

## Bariatric surgery and metabolic syndrome: are the 91 NIH guidelines still adequate.

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### Abstract

US have the highest mean BMI among high income countries. One in three adults has BMI >30. Between 1980 and 2008, global mean BMI increased at an annualized rate of 0.4 kg/m<sup>2</sup>/decade for men and 0.5 for women. Diabetes parallels the obesity trend. Total estimated cost of obesity in US is \$147 billion to nearly \$210 billion per year. Dietary restrictions have demonstrated only 6% success. Physician supervised, medically approached weight loss strategies have about 12% success rate. Bariatric surgery has proved to be the most effective strategy in treating obesity. Currently, indications for bariatric surgery are based on the guidelines established by National Institute of Health (NIH) in 1991 (BMI>35+ associated medical co-morbidities or BMI >40). A significant and growing number of patients who have one or more components of metabolic syndrome and a BMI <35 are left out from bariatric surgery intervention as payers base their coverage for bariatric surgery on the 1991 NIH guidelines. We do review the currently available literature on the topic and present our bariatric surgery center experience and initiatives aiming to overcome the limitations of NIH guidelines for bariatric surgery and to start a constructive and collegial conversation on their possible revision. Standardization of the key measurements of a procedure's finished anatomic configuration strengthens surgical practice, research, and patient outcomes. A consensus meeting was organized to define standard versions of 25 bariatric metabolic procedures.

### Introduction:

The components of the metabolic syndrome account for a substantial portion of the attributable risk for atherosclerotic cardiovascular diseases. All five components of the American Heart Association/National Heart, Lung, and Blood Institute definition of MetS have been linked independently to CV diseases, including increased serum triglycerides, low serum high density lipoprotein cholesterol, elevated blood pressure, increased fasting plasma glucose, and an increased waist circumference. With the increasing prevalence of MetS and its strong association with the development of diabetes and CV disease, this syndrome is a significant public health concern. Substantial evidence suggests that insulin resistance is the underlying abnormality in the pathophysiology of MetS and that lifestyle modifications represent the cornerstone of management. Increased physical activity and a healthy diet in people with impaired fasting blood glucose reduces the incidence of type 2 diabetes mellitus, even when participants experience only modest weight loss of <10%. Because most dietary interventions fail to achieve more than a 10% weight loss and most lost weight is regained, the net effect of significant and long-lasting weight loss on MetS is unknown.

Bariatric surgery, an approved treatment for obesity when other measures have failed, induces longstanding, profound weight loss. Most patients eligible for weight reduction by bariatric procedures have a substantial number of components of MetS with most of the weight loss attributed to reduced caloric intake and, to some extent, partial malabsorption of nutrients or bypass of the duodenum by Roux-en-Y gastric bypass. This patient population presents a unique opportunity to determine the effect of major weight loss on MetS prevalence with little confounding by changes in moderate-intense physical activity. We evaluated the effect of bariatric surgery on MetS in a population-based

cohort of patients with morbid class II-III obesity, with a body mass index  $\geq 35$  kg/m<sup>2</sup>, undergoing RYGB and in a control group of patients who were non-operative. In combating the twin pandemics of obesity and type 2 diabetes, bariatric surgery is the most effective long-term intervention for both disorders. Despite recent dramatic surgical advances, including development of several novel operations and devices, and an exploding database to justify revising patient selection criteria, global bariatric surgery practice remains largely dictated by a seriously outdated set of recommendations from the US National Institutes of Health. Herein, we present a case to impel development of new guidelines for the use of surgery to treat metabolic disease. Pre-operative psychological assessment is commonly done to identify patients who require preoperative intervention or disqualification altogether. Active substance abuse is a standard contraindication to surgery. Although a requirement for mandatory preoperative weight loss among all patients is not justified by published literature, individual patients deemed to be at exceedingly high risk due to the severity of obesity and its comorbid conditions are appropriate in selected cases. The literature surrounding psychological evaluation and its likelihood to predict success is evolving. Psychological assessment prior to bariatric surgery may identify patients with psychopathology such as major depression, binge eating disorder, substance abuse, among others that may impact the decision to proceed with surgery or indicate referral for further preoperative assessment and intervention. In addition, psychological assessment may contribute to predicting postoperative weight loss. Hence, it is safe to say at this point in time that bariatric surgery in eligible patients improves diabetes control and seems to improve both micro- and macrovascular disease, whereas long-term remission, or "cure" of diabetes, is only partial and temporary.

**Conclusion:**

The 1991 NIH recommendations for bariatric surgery use have been enormously influential and clinically useful worldwide, but they are woefully outdated and crying out for revision. New consensus guidelines are needed to give due consideration to many novel operations and devices, increasingly safe minimally invasive techniques, and the remarkable effect of some procedures on metabolic diseases such as type 2 diabetes, through mechanisms beyond just weight loss. Helping to inform policy decisions, a wealth of new data has been generated since 1991 regarding the safety and efficacy of surgical versus non-surgical approaches to obesity and type 2 diabetes, including from very large, long-term observational studies and several RCTs, with many more well underway. Standard versions of the finished anatomic configurations of 22 surgical procedures were established by expert consensus. The BMSS process was undertaken as a first step in developing evidence-based standard bariatric metabolic surgical procedures with the aim of improving consistency in surgery, data collection, comparison of procedures, and outcome reporting. In the absence of standard measurements for the key anatomic alterations of bariatric metabolic procedures, we cannot know our true outcomes, and metabolic effects cannot be finely understood and used to

predict and treat disease. The inaugural 2-day BMSS meeting in New Delhi, India, and the BMSS Consensus Statement were undertaken to establish a conceptual foundation from which to move in stages toward high-level evidence-based studies. A consensus of standards resulting from peer-reviewed evidence and expert opinion was achieved, providing a frame of reference for future research and for dialogue with fellow physicians, providers, government agencies, the media, and, most importantly, patients. To our knowledge, this Consensus Statement of the BMSS Working Group provides the first set of expert opinion-based standards to define the anatomic alterations performed in the majority of available bariatric metabolic procedures. In this meeting, learned presentations were made by several of the originators of procedures under discussion, some of whom have performed their operations for nearly 40 years. The innovators were instrumental in validating the need for a standardization congress and the importance of the use of standard measures to ensure uniformity in comparisons. Standardization will facilitate the development of the safest and most effective procedures to treat specific diseases. Those procedures will not necessarily be the ones described by their originators or proponents, but by the authority of research performed by numerous practitioners over many years. Their precision in measurement will give rise to a consensus of the evidence.