BARIATRIC SURGERY: THE DIET OF LAST RESORT

I. WHAT IS BARIATRIC MEDICINE?

Bariatric medicine is the medically-supervised treatment of obesity and its associated conditions. *American Board of Bariatric Medicine, www.abbmcerttification.org/bariatric_medicine.html, (9/24/2002).* More than 58 million people in the United States are obese. *Id.* Obesity is defined by a person's body mass index (BMI). (*Gastrointestinal Surgery for Severe Obesity. National Institutes of Health Consensus Statement Online 1991 Mar 25-27 (cited (9/16/2002); 9(1):1-20, p. 3.)* Persons with a BMI of 40 kg/m2 or greater are obese. A BMI of 40 kg/m2 is roughly equivalent to being 100 pounds overweight for an average adult male. *Id.* Because obesity was categorized in 1985 as a specific disease process by the National Institutes of Health (*Id.)*, and because obesity is a major risk factor for hypertension, diabetes mellitus, hyperlipidemia, cardiovascular diseases and some cancers, physicians and physicians' groups have determined that this condition should be treated and monitored by a trained physician.

The medical approach to treating obesity is multifaceted. It includes psychological and dietary counseling, exercise, low and very low calorie diets, behavior modification, pharmacological treatment with appetite suppressants and sometimes, in extreme cases, bariatric surgery. *Gastrointestinal Surgery for Severe Obesity. National Institutes of Health Consensus Statement Online 1991 Mar 25-27; (cited 9/16/2002); 9(1):1-20, p. 2 & 4.*

This paper discusses the basic medicine underlying bariatric surgery, its benefits and complications, the standard of care for treating patients who undergo the procedure and the issues inherent in establishing or defending a medical negligence cause of action involving bariatric surgery.

II. WHAT IS BARIATRIC SURGERY?

Bariatric surgery, commonly referred to as "stomach stapling", is a catch-all term for any one of several surgical procedures used to induce significant weight loss. The idea that gastric surgery could cure obesity originated from surgeries performed on patients with certain gastrointestinal cancers and severe ulcers. In these operations, a large portion of the patient's stomach or small intestine was removed, inadvertently resulting in significant weight loss to the patient. *National Institute of Diabetes and Digestive and Kidney Diseases, www.niddk.nih.gov/health/nutrit/pubs/gastsurg.htm, p. 2, (9/16/2002).* Although there are several different surgical procedures available, the gold standard for bariatric surgery in North America is the Roux-en-Y procedure. *Laparoscopic Surgery for Morbid Obesity, Phillip Schauer & Sayeed Ikramuddin, p. 1; Gastric Bypass Surgery in Adolescents with Morbid Obesity, Richard Strauss, Lisa J. Bradley, M.D., Robert E. Brolin, M.D., p. 2.*

Ultimately, which procedure is used is dictated by the patient's medical condition at the time of surgery and the patient's specific needs. The more commonly performed bariatric surgeries are as follows:

1. **Gastric Banding**: In this procedure, a band is placed around the stomach near the upper end, creating a small pouch and a narrow passage into the larger portion of the stomach. *National Institute of Diabetes and Digestive and Kidney Diseases, www.niddk.nih.gov/health/nutrit/pubs/gastsurg.htm, p. 2, (9/16/2002).* The goal for this procedure is solely to restrict the amount of food the patient can eat.

2. **Vertical Banded Gastroplasty**: Both a band and staples are used to partition off a large portion of the patient's stomach, leaving only a small gastric outlet to significantly reduce the amount of food the stomach can hold. *Id.; Operative Treatment of Morbid Obesity, p. 1.*

While this procedure has a lower success rate for long-term weight loss, its relatively low complication rate makes it an acceptable alternative for some bariatric surgery patients. *Townsend: Sabiston Textbook of Surgery, 16th ed., Operative Treatment of Morbid Obesity, p. 4, 2001.)*

3. **Roux-En-Y Gastric Bypass**: The gold standard for bariatric surgery. This is a multi-step procedure. First, a small pouch is created at the top of the stomach near the base of the esophagus by partitioning off the much larger remainder of the stomach with staples. This pouch is the patient's new stomach.

[photo]

Next, the surgeon next dissects (or cuts) the jejunum into two pieces approximately 50 cm from its origin. The bottom portion of the jejunum is then sewn (anastomosed) to the newly created small gastric pouch (described above.) Food will now travel from the mouth to the esophagus, into the gastric pouch and then immediately into the jejunum (or Roux limb.) Food no longer goes into the larger portion of the stomach because it has been stapled off.

