COMMENTS AND RESPONSES

Comment on: Cohen et al. Effects of Gastric Bypass Surgery in Patients With Type 2 Diabetes and Only Mild Obesity. Diabetes Care 2012;35:1420–1428

Cohen et al. (1) are to be commended for their observational study of 30 patients with longstanding diabetes and BMI 30–35 kg/m^2 who were followed for 6 years after laparoscopic Roux-en-Y gastric bypass (LRYGB). The study appropriately challenges using threshold levels to determine indications for treatment based on a continuous variable, BMI (size), which in itself is not a measure of any disease (unlike blood pressure, fasting plasma glucose, or triglycerides).

Several items require clarification:

1. National Institutes of Health Consensus Development Conferences such as the Gastrointestinal Surgery for Severe Obesity conference in 1991 do not "bound" or "set limits" for treatments: they provide recommendations based on presented evidence. However, third-party payers still use these recommendations to set limits for reimbursement, reflecting prevailing biases against the obese.
2. The state of knowledge in 1991 regarding effects of gastrointestinal bypass surgery on hyperglycemia and insulin resistance was based on 2 decades of publications consistently demonstrating improvements (2,3); the latter was presented at the 1991 conference describing 101 type 2 diabetic patients followed for 10 years.
3. Standard LRYGB in the surgical community (4) is a different operation than the "standard, proximal LRYGB..." used by the authors and described in citation 20 of their article, comparing long-limb to long-long limb RYGB. Whether or not limb lengths are significant (controversial), this article exhibits major problems bedeviling the whole field of surgical treatment of obesity throughout its 60-year history: lack of methodological consistency and, more important, failure to allocate patients to a method based on presence or severity of significant morbidities such as type 2 diabetes, dyslipidemia, an eating disorder, or impaired mobility.
4. The authors include patients with very short observation times (1 year) before attaining metabolic steady-state conditions, also common in this field. The abstract states "for up to 6 years," thus claiming it to be the "longest-term study"—yet only 37/66 (56%) of patients were followed for 5 years. The authors do this because they have selected patients with "only" class 1 obesity, defined by size criteria, although the outcome is metabolic. Curiously, they omit their 36-month data. The issue is that outcomes of metabolic operations cannot be adequately evaluated until steady state has been achieved, usually not until 36 months postoperative.

A common, conceptually flawed criticism of this surgery is the lack of studies randomizing to medical treatment. The study by Cohen et al. could justify randomization by comparing gastrointestinal bypass operations with varying technical parameters stratifying for sex, age, and, for example, severity of type 2 diabetes, in contrast to the scientifically and ethically challenged randomizations between operations with different modes of action, or worse—randomizing between instantly, voluntarily reversible regimens and operations requiring scheduling, funds, and increased reoperation risks. Nevertheless a recent U.S. 1-year study randomized LRYGB to intensive medical treatment for type 2 diabetes, using truly standard measurements in 50 diabetic patients (42% men) with mean BMI 36 kg/m^2, among whom 28% had BMI $<$35 kg/m^2 (5). Notably, the Cohen et al. study included 61% men, likely with a lower percentage of postmenopausal women than the U.S. study.

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