

Open and Laparoscopic Surgical Modalities for the Management of Obesity

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INDICATIONS AND RATIONALE FOR SURGICAL MANAGEMENT OF OBESITY

Most surgeons and medical insurance providers today adhere to the guidelines for surgical management of obesity established at the 1991 National Institutes of Health Consensus Conference on Gastrointestinal Surgery for Severe Obesity.¹ The panel of experts reviewed the long-term data on safety and efficacy of medical and surgical weight loss and concluded that surgical therapy should be offered to morbidly obese patients who are unresponsive to non-surgical therapy for weight loss. The rationale for surgery was based on a large volume of studies indicating that “dietary weight reduction with or without behavioral modification or drug therapy had an unacceptably high incidence of weight regain in the morbidly obese within 2 years after maximal weight loss.” Despite the introduction of new pharmacologic therapies since then, results of nonsurgical therapy for weight loss in the morbidly obese remain poor. According to the guidelines, patients are eligible for surgery if they have failed attempts at nonsurgical weight loss and have a body mass index (BMI) ≥ 35 with comorbidity or a BMI ≥ 40 with or without comorbidity. The only operations endorsed by the panel were gastric bypass and vertical banded gastroplasty, which at the time were the primary procedures performed in the United States with well-documented long-term data. Since this conference, there has been a dramatic increase in acceptance of bariatric surgery, with a corresponding increased understanding of alternative procedures and new approaches, particularly laparoscopic bariatric procedures. Because of the significant increase in information regarding outcomes of many different operations, as well as new questions regarding existing indications, many have suggested that a new consensus conference be held to address these issues.

STRATEGIES FOR SURGICALLY INDUCED WEIGHT LOSS

Three primary approaches for surgically induced weight loss affecting the gastrointestinal tract have arisen over the past 50 years. These include restrictive, malabsorptive, and intermediate operations. The restrictive procedures cause early satiety by creation of a small gastric pouch and prolong satiety by creating a small outlet to that pouch. They include the many varieties of gastroplasty (Fig. 1) and gastric banding (Fig. 2). In these procedures the outlet is reinforced by prosthetic material to prevent dilation. The pouch and the outlet must be small enough to adequately restrict intake yet not so small as to cause obstruction. The adjustable gastric banding procedures (Fig. 1), LAP-BAND Adjustable Gastric Banding System (BioEnterics Corp., Carpinteria, CA) and the Swedish Band (Obtech Medical, Barr, Switzerland), allow for fine adjustments of the outlet diameter, which may offset the disadvantages of a fixed, nonadjustable outlet. Significant dietary compliance is required because the intake of high-calorie liquids or soft foods is not inhibited by the narrow outlet and will result in failure to lose weight. Benefits include technical simplicity with no anastomoses or bypasses of any of the intestinal tract. There is also no protein-calorie malabsorption and no vitamin or mineral deficiencies. Relative disadvantages include less weight loss than with alternative procedures and more late failures due to pouch or anastomosis dilation or maladaptive eating behavior. Excessive narrowing by the reinforced outlets may cause frequent vomiting and gastroesophageal reflux. The prosthetic material at the outlets may erode into the gastric lumen. Malabsorptive procedures include the jejunoleal bypass, biliopancreatic diversion, with or without duodenal switch (Fig. 3), and the distal gastric bypass. These operations depend on bypass of various lengths of small intestine to cause malabsorption akin to a “controlled short-gut syndrome.” Benefits include greater sustained weight loss that is less dependent

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on dietary compliance. Problems include increased risk of malnutrition and vitamin deficiencies, with a need for constant follow-up to reduce these risks. Intermittent diarrhea or steatorrhea is likely. The malabsorptive procedures are generally more technically complex than the restrictive operations, with two or more anastomoses and, with the biliopancreatic diversion, partial gastric resection. The standard Roux-en-Y gastric bypass (RYGB) (Fig. 4) has historically been considered a restrictive operation, although many argue that there is a degree of malabsorption due to the foregut bypass, with associated vitamin and mineral deficiencies.

