Published in final edited form as:

JAMA. 2009 April 15; 301(15): 1593–1595. doi:10.1001/jama.2009.541.

Bariatric Surgery and Diabetes:

Who Should Be Offered the Option of Remission?

Dr. Jonathan Q. Purnell, MD and Dr. David R. Flum, MD, MPH

Department of Medicine, Oregon Health & Science University, Portland (Dr Purnell); and
Department of Surgery, University of Washington, Seattle (Dr Flum). Dr Flum is Contributing
Editor, *JAMA*

Diabetes has been considered the model chronic disease—progressive, managed rather than cured, and burdensome to patients and the health care system. But all this changed with the observation that many patients undergoing surgically induced weight loss appear to have a form of lasting remission of their diabetes.¹ Now that the medical community can offer a chance for diabetes remission, why has surgery not become the standard of care for severely obese patients, and what public health strategy could offer bariatric surgery in a sensible manner?

Although conventional weight loss approaches improve insulin sensitivity, long-term weight reduction is rare and therefore an unreliable means to achieve diabetes remission. Conversely, while purely restrictive surgical procedures improve glucose control in parallel with weight loss² (and therefore the effect is more variable), gastric bypass leads to marked improvements in diabetes (near or complete normalization of glycated hemoglobin levels, with reduction or elimination of diabetes medications) in almost all patients within the first few weeks of surgery, often before hospital discharge.¹ Given this dramatic outcome, why has gastric bypass not become the accepted treatment for diabetes for obese patients?

One barrier limiting surgical referral is the perception that gastric bypass offers nothing more than motivation to change unhealthy lifestyle habits; this perception may have its roots in the precept that surgery treats diseases through mechanical changes rather than through alterations in underlying pathophysiological mechanisms. However, it has become increasingly evident that gastric bypass surgery does not “treat” diabetes solely by restriction or malabsorption. Although the mechanism is incompletely understood, gastric bypass alters gut hormone secretion, which results in sustained reductions in food intake (eg, low levels of ghrelin and increased secretion of postprandial peptide YY) and enhanced insulin secretion (eg, increased secretion of incretins such as GLP-1).^{3–5}

A new theory of diabetes resolution after gastric bypass proposes that exclusion of nutrients from the duodenum and proximal jejunum decreases release of a factor that induces insulin

© 2009 American Medical Association. All rights reserved.

Corresponding Author: Jonathan Q. Purnell, MD, Department of Medicine, Oregon Health & Science University, Mailstop L481, 3181 Sam Jackson Park Rd, Portland, OR 97239 (purnellj@ohsu.edu).

Financial Disclosures: Dr Flum reported having run an animal laboratory sponsored by Coviden in 2007–2008 and having traveled to the First World Congress on Type 2 Diabetes, sponsored by Dowden Health, in October 2008. Dr Purnell reported no disclosures.

resistance.⁶ Advancing this theory are experimental devices aimed at excluding nutrients from the duodenum; such devices show promise in humans.⁷ In part because of incomplete understanding of the mechanism of effect, this concept of gastrointestinal surgery as endocrine modifier is not fully embraced by the clinical community and has yet to be incorporated into care strategies. Perhaps more importantly, some clinicians evoke the irreversibility of gastric bypass and the occasional reports of poor outcomes to label this approach “extreme”—to be reserved as a treatment of last resort, if performed at all. The argument is that, given the risks of surgery and considering that intensive medical management can achieve acceptable glycemic control, surgery is unnecessary. The burden of diabetes speaks against the ability of the US health care system to effect optimal medical management for enough individuals. That the lifelong use of multiple oral and injectable medications and their accompanying adverse effects are also not regarded as extreme is perhaps a reflection of the complex ways in which clinicians and patients conceptualize reversibility and risk.

Risks of bariatric surgery are easily quantifiable, and most tend to cluster around the perioperative period—whereas the risks of living with diabetes occur over the course of a patient’s lifetime and may be more difficult to trace to diabetes. Facing such a large difference in up-front risk and a poorly quantified long-term risk can complicate the decision-making process.

