

What's New About Metabolic Surgery?



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The American Society for Bariatric Surgery and the International Federation for Surgery of Obesity changed their names several years ago to incorporate the identifier “metabolic.” Bariatric surgeons have known for decades that their surgical procedures treat metabolic diseases. So, what’s so new about metabolic surgery and why make the change in identity now? One explanation is that bariatric surgery may no longer be reserved for the so-called morbidly obese. Low body mass index (BMI) “metabolic” surgery is upon us.

In mid-February, the Food and Drug Administration (FDA) gave a “thumbs-up” to adjustable gastric banding for treatment of BMI 30-35 patients. This expansion of the scope of interventional treatment will dramatically change the application of bariatric surgery and allow for huge growth in interventional treatment, with surgical treatment becoming an option for an additional 37 million Americans.

About Article

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In this month’s **Viewpoint** column, Drs. Neil Hutcher and Eric DeMaria discuss the implications for metabolic surgery of the recent FDA extension of the availability of Lap-Band™ treatment from the morbidly obese (>40 body mass index [BMI] or >35 BMI with 2 or more comorbidities) to the obese and mildly obese (30-40 BMI with one obesity-related morbidity in the 30-35 BMI range). While this development for LapBand effectively ‘opens the floodgates’ of gastric banding to millions of additional candidates, it also implies insurance coverage challenges, and a new public view of metabolic/bariatric surgical procedures, in general—a view that will instigate the enthusiasm and appreciation of many, while simultaneously raising concern and criticism from others.

The impetus toward low-BMI surgery to address comorbid disease, potentially in the absence of severe obesity, is founded on the outcomes of more than 50 years of metabolic surgery.

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Before the final approval of this indication was announced on February 16th, in December 2010, an FDA panel had voted to support the expansion of gastric banding labeling to the low BMI group based on research evidence that such treatment is safe and effective. News of the FDA panel vote sparked great controversy in the media. Commentators criticized the panel decision, and in doing so, demonstrated typical prejudice against the obese. Familiar viewpoints included the idea that obesity is a "choice" rather than a disease; that patients undergoing surgery are motivated by cosmetic concerns; and that patients are unwilling to do the work required to lose weight. The truth, according to the World Health Organization, is that obesity is the greatest healthcare concern facing humankind today. The primary reason for this concern is not cosmetic, but rather grounded in the prevalence of metabolic diseases, particularly diabetes, hypertension, cardiovascular atherosclerosis, and non-alcoholic fatty liver disease including steatohepatitis (NASH), which are either aggravated or caused by obesity. As an example, NASH is predicted to become the most common cause of liver cirrhosis in the coming decades.

Another source of major media criticism was the disclosure that Allergan, Inc., the manufacturers of the Lap-Band®, paid for the studies confirming these findings. Commentators noted that a potential conflict of interest existed when the company that had the most to gain from favorable results also provided the funding to perform the studies. Sponsorship of clinical studies by the device (or drug) manufacturer is, by far, the most common way such trials are funded, since few others, including the NIH, have the financial resources or care enough about the potential results to pay the costs of major FDA trials.

Dr. Nicola Scopinaro, in pioneering the biliopancreatic diversion (BPD) procedure, noted as early as the 1970s that, in addition to massive weight loss, post-BPD patients' altered caloric intake and absorption correlated with complete resolution of their hyperglycemia and T2DM and facilitated euglycemia without dietary restriction (Scopinaro N, Gianetta E, Friedman D, et al; *Clin Nutr* 1986;5[Suppl]:137-46). Scopinaro et al have recently published outcomes in low-BMI patients (BMI 25-35) that demonstrate improvement or resolution of T2DM following BPD with no excessive weight loss and significantly decreased mean HbA1C (from 9.3%±1.5 to 6.3%±0.8) (*Ann Surg* 2011;Jan 13. [Epub ahead of print]). Dr. Walter Pories, was also central to the inauguration of the field of metabolic surgery, beginning with his 1987 report on the Greenville gastric bypass that theorized that the post-bypass return to euglycemia resulted from hormonal changes secondary to bypass of the antrum and duodenum (Pories WJ, Caro JF, Flickinger EG, et al; *Ann Surg* 1987;206(3):316-23), which was followed by two...

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Public paranoia over the potential for conflict of interest and potential manipulation of results—even in the absence of a shred of evidence that this occurred—further fueled media speculation.

However, there are national data to support the concept of low BMI metabolic surgery as safe and effective. In a study published in the *Annals of Surgery* this past year, researchers used the national Bariatric Outcomes Longitudinal Database (BOLD) to identify 235 diabetic patients with BMI between 30 and 35 who had been treated by metabolic surgery in United States (US) bariatric surgery Centers of Excellence (COEs).¹ The study reports an equal number (109) of patients who underwent adjustable gastric banding and gastric bypass procedures; the results demonstrated the safety of these metabolic procedures in the low-BMI patients, with the vast majority of complications being minor in nature (e.g., self-limited nausea/vomiting) and no deaths in the series. Most impressively, diabetes improved dramatically following both procedures. Overall, 39% of patients were able to discontinue all medications to treat diabetes within just 6 to 12 months of surgery.

