

A Payer's Perspective on the Cost-Effectiveness of Gastric Bypass Surgery

TO THE EDITOR:

"Cost-Effectiveness of Roux-en-Y Gastric Bypass in Type 2 Diabetes Patients," the article by Ikramuddin et al in the September 2009 issue of the *Journal*, presents a cost-effectiveness analysis of Roux-en-Y gastric bypass (RYGB) surgery compared with medical management in patients with severe obesity and type 2 diabetes mellitus in the United States.¹ The analysis uses data on metabolic and cardiovascular benefits of RYGB surgery from 204 patients (2.3 years of follow-up) treated at 1 academic medical center in the United States (University of Minnesota). Data were extrapolated by the CORE Diabetes Model to determine the long-term health outcomes and economic consequences. The control cohort, which had the same observed baseline characteristics as the surgery group, was completely simulated based on the CORE Diabetes Model. The CORE Diabetes Model uses data from the United Kingdom Prospective Diabetes Study (UKPDS) to simulate the risk of diabetic complications.

The analysis shows that, compared with medical management, RYGB surgery for obese diabetic patients has a cost-effectiveness ratio of \$22,000 per quality-adjusted life-year gained. The authors conclude that, in the United States, RYGB surgery is cost-effective from a payer's perspective.

Given the high prevalence of type 2 diabetes, the increasing prevalence of severe obesity, and the high costs of RYGB surgery, an analysis of the cost-effectiveness of RYGB surgery is certainly relevant from a payer's viewpoint. Still, I am concerned about the relevance and validity of this article. First, payers are not necessarily interested in the average cost-effectiveness of RYGB surgery across all US centers. For complex surgical procedures it is well documented that, for example, high-volume hospitals and surgeons have fewer complications and shorter stays.^{2,3} That also holds true for RYGB surgery.⁴ Therefore, payers may be more interested in differences in cost-effectiveness between high-volume and low-volume centers, or the cost-effectiveness of referrals to high-volume hospitals.⁵ Furthermore, not all centers perform RYGB surgery in the same way, potentially resulting in different metabolic and cardiovascular benefits. Differences exist in surgical techniques (eg, the location of the staple line that partitions the stomach and determines the size of the upper gastric pouch, the site of anastomosis to the jejunum, the disruption of the various autonomic nerve fibers that innervate the foregut).⁶ For these reasons, it does not seem reasonable to use outcome data from 1 US center only and make a generalized statement about all US centers.

Second, it has been shown that patients reach their lowest weight 2 years after surgery, but significantly regain weight thereafter.⁷ As the authors do not consider this weight regain, they may have seriously overestimated the cost-effectiveness of the surgery.

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Third, the control cohort in this study is not managed by current US practice. Medical management is simulated partially based on data from the UKPDS, a study that was conducted in the United Kingdom and finished in 1997. Today, US Food and Drug Administration-approved weight-loss medications are available, and these provide at least a moderate benefit. Therefore, the comparator should comprise today's more aggressive weight-loss management.

Fourth, as the observational study did not have a control group and was not randomized, I am concerned that surgery and control arms were not comparable and that a channeling bias exists. That is, patients might have been assigned to surgery based on unobserved prognostic factors (not included in Table 1). Although the authors acknowledge the lack of a controlled study, they do not discuss the resulting bias. This bias potentially aggravated the bias from excluding patients without complete data ($n = 363$) and may have resulted in an overestimate of benefits.

And fifth, the analysis does not consider expenses unrelated to type 2 diabetes that are incurred during the years of life gained by RYGB surgery. These costs may not be negligible. In a cost-effectiveness analysis of obesity prevention in 20-year-olds, van Baal et al show, based on Dutch data, that savings achieved in the first 50 years through a reduced incidence of obesity-related disorders were later more than offset by expenditures resulting from nonobese individuals living longer.⁸

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IN REPLY:

On behalf of my coauthors, I would first like to take this opportunity to thank the writer of this Letter to the Editor in response to our modeling study and also the Editor of *The American Journal of Managed Care* for giving us the opportunity to respond. We would like to respond by taking the areas of question one at a time.

First, the University of Minnesota Medical Center is indeed a higher volume bariatric surgery center and could, potentially, have different outcomes than smaller volume bariatric surgery centers. However, the practice of bariatric surgery (including Roux-en-Y gastric bypass [RYGB]) has undergone a great deal of standardization since 2004, including the development of centers of excellence. The development of surgical centers of excellence and, more importantly, surgical treatment guidelines have aided in standardization of techniques across low-volume and high-volume surgical centers to provide the basis for consistency of bariatric surgery outcomes across the United States. Data on the specific RYGB surgical techniques and associated outcomes over time have shown that stomach pouch size has little to no impact over 2 years of follow-up and that Roux limb size does not impact outcomes after 10 years of follow-up.

Second, the weight regains after RYGB were addressed in the article and were included in Table 4 as the sixth sensitivity analysis. Using the Swedish Obesity Study (Sjöström L, Narbro K, Sjöström D, et al; Swedish Obese Subjects Study. Effects of bariatric surgery on mortality in Swedish obese subjects. *N Engl J Med.* 2007;357(8):741-752), we assumed a 3.322 kg/m² increase in BMI over 10 years. The result of this weight gain was an approximate 20% increase in the incremental cost-effectiveness ratio from \$21,973/QALY in the base case to \$25,588/QALY with the added weight. The result does not substantively change our results or conclusions. The experience of weight regain in our clinic at the University of Minnesota is quite similar to the Swedish Obe-

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sity Study results (data unpublished at present). Our weight loss erodes from 30% at peak to 27%, representing only a 10% change in weight loss over time. Moreover, a large multicenter randomized clinical trial in overweight patients with type 2 diabetes mellitus (T2DM) called the Look AHEAD (Action for Health in Diabetes) comparing intensive lifestyle intervention with traditional methods showed 1-year weight loss of 8.7%, which eroded to 4.2% weight loss after 4 years, representing a 50% reduction in effectiveness over time. Compared with intensive lifestyle intervention, the magnitude of initial weight loss is much greater with RYGB, whereas the weight regain over time seems to be higher with lifestyle intervention than with RYGB. The Swedish Obesity Study demonstrated pancreatic beta cell preservation for patients undergoing RYGB that also was not accounted for in our analysis, providing the potential for additional effectiveness of RYGB.

In order to address both the third and fourth points, we previously decided to go back and retrospectively identify a comparative control cohort, because we recognized the absence of a control group as a weakness of our study. We plan to run all analyses again once this comparative cohort is identified and submit this analysis to a peer-reviewed journal in the near future. We fully acknowledge this as a weakness of our study and plan to address it accordingly.

Fifth, we also agree that we excluded potential benefits of RYGB other than those obtained through prevention of T2DM complications, including fewer orthopedic problems, reduced incidence of cancer, and so forth. If we were to in-

clude these alternative outcomes, the cost-effectiveness of RYGB would simply increase/improve, suggesting that our analysis may represent a worst case scenario regarding the cost-effectiveness of RYGB compared with medical management for obese patients with T2DM. We also acknowledge that patients who live longer cost more money simply because they are alive and not dead. We would argue, though, that these patients are not only alive, but also may have improved health-related quality of life because of decreased weight and improved activities of daily living.

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