparoscopic Adjustable Gastric Banding (LAGB) on type 2 diabetes was published today in the *Journal of the American Medical Association (*JAMA).

As bariatric and metabolic surgeons we have known this for years. But today's study, along with the two landmark studies published in *The New England Journal of Medicine* in August 2007 that showed a significant survival benefit for people who have bariatric surgery, provide new and important evidence that can no longer be ignored – bariatric surgery saves lives and can eliminate or dramatically improve disease!

However, despite this evidence, other clinical studies and the endorsement of the Center for Medicare & Medicaid Services (CMS), many private health insurers continue to restrict access to bariatric surgery. This must change before more lives are lost to obesity, type 2 diabetes and many other diseases.

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The following is a summary of the JAMA study followed by the abstract:

Significance and Impact of Study

1) This is the first randomized controlled trial in the medical literature demonstrating superior efficacy of bariatric surgery (Laparoscopic Adjustable Gastric Banding) compared to conventional medical therapy for the treatment of early type 2 diabetes. The complete remission rate of 73% vs. 13% for medical management is among the highest reported in the literature for any combination of therapy used to treat type 2 diabetes in a randomized controlled trial. The results suggest that bariatric surgery should be considered a treatment option for patients with Type 2 diabetes and mild to moderate obesity.

2) This study is the first randomized controlled trial demonstrating superior efficacy for bariatric surgery compared to conventional therapy in diabetic patients with BMI < 35. It supports evidence from other studies that demonstrate select groups of patients with BMI < 35 may benefit from bariatric surgery. It further calls in to question the NIH guidelines established in 1991 that hold BMI of 35 as an absolute lower limit for suitability for bariatric surgery.

3) Though the study was not powered sufficiently to compare complication rates between medical and surgery treatment of diabetes, complication rates for medical and surgical therapy were comparable. No serious adverse events occurred in either group. Other

studies support a relatively low complication rate for bariatric surgery in this patient population suggesting a reasonable risk/benefit for bariatric surgery in this population.

4) The very positive results for surgery achieved in this trial together with the improved survival data from SOS and Adams et al (NEJM, Aug 2007) support the justification for a new multidisciplinary consensus conference for the role of surgery in the treatment for obesity as well as diabetes.

5) This study suggests other areas for examination. These include durability of remission, effect of surgery on more advanced diabetes, the relative risk/benefit of other bariatric procedures, and the impact of surgery on secondary complications of diabetes such as blindness, renal failure, and cardiovascular events. More government-supported research, specifically well designed clinical trials, should commence to address the important issues raised by this and other studies. The US government has invested relatively little in evaluation of surgical treatment for diabetes or obesity.

6) The very positive results for surgery achieved in this trial together with the improved survival data from SOS and Adams et al (NEJM, Aug 2007) raise an ethical and legal argument against 3rd party payors who refuse to provide coverage for bariatric surgery based on widely accepted criteria adopted by Medicare, NIH and many other US government agencies.

7) Prevention: Although this study provides strong evidence for bariatric surgery as an effective treatment for type 2 diabetes, the U.S. government, health care providers, civic leaders, and policy makers must place more focus on diabetes prevention in order to reduce the impending burden of diabetes for generations to come.

ABSTRACT

Summary and Implications of Adjustable Gastric Banding and Conventional Therapy for Type 2 Diabetes. A Randomized Controlled Trial Published in JAMA Jan 23, 2008

Dixon JB, Obrien PE, Playfair J, Chapman L, Schachter LM, Skinner S, Proietto J, Bailey M, Anderson M. JAMA. 2008:299 (3): 316-323

Abstract

- **Context** Observational studies suggest that surgically induced loss of weight may be effective therapy for type 2 diabetes.
- **Objective** To determine if surgically induced weight loss results in better glycemic control and less need for diabetes medications than conventional approaches to weight loss and diabetes control.
- **Design, Setting, and Participants** Unblinded randomized controlled trial conducted from December 2002 through December 2006 at the University

Obesity Research Center in Australia, with general community recruitment to established treatment programs. Participants were 60 obese patients (BMI >30 and <40) with recently diagnosed (<2 years) type 2 diabetes.

- **Interventions** Conventional diabetes therapy with a focus on weight loss by lifestyle change vs laparoscopic adjustable gastric banding with conventional diabetes care.
- **Main Outcome Measures** Remission of type 2 diabetes (fasting glucose level <126 mg/dL [7.0 mmol/L] and glycated hemoglobin [HbA1c] value <6.2% while taking no glycemic therapy). Secondary measures included weight and components of the metabolic syndrome. Analysis was by intention-to-treat.
- **Results** Of the 60 patients enrolled, 55 (92%) completed the 2-year follow-up. Remission of type 2 diabetes was achieved by 22 (73%) in the surgical group and 4 (13%) in the conventional-therapy group. Relative risk of remission for the surgical group was 5.5 (95% confidence interval, 2.2-14.0). Surgical and conventional-therapy groups lost a mean (SD) of 20.7% (8.6%) and 1.7% (5.2%) of weight, respectively, at 2 years ($P < .001$). Remission of type 2 diabetes was related to weight loss ($R2 = 0.46$, $P < .001$) and lower baseline HbA1c levels (combined $R2 = 0.52$, $P < .001$). There were no serious complications in either group.
- **Conclusions** Participants randomized to surgical therapy were more likely to achieve remission of type 2 diabetes through greater weight loss. These results need to be confirmed in a larger, more diverse population and have long-term efficacy assessed.