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CLINICAL CASE

Prophylactic Bariatric Surgery

Commentary by Robert E. Brolin, MD, Bruce Schirmer, MD, and Angelique M. Reitsma, MD, MA

Mrs. Brown, who is 35 years old, has a BMI of 37. Her father struggled with diabetes mellitus type 2 for 30 years. She was his sole caretaker, nursing him through complications of peripheral neuropathy and helping him to complete his tasks of daily living after a leg amputation. Recently, he went into renal failure and died. Mrs. Brown also has a 45-year-old brother and several other first-degree relatives who have diabetes type 2 and are insulin dependent. Mrs. Brown confided her worries to her physician and was referred to a bariatric surgeon for a consultation. She says that she has worked with nutritionists and tried to exercise more, but her efforts have not been successful over the long term. Determined to avoid becoming a diabetic, she would like to have bariatric surgery. The surgery cured her friend's diabetes. With a BMI of 37 and no obesity-related diseases, Mrs. Brown does not qualify as a candidate for the surgery under the current guidelines. But were she either to gain weight (raising her BMI to 40) or develop diabetes (a condition which would lower the recommended BMI to 35), she would qualify for the intervention. She understands that insurance is not likely to cover the procedure, but money is not an obstacle. What should the consulting surgeon say to Mrs. Brown?

Commentary 1

by **Robert E. Brolin, MD**

The incidence of type 2 diabetes mellitus (DM type 2) in the U.S. is increasing at an alarming rate that appears to parallel the growing prevalence of obesity. The effectiveness of bariatric surgery in ameliorating DM type 2 has been well documented during the past 3 decades [1-3]. Although the mechanisms that induce weight loss among the various operations vary widely, any operation that results in substantial weight loss is likely to improve or resolve DM type 2.

The weight criteria that determine candidacy for bariatric surgery were first established in the 1970s. In that early era, the minimum weight for considering bariatric surgery was 100 pounds above one's so-called ideal body weight as established by standard life insurance tables [4]. In 1991, the NIH held a consensus development conference on gastrointestinal surgery for treatment of severe obesity. At the conclusion of that conference, the panel recommended that surgery could be considered for any patient with a body-mass index (BMI) equal to or greater than 40 for patients with a BMI between 35 and 40 who had medical diseases that most likely resulted from severe obesity [5]. These weight criteria—unmodified for nearly

2 decades—are still used by virtually all third-party payors who cover the costs of bariatric surgery.

Recently, several groups from abroad have published results of weight-loss surgery on patients with a BMI equal to or less than 35. One group prospectively compared outcomes after laparoscopic adjustable gastric banding (LAGB) and a diet/exercise program in patients with a BMI between 30 and 35. After 2 years weight loss, evidence of the metabolic syndrome and quality of life were significantly improved in the LAGB group compared with the nonsurgery group [6].

Prophylactic Surgery

The concept of “prophylactic surgery” is not new, and its use to avoid complications of the underlying disease has been ethically justified in a variety of areas. Until recently the strategy of repairing asymptomatic inguinal hernias to prevent incarceration was almost universally applied. Likewise, cholecystectomy is frequently recommended for asymptomatic gallstones to avoid subsequent complications. Repair of congenital atrial or ventricular septal defects in children is routinely performed to avert cardiopulmonary disease in adulthood, and incidental appendectomy to eliminate the potential for later appendicitis is still performed by many surgeons during abdominal operations for other causes. In each of these circumstances, the surgery is justified on the perceived basis of a favorable risk-to-benefit ratio.

Risks Associated with Bariatric Surgery

The perioperative risks associated with bariatric surgery have decreased substantially during the past decade. The mortality risk of all currently performed bariatric operations is less than 1 percent, ranging from perhaps 0.1 percent with LAGB to nearly 1.0 percent for biliopancreatic diversion with the duodenal switch (BPD/DS) [7-9]. The mortality rates of Roux-en-Y gastric bypass (RYGB) and the new sleeve gastrectomy (SG) fall somewhere in between [8-9]. Increased morbidity and mortality with RYGB is consistently correlated with male gender, age 50 years or older, and BMI equal to or greater than 50 [10, 11].