THE GOLD STANDARD FOR OPEN BARIATRIC SURGERY

In order to assess new laparoscopic bariatric operations, it is appropriate to establish benchmark outcome goals for comparison. The RYGB is most suitable for comparison because there is significant evidence to document both short-term and long-term outcomes, and it is considered by most surgeons in North America to have the most favorable risk/benefit profile. Table 1 demonstrates selected series of open RYGB published primarily over the past decade with key outcome parameters.²⁻¹² These studies varied considerably with regard to which outcome

parameters were reported. Notably absent are data reflecting operative time and perioperative recovery, such as hospital stay and return to work (not reported in any of the studies). Routinely reported data reflecting recovery after surgery have apparently only recently been considered important. Collectively these studies suggest that open RYGB results in a hospital stay ranging from 4 to 8 days with a perioperative complication rate of 3% to 20% and a mortality rate of approximately 1%. The most common major complications occurring early (<30 days) include pulmonary embolus (1% to 3%), gastrointestinal leak (1% to 5%), and anastomotic stricture (3% to 10%). Common late complications include hernia (5% to 24%), marginal ulcers (3% to 10%), and bowel obstruction (1% to 3%). Vitamin B₁₂ deficiency and iron deficiency anemia are the most common nutritional sequelae after gastric bypass, although both can be prevented in most patients with supplementation. Significant malnutrition or hypoalbuminemia is extremely rare in the absence of infection, obstruction, or other medical disorders. Long-term weight loss at 5 to 14 years appears to be 49% to 62% of excess body weight. Pories et al.⁹ have the longest reported follow-up for gastric bypass demonstrating a nadir weight loss of 65% excess body weight at 2 years, with an approximate 15% weight regain over 14 years that appears to stabilize (Fig. 5).

Table 1. Outcomes for open gastric bypass: Selected series

	N	Patient size (BMI, kg, or %IBW)	OR time (min)	Hospital stay (day)	Early complication rate (%)	Mortality (%)	PE rate (%)	Leak rate (%)	Hernia (%)	Follow-up (mo)	Weight loss
Mason 1969 ²	26	42	—	—	19	7.7	3.4	0	11.5	12	43 kg
Griffin 1981 ³	402	134 kg	—	—	4.2	0.75	0.25	5.47	3.5	6	35 kg
Linner 1982 ⁴	174	126 kg	—	—	10.4 (all)	0.57	0	0.57	0	24	64% EWL
Sugerman 1989 ⁵	182	213%	—	6-7*	—	1	0	1.6	18*	12	67% EWL
Hall 1990 ⁶	99	198%	120	8	20	0	3	0	2	36	67% lost >50% EBW
Brolin 1992 ⁷	90	62	—	—	5	0	1.1	0	6.6	43	64% EWL
MacLean 1993 ⁸	106	50	—	—	—	0	—	5.6	—	33	58% lost >50% EBW
Poires 1995 ⁹	608	50	—	5-6*	25.5	1.5	—	—	23.9	168	49% EWL
Capella 1996 ¹⁰	560	52	—	—	1	0	0	0 [†]	—	60	62% EWL
Fobi 1998 ¹¹	944	46	—	4*	2.7	0.4	0.6	3.1	4.7	24	80% EWL
MacLean 1999 ¹²	243	49	—	—	—	0.41	—	—	16	66	BMI 44→29 [‡]

BMI = body mass index; EBW = excess body weight; EWL = excess weight loss; IBW = ideal body weight; PE = pulmonary embolism; — = not reported.

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*As reported by the investigator, without mean and standard deviation of the mean.

[†]One subphrenic abscess.

[‡]Change in BMI for patients with initial BMI 40-50.

