COMMENTS AND RESPONSES

Response to 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

We thank Dr. Kral for his thoughtful comments on our article regarding the use of Roux-en-Y gastric bypass surgery (RYGB) to treat type 2 diabetes (T2DM), and we would like to respond and add to his comments (1).

Although the 1991 National Institutes of Health (NIH) guidelines were thoughtfully constructed and have been highly valuable, we agree that they were not originally intended as stringent dictums governing bariatric surgery. The NIH itself posts the following concession atop their related website (http://consensus.nih.gov/1991/1991gisurgeryobesity084html.htm). "This statement is more than 5 years old and is provided solely for historical purposes. . . . Some of the material is likely to be out of date, and at worst simply wrong."

Nevertheless, no updated NIH guidelines have since been rendered, and the 1991 recommendations have had enormous impact. American insurance coverage follows their BMI-based surgical criteria, and at least 9 reiterative guideline sets have subsequently been articulated by medical societies worldwide, all limiting surgery to persons with a BMI >40 kg/m^2, or >35 with complications such as T2DM. Thus, the 1991 recommendations have established current global surgical selection standards.

As the NIH admits, however, their recommendations are outdated. They were based on data entirely from open operations, rather than the far safer laparoscopic approaches that are now standard. Only one operation they condoned, RYGB, still survives, and numerous new bariatric/metabolic operations have subsequently evolved. NIH focused only modestly on diabetes, but it has become even clearer that bariatric operations exert dramatic antidiabetes effects through mechanisms beyond just reduced food intake and body weight (2). Consequently, usage of "metabolic surgery" to treat T2DM expressly, including in patients with a BMI <35 kg/m^2, is increasingly considered.

Our study examined this strategy. We found that RYGB safely and effectively ameliorated T2DM and other metabolic syndrome features, reducing cardiovascular risk for up to 6 years in patients with a BMI of only 30–35 kg/m^2, despite severe, longstanding baseline diabetes.

We thank Dr. Kral for highlighting some limitations of our work. Admittedly, not all of our 66 patients had yet reached the 6-year postoperative time point, and a few had reached only 1 year. However, the median follow-up was 5 years, with 100% retention, and in the year since our article was written, none of the 88% of patients who achieved diabetes remission have relapsed. Moreover, a subsequent article from the huge Swedish Obese Subjects study confirms improved glucose homeostasis for up to 15 years after bariatric surgery (3). We agree that methodological inconsistencies, such as variable bypassed intestinal limb lengths, have beclouded bariatric surgery research, but everyone in our study underwent a standardized, conventional RYGB, with equivalent limb lengths and gastric reservoir. That our cohort was 61% male, whereas bariatric surgery is generally performed more in women, could theoretically limit generalizability of our findings; however, we found no gender-related differences in surgical safety or efficacy.

Although observational studies such as ours, the Swedish Obese Subjects study, and others provide promising evidence regarding long-term benefits of bariatric/metabolic surgery for T2DM, including among less obese patients, we feel that confirmation from randomized trials of surgical versus nonsurgical approaches is necessary. Fortunately, three such trials have recently been published, demonstrating superiority of all four commonly performed bariatric operations over medical/behavioral interventions for T2DM, for 1–2 years (4–6). Additional level 1 data are needed, especially to evaluate longer-term results and "hard" cardiovascular end points.

Nevertheless, we consider the evidence generated in the past 21 years more than adequate to justify now developing new NIH guidelines for bariatric/metabolic surgery, looking to move beyond BMI as the dominant surgical criterion.

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DOI: 10.2337/dc12-2243

Acknowledgments—D.E.C. is a principal investigator on the COSMID trial, which is funded by Johnson & Johnson. No other potential conflicts of interest relevant to this article were reported.

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