Prophylactic Bariatric Surgery

Assuming that Mrs. Brown in the case scenario we are asked to consider has made serious attempts at weight loss using dieting in conjunction with exercise and behavior modification, I believe it is ethical to perform bariatric surgery. The perioperative risks in a woman of Mrs. Brown’s age who has a BMI of 37 and no overt comorbidities should be very low. Conversely, the potential benefit of avoiding DM type 2, with its attendant end-organ complications, seems worthy of pursuit. Mrs. Brown’s strong family history of both obesity and DM type 2 suggests that eventual development of diabetes is likely. Moreover, in evaluating Mrs. Brown’s lifetime health, the risks associated with clinically severe obesity (defined as BMI equal to or greater than 35) cannot be ignored. The mortality risk at her current weight is more than double that of a woman of the same age with normal weight [12]. Life table models suggest that a 40-year-old woman with a BMI of 40 will live

about 4 years less than her normal-weight counterpart [13]. Moreover, virtually all morbidly obese patients will develop obesity-related comorbidities over time. Our group reported presence of at least one obesity-related comorbidity in 95 percent of our bariatric surgery patients who were 45 years or older [14].

Selection of the most appropriate operation for Mrs. Brown requires a detailed discussion with her bariatric surgeon. Most bariatric surgery patients have a strong preference for a specific operation prior to their initial surgical consultation. Frequently these preferences are based entirely upon anecdotal information gleaned from other bariatric surgery patients and materials available through the internet. It is uncommon, however, for prospective patients to have a clear understanding of the risks of the various procedures or how specific operations produce weight loss. I would present both LAGB and RYGB as reasonable alternatives for Mrs. Brown. (Sleeve gastrectomy might also be considered, but the long-term results are unknown, and, although the BPD/DS provides excellent long-term weight loss in a clear majority of patients, the metabolic risk seems excessive for a woman without overt comorbidities and a BMI of 37 [15].)

Because there is no anatomical rearrangement or malabsorption with LAGB, improvement of DM type 2 is directly related to postoperative weight loss. LAGB requires considerable patient compliance in terms of the adjustments involved with tightening the band. Weight loss after RYGB is greater and more rapid than with LAGB. Moreover, DM type 2 may resolve immediately after RYGB prior to substantial weight loss [2]. These benefits must be contrasted with the long-term risks of slip or device malfunction after LAGB or the potential risks of marginal ulcer and vitamin and mineral deficiency that can develop after RYGB.

In summary, there is little if any justification for waiting until Mrs. Brown gains weight to perform bariatric surgery. The available data strongly suggest that the long-term mortality risk of not having bariatric surgery in qualified patients is significantly greater than having a gastric restrictive operation during the same time interval [1, 16, 17].

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Commentary 2 **by Bruce Schirmer, MD**

One can readily sympathize with Mrs. Brown's concern about (probably bordering on fear of) developing diabetes. She has seen the consequences of the disease over the long term and wishes to avoid a fate similar to her father's. Consequently, she has requested bariatric surgery to avoid becoming a diabetic. Mrs. Brown has evidence that bariatric surgery can work to reverse the diabetic state, and she has the

means to pay for the operation. From her point of view, this is a reasonable request, and she seeks the help of a bariatric surgeon who will perform surgery for her.

The patient is correct that bariatric surgery can eliminate the active disease state in type 2 diabetes patients. Blood glucose comes under control, medications are often eliminated, and hemoglobin A1c levels can fall to normal. The Roux-en-Y gastric bypass (RYGB) is the best operation for reversing the active state of diabetes and allowing patients to eliminate medications and insulin. Multiple large series in the literature have shown that about 85 percent of patients with type 2 diabetes, who have been on diabetes medications for 5 years or less, become euglycemic without medications after having RYGB [1-3]. Patients who have been on medications for longer periods of time are less likely (about 50 percent) to become medication free.

The mechanism by which RYGB reverses diabetes is still being investigated. Multiple observations by hundreds of bariatric surgeons on thousands of diabetic patients after RYGB confirm that the reversal of diabetes occurs in a much more rapid time frame than would be expected based on weight loss alone after the operation. Recent studies have shown that, in the animal model, diversion of the food stream from the duodenum and proximal jejunum produce amelioration of diabetes, which then returns if the operation which produced the diversion is reversed. In South America, RYGB has been performed on patients who are not obese but do have type 2 diabetes. The amelioration of symptoms in these patients has been as good as in the obese population, with only modest associated weight loss [4]. There is much more to say about these findings, but for purposes of this commentary, we can accept the fact that Mrs. Brown's belief in the operation's effectiveness in treating type 2 diabetes is well-founded.

Currently accepted guidelines for the performance of bariatric surgery are that a patient has a body mass index of 40 or a body mass index of 35 with a co-morbid medical condition caused by or exacerbated by obesity. These guidelines have been in place since an NIH Consensus conference in 1991 [5]. They have not yet been modified, though recent data, such as those collected in South America, suggest there may be appropriate indications for broadening the application of bariatric surgery beyond its present guidelines. At this time, however, no changes have been made to the standards.