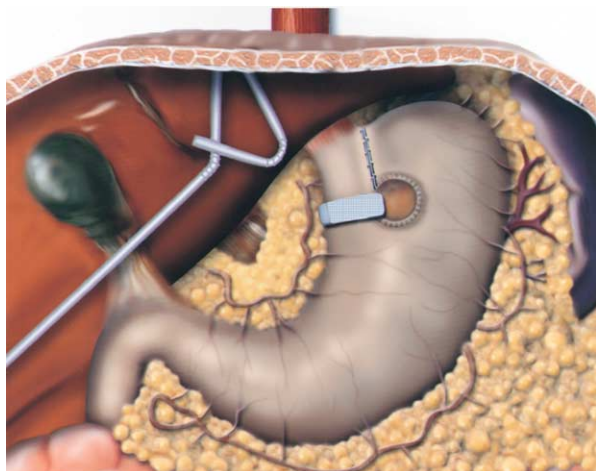


Fig. 1. Vertical banded gastroplasty (open or laparoscopic).

LAPAROSCOPIC SURGERY FOR OBESITY

Laparoscopic approaches to bariatric operations, including vertical banded gastroplasty (VBG), adjustable silicone gastric banding, and gastric bypass, all emerged at about the same time in the early to mid-1990s in the wake of laparoscopic cholecystectomy. Because of the complexity of these procedures in morbidly obese patients, the transition to common practice has been slower than some of the second-generation procedures such as laparoscopic hernia repair and Nissen fundoplication. Currently there is sufficient early experience to review technique and outcomes of three bariatric operations including laparoscopic VBG, gastric banding (with adjustable bands), and gastric bypass. Laparoscopic malabsorption operations are just beginning to emerge. Hybrid procedures that use hand-assisted laparoscopic techniques have been developed with the intention of

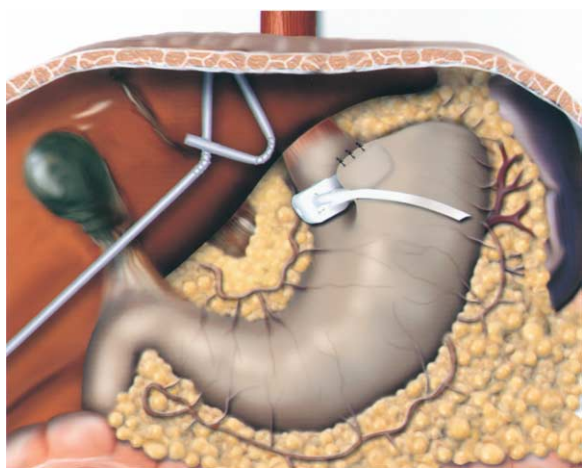


Fig. 2. Adjustable gastric band (open or laparoscopic). The device in the figure is the Lap Band (BioEnterics, Carpinteria, CA).

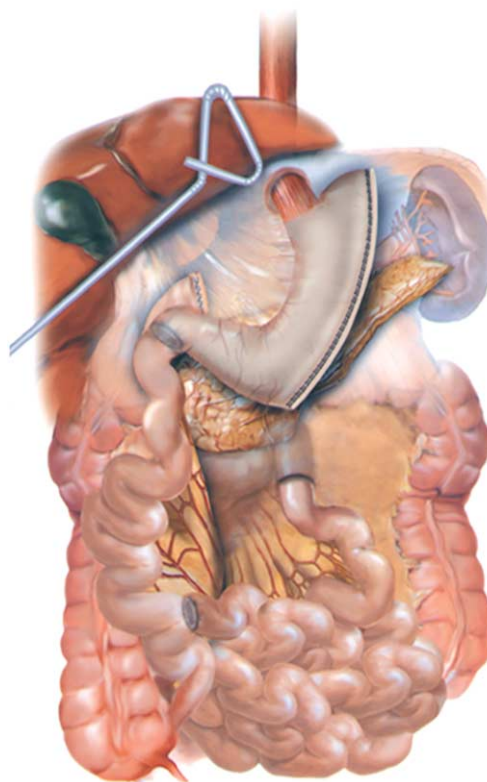


Fig. 3. Biliopancreatic diversion with duodenal switch (open or laparoscopic).

providing similar benefits seen with completely laparoscopic procedures. A major element of laparoscopic bariatric surgery that should be addressed is the importance of adequate training in both advanced laparoscopic surgery and bariatric surgery.