Metabolic surgery for low-BMI persons is about to emerge as a major change in the standard treatment of the American obesity crisis; this emergence will bring increased attention to surgical treatment in general, as well as awareness that surgery offers the only successful, durable treatment identified to date to control obesity. Metabolic surgery is moving onto a bigger stage, beyond that reserved for the most severe and disabling cases of morbid obesity. America's determination to win the battle of the bulge combined with the aging population fighting comorbidities related to obesity will work

... additional *Annals of Surgery* articles (1992 and 1995) presenting evidence that bariatric procedures might be just as effective in treating T2DM in *nonmorbidly* obese patients.

There is more recent evidence, in addition to the BOLD study described by Drs. Hutcher and DeMaria, that anticipates the FDA expansion of the LapBand indication and suggests that most of the currently accepted metabolic surgical procedures, and some experimental variations (e.g., duodenal-jejunal bypass, ileal interposition with sleeve gastrectomy), yield marked comorbidity reduction in low-BMI patients, particularly for type 2 diabetes mellitus (T2DM). A 2010 integrative literature review of English language articles over the last 30 years (1979-2009) provided preliminary evidence of the safety and effectiveness of metabolic surgery specifically for the resolution of T2DM in patients with a mean BMI <35 (Fried M, Ribaric G, Buchwald JN, et al; *Obes Surg* 2010 Jun; 20[6]:776-90). Patients in 16 studies (n=343) lost a clinically meaningful, not excessive, amount of weight, achieving a BMI in the...

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synergistically to elevate metabolic surgery to new levels of acceptance in our culture.

What's new is nothing short of a revolution in the management of obesity. The concept of treating metabolic diseases with bariatric surgery is not new, but the term, "metabolic surgery," is driving the reinterpretation of weight-loss surgery to become a mainstay in the treatment of obesity. Application of metabolic surgery to lower body weight individuals who suffer from the early stages of this chronic, unrelenting and debilitating disease offers hope that they may avoid the long-term health consequences of obesity, including organ damage to the heart, lungs, kidneys, liver, blood vessels, eyes, joints and spine, to name but a few systems assaulted by progressive obesity. Metabolic surgery's critical contribution will be the reinvention of bariatric surgery as a preventative intervention, rather than a "last-ditch" attempt to rescue patients with end-stage disease. Tremendous results can be expected as surgeons bring the proven strategy of bariatric surgery into the general metabolic surgery armamentarium to aid in precluding progressive obesity.

... upper end of the normal weight category, with 85% resolution of T2DM. Subgroup comparison demonstrated the greatest T2DM resolution in the mildly obese (BMI 30.0-35.0) relative to the overweight (BMI 25.0-25.9), and in patients receiving malabsorptive/restrictive procedures.

In pioneering, and navigating, this new lower-BMI environment, the challenge to the multidisciplinary metabolic/bariatric surgery community will be to continue to define the therapeutic distinctions between bariatric and metabolic surgery, where they exist, and to lead the broad public conversation. The ASMBS, IFSO, and Surgical Review Corporation, with its COE and BOLD initiatives—more relevant than ever—are needed to provide a much-needed conservative and research-based voice for the field, with long-term patient wellbeing their preeminent concern.

References

1. DeMaria EJ, Winegar DA, Pate VW, et al. Early post-operative outcomes of metabolic surgery to treat diabetes from sites participating in the ASMBS Bariatric Surgery program as reported in the Bariatric Outcomes Longitudinal Database. *Annals of Surgery* 2010; 252(3):559-567.

About the Authors

Dr. Neil Hutcher is Chairman of the Surgical Review Corporation (SRC) Board of Directors and a member of the Executive Committee. Dr. Hutcher is a long-time leader in the advancement of bariatric surgery, particularly patient education and advocacy on the federal and state levels. He began practicing medicine in Richmond in 1973, served on the staff of Commonwealth Surgeons, and was Chairman of the Department of Surgery at St. Mary's Hospital and Clinical Associate Professor of Surgery at both the Medical College of Virginia and McGuire Veterans Administration Medical Center. Dr. Hutcher is also a past president of the American Society for Metabolic and Bariatric Surgery (ASMBS). In 2010, he transitioned from clinical practice to Chief Medical Officer at the SRC, and medical consultant for Stevens & Lee law firm, Lancaster, PA.

Dr. DeMaria served on the faculty of the Medical College of Virginia at Virginia Commonwealth University (VCU) where he became the founding director of the VCU Minimally Invasive Surgery (MIS) Center in 1995. Dr. DeMaria established a postgraduate fellowship training program in MIS and Bariatric Surgery. In 2001, he assumed directorship of the Obesity Surgery Center, was subsequently appointed General Surgery Division Chair, and received the Paul Nutter Endowed Professorship in Surgery at VCU. In 2005, Dr. DeMaria joined the faculty of Duke University as a Professor and Vice Chair in the Department of Surgery, and Chief of programs in MIS, Metabolic and Bariatric Surgery, the MIS/Bariatric Surgery Fellowship training program, and the Duke Surgery Service at Durham Regional Hospital. He currently works at Surgical Review Corporation as a Director in the Research Division. His interests are in the areas of risk stratification, innovations in treatment for obesity, revisional bariatric surgery, and clinical research trials. Dr. DeMaria has authored/co-authored 120 peer reviewed scientific articles, 6 books, and 31 book chapters during his career.