[photo]

This larger remainder of the stomach, now called the "gastric remnant", produces secretions which travel down the stomach into the duodenum and combine with secretions from the pancreas and liver. These fluids are essential for the digestion of fats, protein and complex carbohydrates and come into play in the last step of the Roux-en-Y.

[photo]

Finally, the first 50 cm of the jejunum and the duodenum (containing the gastric digestive secretions) are reconnected to the segment of small bowel that is now connected

to the gastric pouch (or new stomach.)

The purpose of the Roux-en-Y is to create not only a significantly smaller stomach, but to also cause malabsorption of nutrients. *www.lgbsurgery.com/howis.html, 9/16/2002, p. 2.*

[photo]

III. FAT CHANCES: WHO IS ELIGIBLE FOR BARIATRIC SURGERY?

The list of selection criteria of obese patients for surgical treatment is unequivocal. It was created by the National Institutes of Health in 1991 and continues to remain the gold standard for determining the appropriateness of surgery in any given patient today. The criteria are outlined generally below:

- BMI of 40 kg/m^2 or greater, or BMI of 35 kg/m^2 with significant obesity co-morbidities such as hypertension, sleep apnea, diabetes and incapacitating osteoarthritis.
- Documented failure of long term weight loss by nonsurgical methods such as behavioral modification, very low calorie dieting, exercise and appetite suppressants.
- Psychological ability to tolerate surgery and the significant change of life style associated with it, and a willingness to undergo indefinite medical surveillance.
- Adult, not pregnant.
- Absence of drug or alcohol addiction.
- Absence of chronic disease unrelated to obesity.
- Understanding that surgery itself does not guarntee long-term weight loss.

Compiled from Feldman: Sleisenger & Fordtran's Gastrointestinal & Liver Disease, p. 13 and Gastric Bypass, Robert. E. Brolin, M.D., p.14.

In practice, in order to ensure that he or she complies with these criteria, a surgeon must do a battery of tests before recommending surgery. Patients should first be evaluated by a multidisciplinary team of nutritionists, nurse clinicians, internists, psychologists or psychiatrists, and surgeons. They should also undergo a number of diagnostic tests to screen for obesity-related and non-obesity-related conditions which may render them improper for surgery. Recommended tests are chest x-ray, electrocardiogram, cardiac stress testing, echocardiogram, arterial blood gas screening, pulmonary function testing, polysomnography for sleep apnea syndrome screening, lower

extremity Doppler ultrasound for deep venous thrombosis screening, and glucose tolerance testing to screen for diabetes. *Townsend: Sabiston Textbook of Surgery, 16th ed., Operative Treatment of Morbid Obesity, p. 2, 2001.)*

It is important to note one trend in bariatric medicine. One of the criteria is that the patient be an adult. However, when the NIH published its selection criteria in 1991, there were insufficient data on the use of bariatric surgery in adolescents. *Gastric Bypass Surgery in Adolescents with Morbid Obesity, Richard Strauss, Lisa J. Bradley, M.D., Robert E. Brolin, M.D., p. 2.)* Since then, bariatric surgery has become an accepted option of last resort in adolescents who have exhausted all non-surgical methods of weight loss. *Id. at p. 6.* Like adult bariatric surgery candidates, adolescents are carefully and extensively screened beforehand to ensure optimal success.

Because gastric bypass surgery is complicated and risky under even the most ideal circumstances, a physician's failure to rigidly adhere to these screening criteria is likely to expose him or her to potential liability. The omission of even one test or evaluation could have devastating results to the patient and his family.

IV. DYING TO BE THIN: COMPLICATIONS OF BARIATRIC SURGERY

Statistics range from 1 in 200 to 1 in 350 people die of bariatric surgery. Considering there were some 45,000 operations performed in 2001 and an estimated 62,000 operations to be performed in 2002, a lot of people are dying to be thin. *Fat Chance, Genevieve Roja, Metroactive News and Issues, Nov. 1, 2001.* Complications are so commonly associated with these operations that practitioners have coined the acronym "GBGB" -- meaning gastric bypass gone bad. *The Diet of Last Resort, Newsweek, p.47.* Below, the more severe complications are discussed, followed by a table outlining several of the more common and/or severe complications and their occurrence rate.