Although perioperative morbidity for bariatric surgery has steadily diminished, cardiopulmonary and wound complications remain a major problem.^{13,14} Furthermore, recovery after these bariatric procedures may take many weeks or months. The access laparotomy is largely responsible for the prolonged recovery and perioperative morbidity. By minimizing the access incision, a laparoscopic approach to bariatric procedures has a strong potential to significantly enhance recovery and reduce morbidity (Fig. 6). Because conventional bariatric procedures require extended abdominal incisions in patients with high comorbidity, the relative reduction in perioperative morbidity after laparoscopic bariatric procedures may be even greater than what has been observed for laparoscopic cholecystectomy.

Laparoscopic Vertical Banded Gastroplasty

Most laparoscopic versions of VBG are derived from the Mason gastroplasty.¹⁵ Current experience with a laparoscopic approach to VBG is limited (Fig. 1).

There appears to be reluctance among surgeons, at least in the United States, to consider laparoscopic VBG, perhaps because long-term results of open VBG appear to be less favorable than those of RYGB. A recent study from the Mayo Clinic showed only a 26% success rate for VBG after 10 years of follow-up.¹⁶ At the present time, only a few studies primarily from Europe have been published.^{17,18} These studies include patients with a lower mean BMI (low 40s) than what is encountered in North American studies. The laparoscopic approach appears to have an advantage over the open approach in terms of length of hospital stay (4 days) and rapid recovery. Conversion rates have generally been less than 5%. Early and late complication rates (2% to 6%) appear comparable to those for open VBG. Short-term weight loss also is comparable with a mean excess weight loss of 61% to 75% at 18 months to 3 years. The greatest concern regarding the laparoscopic VBG is that, similar to the open VBG, it will likely not achieve good long-term weight control.

Laparoscopic Gastric Banding

Laparoscopic adjustable silicone gastric banding (LASGB) was first introduced outside the United States in the early 1990s, and only recently (in June 2001) was it approved by the FDA for use in the United States. It is a purely gastric restriction procedure that involves the use of an adjustable silicone band that is placed around the gastric cardia creating a small gastric pouch, 15 to 20 ml, with a narrow outlet similar in concept to the VBG (Fig. 4). It differs from the VBG in that the band diameter may be increased to minimize side effects (i.e., vomiting) or decreased to enhance weight loss. Multiple series with 3- to 5-year follow-up have been published primarily by surgeons from Europe and Australia.¹⁹⁻²² These studies suggest that the technique is associated with a short hospital stay, rapid recovery, and minimal perioperative morbidity. Weight loss with follow-up (less than 5 years in most cases) appears to be similar to that achieved with VBG (i.e., 40% to 70% excess body weight loss). Potential advantages include complete reversibility on removal of the device and no stapling or dividing of native tissue. Disadvantages include the development of device-specific complications such as band migration, band erosion into the gastrointestinal tract, esophageal dilatation, and foreign body reaction. Experience with laparoscopic gastric banding in the United States is limited. One recently published study by DeMaria et al.²³ demonstrated that 15 (41%) of 37 patients required band removal for complications or poor weight loss. Although LASGB remains the most popular bariatric

operation in Europe and Australia, its role in the United States population remains in question until more United States based studies are completed.