In my opinion, the ethical dilemma in this case is a fairly straightforward one: should one perform bariatric surgery as a prophylactic procedure for someone who does not meet the currently accepted guidelines for bariatric surgery? While this may seem an ethical dilemma in some ways, there really is only one answer: no. Standards and rules are created for a purpose—to be followed. It would be easy to justify “fudging” just a little bit on an indication such as this. A surgeon could perhaps, if swayed by the patient, feel justified in performing bariatric surgery for her. After all, she is close to the BMI limit for surgery. Such a rationalization, however, can serve as justification for breaking all sorts of rules and standards. If it were appropriate to

operate on this patient with a BMI of 37 and no co-morbidities, then it would be easy to say that 36 would also be OK. Where would the rule-bending end?

The guidelines for performing bariatric surgery are, one could argue, arbitrary. They are based on a decision of a panel of experts rendered almost 20 years ago. Nevertheless, they are the only available guidelines, and they are recognized internationally. They form a distinct line in the sand over which one should not step without the expected consequences of potential legal or professional sanction. If Mrs. Brown were to have an operation and develop a complication, the surgeon would not be able to defend his decision to operate in a court of law.

As surgeons, we face many situations in which the recommendation for performing an operation is not strictly black and white. Guidelines for determining whether to operate do not always exist. This can even apply to fairly significant extirpative surgery, such as the performance of a mastectomy as a prophylactic procedure for a woman at extremely high genetic risk for developing breast cancer. Such surgery is felt to be justified by the potential loss if the woman were to have undetected breast cancer that developed beyond an early stage. Similarly, removal of the esophagus for severe dysplasia in the setting of Barrett's esophagus is justified because development of esophageal cancer would likely occur in a short time for such a patient, and that diagnosis would carry a significant percentage of death from the disease. Less severe operations, such as a cholecystectomy, may be thought to indicated or not indicated by different surgeons based on their individual interpretation of whether the patient has symptoms from the stones. For bariatric surgery, however, the guidelines are well established and understood. The decision in this case scenario is clear. Mrs. Brown should not be offered the operation.

While that is the long and short of this scenario, I would feel remiss if I were to ignore the significant ethical dilemmas that bariatric patients currently face in our society. The ongoing discrimination against people who are obese—the last unaddressed discrimination in our society—is the first dilemma faced by these patients. The second is the lack of understanding on the part of the public and much of the medical profession that obesity is a disease. Laziness, lack of discipline, and other negative character traits are not solely responsible for the condition of severe obesity in many of the patients who have that problem. Finally, the arbitrary determination for access to potentially lifesaving surgical therapy remains largely in the hands of insurance companies, which have enacted many measures to limit the ability of qualified patients to secure coverage for bariatric surgery. Special riders on insurance policies, blanket denials for minimally invasive “experimental” procedures after hundreds of articles in the literature have established their appropriateness, creation of special 6-month preoperative diet periods (which have been shown to decrease patient overall outcomes, not improve them), and other hurdles intended to minimize the number of procedures the company pays for are all ethical issues much more pressing than adhering to accepted guidelines for determining bariatric surgery candidates. Obesity is the second-largest cause of health care expenditures and morbidity after smoking, and probably will take first place in the near future. Its

worst form, severe obesity, is highly curable with surgical therapy. Yet, in 2009, less than 2 percent of the patients who qualified to undergo bariatric surgery in the United States received and benefited from it. Bariatric surgery is proven to be life-lengthening and highly capable of eliminating comorbid medical problems and vastly improving the quality of life for patients who undergo it. Any discussion of the surgery must underscore these points.

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Commentary 3

by **Angelique M. Reitsma, MD, MA**

Even after a lengthy debate between bioethicists, physicians and surgeons and a plethora of publications, there currently are no formal, federal regulations that apply specifically to surgical innovation [1-3]. Consequently, the gap between regulatory goals and professional reality still exists, and as some argue, is widening due to increasing call for evidence-based surgery [4].

To close the reported gap between research idealism and surgical innovation, several authors have presented solutions to this ethical challenge. Recently published recommendations from a multidisciplinary group, which included both surgeons and bioethicists, put forth some specific and detailed guidelines for surgical innovators [3]. These guidelines were designed to help surgeons determine at what point their efforts to improve their operative techniques and therapies become innovations that would warrant additional scrutiny and outside review. Basically, they explain exactly how and when such innovations become different enough to be viewed as a form of experimentation. This signifies a point at which clinical practice goes beyond the existing standard of care, and outside of the realm of tried-and-true treatments [3]. The guidelines that were firmly founded on earlier work [2], stipulate the following:

An “innovation” is a new or modified surgical procedure that differs from currently accepted local practice, the outcomes of which have not been described, and which may entail risk to the patient. Many innovations are used on an ad-hoc basis as dictated by the clinical situation. Some innovations, however, may be developed in a more systematic fashion and may ultimately meet the criteria for human subject research, although they do not meet the criteria at the time they are performed. Example: A surgeon decides to perform Natural Orifice Transluminal Endoscopic Surgery, removing an appendix via a patient’s vagina [3].