A “back of the envelope” calculation highlights the issue. If the number of gastric bypass operations performed in patients with diabetes increased to 1 million per year (from the total number of procedures being performed in the United States, which is now estimated at 225 000 per year),⁸ the currently estimated 1-in-200 risk of perioperative death for all patients undergoing gastric bypass¹ would mean that nearly 5000 patients would be expected to die of surgically related complications (0.5% per 1 million). On the other hand, using survey data from 2005 and estimating a per-year mortality rate of 3 per 1000 patients with diabetes⁹ would suggest that approximately 15 600 deaths would occur over 5 years in a cohort of 1 million medically managed patients with diabetes. Extrapolating from recent data that show an up to 90% reduction in diabetes-related mortality after gastric bypass¹⁰ suggests that as many as 14 310 (90% of 15 600) diabetes-related deaths might be prevented by bariatric surgery over 5 years. These types of competing timelines and risks should be part of risk-benefit discussions with patients and policy makers. Whether that is happening now is unclear, and how best to present these complex data remains a challenge.

What is clear is that only a fraction of eligible patients with diabetes is undergoing bariatric surgery and that it is likely that many eligible patients are not well informed about this surgical strategy. Which patients with diabetes should be offered surgery? In 1991, a consensus panel sponsored by the National Institutes of Health suggested restricting bariatric surgery only to patients with a body mass index (BMI) of 35 (calculated as weight in kilograms divided by height in meters squared) or higher and with a comorbid condition such as diabetes; this recommendation has become the standard.¹¹ This decision was formulated prior to minimally invasive techniques and the significant improvements in perioperative risk. None of the current data from long-term observational studies on outcomes, including marked improvement in mortality rates from diabetes, were available at

that time. Given the observed benefits of diabetes control, reduced medication use, and reduced mortality, it is being increasingly argued that while BMI cutoffs may have been appropriate at the time, they are no longer evidence-based.

Professional societies have recently proposed that the Centers for Medicare & Medicaid Services (CMS) expand eligibility criteria to include patients with diabetes and with BMI of 30 or greater, and already there has been international interest in including patients with BMI less than 30. However, CMS recently ruled that current evidence was insufficient to expand the national coverage decision about bariatric surgery to include patients with diabetes and with BMI in the 30 to 35 range.¹² The Center's refusal to expand coverage offers an opportunity to create a rational strategy for including surgery into a public response to diabetes.

How would a public health approach help in deciding which patients should be offered gastric bypass for diabetes? One way to think of surgery in the context of public health is to consider the economic implications of adopting the surgical strategy. Surgery is economically advantageous for insurance companies, other payers, and the public if the costs are recouped from reduced medication use, clinic visits, hospitalization, and improved productivity. Since the accumulated benefits of bariatric surgery are most apparent in the long term, a broader perspective is necessary to reconcile the up-front costs of expanding this surgical strategy. Given the economic constraints on large amounts of up-front health care spending, one public health response to offering surgery as diabetes therapy could be the creation of a triage system. Mandating provision of information about competing risks and benefits, along with standard coverage for the surgical option only for high-risk patients with diabetes, would be similar to approaches used for areas with other limited resources such as organ transplantation. This might provide for a more rational distribution of surgical resources rather than what is expected to occur through private sector mechanisms, by which surgery is available only to those with insurance coverage and an interest in the procedure.

Offering surgery as a treatment option for diabetes for patients at higher risk would not necessarily mean that all eligible patients would have surgery but only that they would be informed decision makers and that the option would really be available to them. The medical community would then need to redefine the standard of care to at least include presenting information about the surgical option to these higher-risk patients with diabetes; all insurers would have to have this as a coverage option. Providing a structured, shared decision making (SDM) tool specific for patients with diabetes similar to the SDS tools already available for patients with obesity who are interested in bariatric surgery¹³ would help to deliver the best evidence regarding risks, benefits, and alternatives as well as provide testimonials from other obese patients with diabetes.

For instance, an SDM tool could be targeted to patients at highest risk of death from diabetes and obesity—ie, perhaps those with diabetes and BMI of 50 or greater; this group represents an estimated 420 000 adults (1 in 238 are estimated to have BMI greater than 50¹⁴ of the 300 million adults estimated by the US census [1 260 000] and an estimated 30% of these have diabetes).¹⁵ Widespread use of such a tool by diabetologists and internists could be reinforced by making this a component of American Diabetes Association Certificate of

Excellence accreditation, health plan quality metrics, and pay-for-performance strategies. If only one-third of these patients had the operation (approximately 140 000), this would be a significant increase in yearly bariatric surgery but would be more likely accommodated with existing resources. The surgical community would have to increase the trained workforce and capacity to meet the demand for surgery and to refine the techniques of bariatric surgery to make it safer still. They would also have to reconcile the observation that patients with BMI greater than 50 are probably at higher risk for surgery, are more likely to be disabled, and are less likely to have commercial insurance.