Laparoscopic Gastric Bypass

A laparoscopic approach to RYGB was first described by Wittgrove et al.²⁴ Their technique involves creation of a 15 to 30 ml gastric pouch isolated from the distal stomach, a 21 mm stapled circular anastomosis, a 75 cm retrocolic retrogastric Roux limb, and a stapled side-to-side jejunojunctionostomy. They have reported on their experience with 75 patients with 3 to 30 months' follow-up. The operating time was 159 to 343 minutes. The mean hospital stay and recovery time were 2.8 days (range 2 to 75 days) and 15 days (range 7 to 30 days), respectively. Excess weight loss at 12 to 30 months was 81% to 95%. The incidence of major complications was 11%, and the leakage rate was 5% (4/75). The mortality rate was zero. The majority of comorbid conditions such as hypertension or non-insulin-dependent diabetes mellitus were either resolved or significantly improved. Their experience with 500 patients with a 5-year follow-up has been similar with good long-term weight loss. Several other large series with follow-up ranging from 1 to 3 years show equally good results.²⁵⁻³⁰

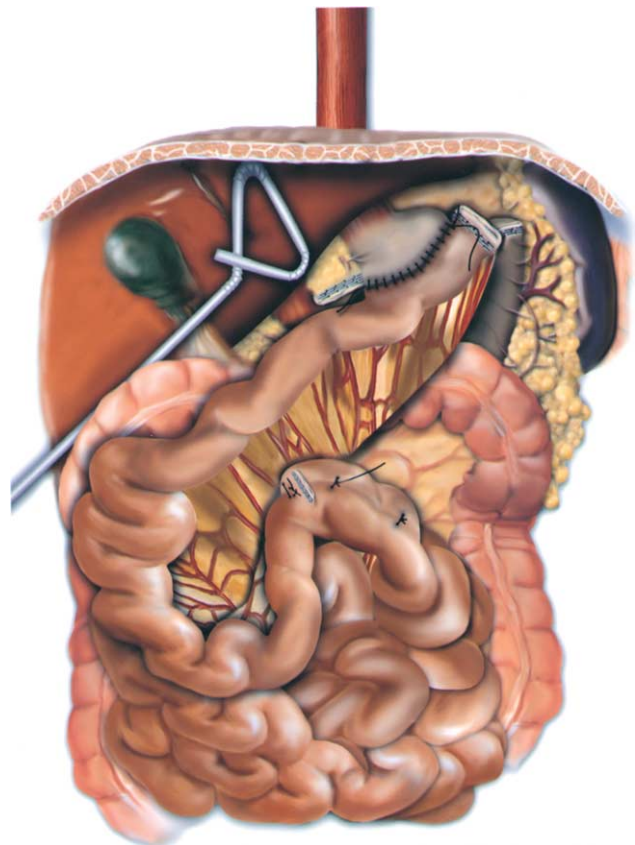


Fig. 4. Roux-en-Y gastric bypass (open or laparoscopic).

Our approach to laparoscopic RYGB at the University of Pittsburgh is shown in Fig. 4.³⁰ Consecutive patients ($n = 275$) who met the National Institutes of Health criteria for bariatric surgery were offered laparoscopic RYGB between July 1997 and March 2000. A 15 ml gastric pouch and a 75 cm Roux limb (150 cm for superobese patients) were created using five or six trocar incisions. The conversion rate to open gastric bypass was 1%. The start of an oral diet began a mean of 1.58 days after surgery, with a median hospital stay of 2 days and return to work at 21 days. The incidence of early major and minor complications was 3.3% and 27%, respectively. One death occurred, which was related to a pulmonary embolus (0.4%). The hernia rate was 0.7%, and wound infections requiring outpatient drainage only were uncommon (5%). Excess weight loss at 24 and 30 months was 83% and 77%, respectively (Fig. 7). In patients with more than 1 year of follow-up, most of the comorbid conditions were improved or resolved, and 95% reported significant improvement in quality of life (Table 2). Our experience suggests that laparoscopic RYGB is effective in achieving weight loss and in improving comorbidity and quality of life while reducing recovery time and perioperative complications.

The early results of laparoscopic RYGB compare favorably with those of open RYGB (see Table 1), particularly with regard to perioperative morbidity and recovery. Nygen et al.³¹ reported, in a prospective randomized study, that the laparoscopic approach resulted in less blood loss, fewer admissions to the intensive care unit, a shorter hospital stay, and faster recovery compared to the open approach, with no difference in total cost. This same group also showed that the laparoscopic approach resulted in a significant reduction in postoperative pulmonary impairment.³² The laparoscopic approach appears to significantly reduce wound-related complications, which may be its greatest advantage over open RYGB.