Deep Venous Thrombosis and Pulmonary Embolus:

This is the most common unexpected cause of death in morbidly obese patients. It typically occurs in the immediate post-operative period, but has also been documented to have caused deaths as long as a month after the procedure. *T. Karl Byrne, Complications of Surgery for Obesity, p. 2.* Obese patients are more susceptible to DVT/PE than the general population because they are less active, sometimes confined to a bed, they usually have joint or disc disease that limits their movement and many have respiratory insufficiency. *Id.* These factors, combined with the fact that the patient is on the operating table for several hours leads to a classic circumstance under which DVTs/PEs are created. *Id.* Ironically, the patient in whom the condition occurs most frequently (the obese) is the patient hardest to resuscitate. Resuscitation is often futile because external cardiac massage is typically ineffective in such large patients. *Id.*

Abdominal Catastrophe:

"Abdominal catastrophe" is the term used to describe what happens when a staple line leaks. This is the most serious complication of bariatric surgery. Failure to diagnose and treat an abdominal catastrophe immediately almost always leads to severe systemic sepsis, multiple organ failure and death. *Id.* Unfortunately, the diagnosis of an anastomotic or staple line leak can be difficult to make because the symptoms often mimic those of a pulmonary embolism. *Id.* The diagnosis often is not made until signs of severe sepsis appear. By then, significant injury has already occurred.

Often the patient experiences anxiety and the feeling of impending doom. *Id.* The patient may be short of breath, have an increased pulse rate, abdominal pain, back pain, pelvic pressure or hiccups. Failure to reasonably follow-up on any of these complaints could subject the physician to significant exposure in a medical negligence case.

Incisional Hernia:

An incisional hernia occurs when part of the bowel pushes through the abdominal wall. The rate of post-operative incisional hernias -- hernias that occur through the midline abdominal incision -- is high in the bariatric patient population, between 15 and 20%. *Id.* Part of the reason for the increased rate is that bariatric patients often have increased intra-abdominal pressure. In addition, they have pre-existing respiratory dysfunction and sleep apnea due to their obesity, which further increases intra-abdominal pressure. *Id.* Finally, bariatric patients are often diabetic due to their obesity which can impair wound healing and put the pateint even firther at rsik for developing an incisional hernia. *Id.*

Whether these hernias should be treated or not usually depends on their severity and whether they are symptomatic. If left untreated, symptomatic hernias can result in bowel strangulation, bowel resection and a necrotizing wound infection. *Id.* at 4. Laparoscopic Roux-en-Y procedures, versus open procedures, significantly decrease the risk of incisional hernias.

Gallstones:

More a complication of rapid weight loss (whether by dieting or surgery) than of bariatric surgery itself, the post-operative formation of gallstones is another factor to consider when a patient is electing to undergo a procedure. *Id.* Some physicians remove the gallbladder prophylactically during surgery to avoid this complication altogether. Others believe that removal increases the likelihood of other complications. As there is no definitive on the matter, it would be difficult for a claimant to prove that a physician's removal or failure to remove the gallbladder was below the standard of care. *Id.*

Acute Gastric Distension:

This is the term used to describe a gaseous build up in the stomach after surgery. While its presence alone is not indicative of malpractice, if left undiagnosed and untreated, it could lead to abdominal catastrophe which, in turn, could lead to liability exposure.

Malnutrition:

The absorption of nutrients essential to health such as B12, calcium, and iron is often compromised after bariatric surgery. This is due to the nature of the operations themselves. Whether a restrictive-only procedure (designed only to reduce the size of the stomach) or a combination malabsorptive and restrictive procedure (such as the Roux-en Y, designed to not only reduce the size of the stomach, but to cause poor absorption of fats and proteins that can cause weight gain), the potential for malnutrition is great. The injuries to the patient caused from malnutrition can be significant. Anemia, osteoporosis, enteritis, nephritis, rheumatoid arthritis, GI-tract bleeding, and cirrhosis of the liver. *Id.*

Because this complication is known and patients are educated about it, it would be extremely difficult to base a cause of action on the presence of malnutrition itself. However, a physician's failure to follow-up on and treat the malnutrition could reasonably support a cause of action. Blood tests, vitamin levels and liver function tests are a few of the tests available to a physician to monitor and treat surgery-induced malnutrition. *Id.* at 7. Similarly, a patient's failure to follow his or her physician's instructions on how to avoid malnutrition problems would support an affirmative defense of contributory negligence.

Staple Line Disruption:

Not to be confused with a catastrophic staple line leak, staple disruption refers to those cases involving an undivided gastric bypass and vertical banded gastroplasty. *Id.* at 6. Patients literally eat until their stomachs burst, tearing out the staples and, ultimately defeating their chances for significant weight loss. The remedy is re-stapling., which means another surgery. *Id.* This is one of the reasons the Roux-en-Y is the preferred procedure of bariatric surgeons.