This “50+ first” strategy differs substantially from the request from professional societies to expand coverage to patients with diabetes and BMI less than 35. That proposal was framed as an issue of an individual’s right to an operation, but because the request was made to the public’s insurer (the CMS), this request for expanded coverage was really a call for a change in the public health perspective about the role of surgery in the treatment of diabetes. These calls for expansion do not appear to recognize that surgery currently is not “standard of care” for the patients at highest risk, and that the up-front resources necessary for a substantial expansion of surgical services may not be realistic. This proposed strategy is a targeted approach and should help determine how many patients would avail themselves of surgery if properly informed. This proposal does not call for a change in the current surgery coverage guidelines for patients with diabetes and BMI of 35 or greater. Instead, the proposal would for the first time elevate surgery to be a standard treatment option for those with BMI of 50 or greater. If this strategy saves lives and health care dollars, and if resources for up-front investment become more available, the threshold for the compulsory use of the SDM tool and universal coverage of the procedure could then be expanded to patients with lower BMI.

Surgical treatment offers a chance for remission of diabetes among patients with extreme obesity. The pressing challenge is to determine how to offer this chance in a responsible fashion. If left to market forces, patients with the best insurance and those who are sufficiently informed to demand it—not necessarily those who are most at risk—will be the most likely to undergo surgery for diabetes. Instead of relying on market forces alone to determine the role of surgery for diabetes, what is needed is a pragmatic public health perspective. The “50+ first” strategy is a step in that direction.

References

1. Buchwald H, Avidor Y, Braunwald E, et al. Bariatric surgery: a systematic review and meta-analysis. *JAMA*. 2004; 292(14):1724–1737. [PubMed: 15479938]
2. Dixon JB, O’Brien PE, Playfair J, et al. Adjustable gastric banding and conventional therapy for type 2 diabetes: a randomized controlled trial. *JAMA*. 2008; 299(3):316–323. [PubMed: 18212316]
3. Whitson BA, Leslie DB, Kellogg TA, et al. Entero-endocrine changes after gastric bypass in diabetic and nondiabetic patients: a preliminary study. *J Surg Res*. 2007; 141(1):31–39. [PubMed: 17574036]
4. Laferrère B, Teixeira J, McGinty J, et al. Effect of weight loss by gastric bypass surgery versus hypocaloric diet on glucose and incretin levels in patients with type 2 diabetes. *J Clin Endocrinol Metab*. 2008; 93(7):2479–2485. [PubMed: 18430778]
5. Ferrannini E, Mingrone G. Impact of different bariatric surgical procedures on insulin action and beta-cell function in type 2 diabetes. *Diabetes Care*. 2009; 32(3):514–520. [PubMed: 19246589]

6. Rubino F. Is type 2 diabetes an operable intestinal disease? a provocative yet reasonable hypothesis. *Diabetes Care*. 2008; 31(suppl 2):S290–S296. [PubMed: 18227499]
7. Tarnoff M, Rodriguez L, Escalona A, et al. Open label, prospective, randomized controlled trial of an endoscopic duodenal-jejunal bypass sleeve versus low calorie diet for pre-operative weight loss in bariatric surgery. *Surg Endosc*. 2009; 23(3):650–656. [PubMed: 19067075]
8. American Society for Metabolic & Bariatric Surgery Web site. [Accessed March 25, 2009] <http://www.asbs.org>
9. [Accessed March 25, 2009] statehealthfacts.org Web site. <http://www.statehealthfacts.org/>
10. Adams TD, Gress RE, Smith SC, et al. Long-term mortality after gastric bypass surgery. *N Engl J Med*. 2007; 357(8):753–761. [PubMed: 17715409]
11. National Institutes of Health. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults—the evidence report. *Obes Res*. 1998; 6(suppl 2):51S–209S. [PubMed: 9813653]
12. CMS programs and information. Department of Health and Human Services; Web site. <http://www.cms.hhs.gov/> [Accessed March 25, 2009]
13. Weight management. Dartmouth-Hitchcock Medical Center; Web site. http://www.dhmc.org/webpage.cfm?site_id=2&org_id=108&morg_id=0&sec_id=39685&gsec_id=39685&item_id=39697 [Accessed March 25, 2009]
14. Sturm R. Increases in morbid obesity in the USA: 2000–2005. *Public Health*. 2007; 121(7):492–496. [PubMed: 17399752]
15. Bays HE, Chapman RH, Grandy S. SHIELD Investigators' Group. The relationship of body mass index to diabetes mellitus, hypertension and dyslipidaemia: comparison of data from two national surveys. *Int J Clin Pract*. 2007; 61(5):737–747. [PubMed: 17493087]