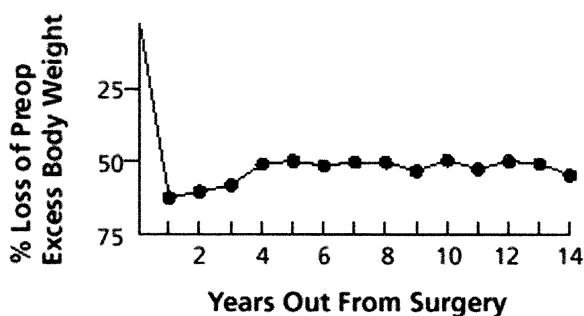


Fig. 5. Excess body weight loss after gastric bypass. Reprinted with permission from, MacDonald KG Jr, Long SD, Swanson MS, Brown BM, et al. The gastric bypass operation reduces the progression of mortality of non-insulin-dependent diabetes mellitus. *J GASTROINTEST SURG* 1997;1(3):213-220.

Because cardiopulmonary complications are less common, comparison of results from larger series will be necessary to detect differences from open RYGB.

The laparoscopic approach for RYGB, however, is not without developmental challenges. The learning curve is very steep, and long operating times are required. The incidence of intestinal leakage at the gastrojejunal anastomosis may be higher after the laparoscopic approach than after open RYGB during the learning curve. Measures to reduce staple line leaks, such as minimizing tension at the gastric pouch/Roux limb junction, careful endoscopic examination of the anastomosis, and oversewing of the staple line, may reduce leaks. The laparoscopic approach is technically more difficult in superobese persons, especially those with a preponderance of abdominal adipose tissue. Patients with prior abdominal surgery may also pose significant challenges with respect to managing complex adhesions. Finally, the laparoscopic approach may be exceedingly difficult in patients with enlarged livers because of inadequate exposure of the esophagogastric junction.

Laparoscopic Malabsorption Procedures

Laparoscopic approaches to malabsorption procedures, such as the biliopancreatic diversion operation developed by Scopinaro et al.³³ and the duodenal switch operation advocated by Marceau et al.,³⁴ are currently being developed (Fig. 3). Ren et al.³⁵ have published the only study to date evaluating early results of a laparoscopic malabsorption procedure. They performed a laparoscopic approach to biliopancreatic diversion with duodenal switch (BPD-DS) in 40 patients with a mean BMI of 60 kg/m². The operation involved a 150 to 200 ml sleeve gastrectomy with the remaining stomach anastomosed to the distal 250 cm of divided ileum, leaving a common channel of 100 cm. The conversion rate was 2.5% with a mean operating time of 210 minutes and a hospital stay of 4 days. Major morbidity occurred in 15% and the mortality rate was 2.5%. Median follow-up at 9 months showed a loss of 58% of excess body weight. This study showed that laparoscopic BPD-DS is feasible with a reasonable perioperative morbidity and mortality. Whether it offers significant advantages over other open or laparoscopic procedures remains to be seen.

Hand-Assisted Laparoscopic Bariatric Surgery

Because of the formidable technical challenges of laparoscopic approaches to bariatric operations, hand-assisted modifications are emerging to facilitate these operations. Hand-assisted approaches involve the use of devices that allow the surgeon to insert one hand intra-abdominally through a small access



Fig. 6. Operative set-up and postoperative scars for open gastric bypass (*top left and bottom left* respectively) versus laparoscopic gastric bypass (*top right and bottom right* respectively).

incision (6 to 8 cm) to assist with the laparoscopic procedure.³⁶ These devices form an airtight seal around the surgeon's arm to prevent leakage of the pneumoperitoneum. In concept, hand-assisted laparoscopy is a hybrid between open surgery and laparoscopy, and attempts to maximize the benefits of both approaches. Two currently available devices include the Dexterity Pneumo Sleeve (Dexterity Surgical, Roswell, GA) and the HandPort System (Smith and Nephew, London, UK). Early reports of hand-assisted bariatric operations suggest that the technique may facilitate the arduous learning curve for laparoscopic bariatric surgery, but advantages over conventional surgery are not clear.^{32,36-38}