In earlier work published by two authors from the same group [1], an additional definition of innovation was offered. Innovative use of a procedure included its application to a disease or diagnosis for which it had never been used before. This particular situation appears to apply to the clinical scenario we are discussing—performing prophylactic bariatric surgery for diabetes mellitus type 2.

First, let us take a step back and frame the ethics of surgical innovation in general. Innovative or experimental surgery has the potential to provide great benefit to patients who undergo new, sometimes life-saving procedures. In and of itself, surgical innovation is not an unethical thing, but because its risks are partly unknown and its benefits equally so, because of the lack of existing evidence, it is ethically contentious. Striking the right balance between beneficence and non-maleficence is challenging. The flipside of non-maleficence, in the case of surgical innovation, is that not offering the latest available therapies to a patient may constitute doing harm. Performing an older procedure that is going out of fashion because of disappointing outcomes instead of a newer, more promising technique seems harmful. Surgeons are required to stay current with the developments in their profession, and adopt techniques that are proven superior to the existing ones. The importance of this is reflected in the obligation to earn continued medical education (CME) credits and in (medico-legal) licensing procedures. Not staying up-to-date and hanging onto obsolete techniques while being wary of innovation is not considered good surgical practice. This stance was underscored by some of the responses to a survey among US surgeons [1]. One respondent wrote: “Surgeons that do not innovate should be the ones that need to be regulated!” One might conclude that the balance between harming and doing good is indeed delicate, and perhaps even ambiguous, when it comes to innovative surgery.

Even more ethically ambiguous is prophylactic innovative surgery. Bariatric surgery in and of itself is not an innovative or experimental surgical procedure. It has been performed for a number of years, studied and evaluated for its merits. What is innovative is the application discussed in this case: performing bariatric surgery for a new diagnosis, essentially a possible future diagnosis, one that does not exist yet but is a possible occurrence, though by no means a certainty, at a later point in the patient’s life. As is well established, diabetes mellitus type 2 (DM type 2) can develop over time in overweight individuals, particularly those with a family history

of the disease. While it would be wise for everyone to avoid becoming obese for a wide variety of health—and other related—reasons, anyone with a family history of DM type 2 especially should avoid obesity in order to have a better chance to ward off DM type 2. This can be done by adhering to a healthy lifestyle, which includes regular exercise (as little as a 30-minute brisk walk each day) and a wholesome diet. For most people, this should be adequate to retain a healthy weight and a normal body mass index (BMI), which subsequently diminishes the chances of developing DM type 2. Some might argue that for particular individuals, such as those with a predisposition toward weight gain and a family history of obesity or those who cannot exercise regularly because of severe physical limitations, these measures may not be able to control weight. For such individuals, bariatric surgery may be viewed as an extreme but appropriate measure to ensure the lowest calorie intake possible, leading to reaching a healthy weight.

Bariatric surgery significantly minimizes the size of the patient's stomach, thereby allowing only small amounts of food and drink to be taken in at one time. This makes it difficult for a person to eat large amounts of food throughout the day and, hence, reduces caloric intake, resulting in weight loss. But bariatric surgery is by no means a guarantee for continued weight loss or, better said, maintaining a healthy weight. Although the stomach may be small, patients who consume calorie-dense food and drinks and do not exercise enough will gain weight. We have only to look at the tabloids and see the celebrities who had their stomachs stapled, lost huge amounts of weight, and then gained some, sometimes a lot, of it back within years. This means that even after bariatric surgery, patients must be counseled about a lifelong healthy diet, learning which foods and drinks to avoid reversing the effects of the operation. Bariatric surgery in and of itself is no long-term guarantee for maintaining low weight and thereby indirectly minimizing the chances of developing DM type 2. Significant lifestyle changes would still be necessary to achieve that.

To offer this surgery to someone for the purpose of avoiding the potential long-term effects of her obesity, given this knowledge and the fact that this is a major surgical procedure with significant risk and morbidity, is not good surgical practice. With this in mind, I think it is clear that using bariatric surgery prophylactically in this case is not ethical and should not be performed.

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