Some of the significant complications of bariatric surgery and their rate of occurrence are outlined below:

Complication	Frequency	Notes
Deep Venous Thrombosis and Pulmonary Embolism	2%	T. Karl Byrne MD, Complications of Surgery for Obesity, p. 2.
Abdominal Catastrophe: infection, abscess, peritonitis and death caused by staple line leak.	1:200 to 1:350 deaths caused by this complication.	T. Karl Byrne MD, Complications of Surgery for Obesity, p. 3; various sources have reported the incident of death.
Incisional hernias	15 to 20%	T. Karl Byrnes MD, Complications of Surgery for Obesity, p.3.

Gallstones	up to 50%	T. Karl Byrnes MD, Complications of Surgery for Obesity, p. 4.
Stomal Ulceration: may be caused by acid leaking through the staple line.	12 to 15%	T. Karl Byrnes MD, Complications of Surgery for Obesity, p. 5.
Acute Gastric Distension: the development of massive gaseous distension, can cause a catastrophic staple line leak.	NA	T. Karl Byrnes MD, Complications of Surgery for Obesity, p. 4
Malnutrition: can be life threatening	20 to 70%	Robert E. Brolin MD, Gastric Bypass, p.11.
Intestinal Obstruction	3%	Robert E. Brolin MD, Gastric Bypass, p.10.
Revision/Repair Operations: to address unsatisfactory weight loss or have suffered a complication.	NA	Robert E. Brolin MD, Gastric Bypass, p.11.
Small Bowel Obstruction	4.7%	Townsend: Sabiston Textboook of Surgery, 16th ed., 2001, Operative Treatment of Morbid Obesity, p. 252.
Staple Line Disruption in banding procedures.	Unknown because many cases are asymptomatic.	T. Karl Byrnes MD, Complications of Surgery for Obesity, p. 6.

The above table lists only the more significant complications to gastric bypass surgery. Other complications are stomal stenosis, nausea, vomiting, diarrhea, skin suture line infection, and electrolyte imbalances *Byrne & Brolin, in general.*

The problem occurs in communicating with the patient just how significant and common these complications are. A patient's decision whether to undergo the operation is often tainted by dramatic "before and after" photographs showing other "success stories" of massive weight reduction. This is why a physician's failure to painstakingly screen his or her patients before surgery can be devastating.

V. BUILDING A BARIATRIC MEDICAL NEGLIGENCE CASE:

Because any of the above complications can be life threatening, it is imperative that the patient have close post-surgical monitoring. The following is a list of acts or omissions that can expose a physician to liability:

- Failing to properly screen a patient for bariatric surgery, including failing to use the proper diagnostic tests.
- Failing to choose the appropriate bariatric procedure. (The Roux-en-Y is the gold standard. Electing to use a different procedure may be below the standard of care.)
- Failing to immediately respond to *any* complaint immediately following bariatric surgery.

- Failing to recognize the signs and symptoms of a gastric leak.

- Failing to repair a gastric leak.

- Failing to diagnose the cause of and treat specific complaints such as abnormally high level of pain, difficulty breathing, trouble urinating or excessive urinating, vomiting or diarrhea, left shoulder pain, back pain, and significant anxiety or lethargy.

Whether prosecuting or defending cases involving post-surgical complications of bariatric surgery, it is important to keep the above issues in mind. The existence of any of the above omissions could be a breach in the standard of care. Similarly, the absence of any of these omissions could mean compliance with the standard of care. Causation in bariatric surgery cases is usually easy to prove (although it is never to be taken for granted in any medical negligence case.) Staple line leaks, small bowel obstructions, severe wound infections, and malnutrition would have few, if any, causative sources other than the surgery. However, proving a breach in the standard of care in these cases may be difficult because these are known risks and often occur in the absence of negligence. It may be difficult to establish causation in post-surgery pulmonary embolus cases because the obese patient's pre-surgical predisposition to forming and throwing emboli makes it difficult to prove that, but forthe surgery, the pulmonary embolus would not have occured. Although, again, because it is a known complication, causation is not impossible to establish. Negligence in any case is going to occur in either failing to properly screen for the particular complication or failing to diagnose and treat it timely.

VI. **WEIGHING IN: THE CONCLUSION**:

There is little doubt that bariatric surgery can have long-term benefits. Significant long-term weight loss and resolution of obesity-related conditions such as diabetes, hyperlipidemia, hypertension, severe sleep apnea, along with a greatly increased quality of life are all well documented. *Feldman: Sleisenger & Fordtran's Gastrointestinal & Liver Disease 1998, p. 288.* Patients whose treatment has been successful are able to return to work, travel, exercise, sleep better, and socialize. However, these potential benefits have to be carefully weighed against the potential harm. Because the complications are so frequent and so severe, it takes more than a gut reaction to opt for bariatric surgery.