TRAINING ISSUES FOR LAPAROSCOPIC BARIATRIC OPERATIONS

Laparoscopic bariatric surgery, particularly the laparoscopic RYGB and malabsorption procedures, are technically very challenging because they require

skills not required of many advanced laparoscopic procedures. Both the obese patient and the complexity of these reconstructive procedures create the major technical barriers. Patient factors such as massive obesity (BMI >60), severe hepatomegaly, prior abdominal surgery, and reoperative bariatric surgery may increase the degree of difficulty by several magnitudes. This high degree of difficulty translates into a steep learning curve and potentially a higher rate of perioperative technical complications such as intestinal perforation, anastomotic leaks, bleeding, bowel obstruction (failure to adequately close mesenteric defects), and inadvertent visceral injury. Other undesirable consequences attributed to the complexity of this operation include a longer operating time (at least initially) and potentially higher conversion rate. Acquisition of advanced laparoscopic skills is essential for safe and effective performance of laparoscopic bariatric operations. Surgeons who do not have the benefit of experience with at least some of the other advanced laparoscopic procedures will be at a significant disadvantage. Equally important to success is

Table 2. Changes in comorbidity after laparoscopic Roux-en-Y gastric bypass

Comorbidity	Total	% Aggravated	% Unchanged	% Improved	% Resolved
OA/DJD	64	2	10	47	41
Hypercholesterolemia	62	0	4	33	63
GERD	58	0	4	24	72
Hypertension	57	0	12	18	70
Sleep apnea	44	2	5	19	74
Hypertriglyceridemia	43	0	14	29	57
Depression	36	8	37	47	8
Peripheral edema	31	0	4	55	41
Urinary incontinence	18	0	11	39	44
Asthma	18	6	12	69	13
Diabetes	18	0	0	18	82
Migraine headaches	7	0	14	29	57
Anxiety	7	0	50	17	33
Venous insufficiency	7	0	71	29	0
Gout	7	0	14	14	72
CAD	6	0	0	75	26
COPD	3	0	33	67	0
CHF	3	0	33	67	0
OHS	2	0	0	50	50

CAD = coronary heart disease; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; GERD = gastroesophageal reflux disorder; OA/DJD = osteoarthritis/degenerative joint disease; OHS = obesity hypoventilation syndrome.

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the knowledge and experience with management of the bariatric patient including appropriate indications for surgery, preoperative evaluation, perioperative management, and long-term follow-up care. Either fellowship training or extended mentoring by an experienced surgeon are the two most optimal methods of obtaining the necessary skills. Both fundamentals of bariatric surgery and advanced laparoscopic surgery

should be mastered before performing laparoscopic RYGB or laparoscopic malabsorption procedures.

CONCLUSION

Two major advances in surgery for morbid obesity over the past decade are responsible for the dramatic transition from skepticism to widespread adoption. The first involves the accumulation of many studies documenting reproducible long-term weight loss in the range of 50% to 70% excess weight loss for gastric bypass, with profound reduction in comorbidity and improvement in quality of life while maintaining major operative morbidity and mortality under 10% and 1%, respectively. Apart from the gastric bypass, LASG or malabsorption procedures appear to have favorable risk/benefit ratios but do not have the same weight of evidence. Although surgical management does carry a higher risk than medical management of severe obesity, it clearly is superior in terms of long-term weight loss, which at best is 10% to 15% of excess body weight for the best medical (nonsurgical) therapy. The second major advance is the development of less invasive bariatric operations that use laparoscopic techniques. The reduction in perioperative morbidity particularly related to wound complications and recovery clearly provides significant advantages over the conventional (open) approach. Essentially all major bariatric operations can now be performed laparoscopically. Patient

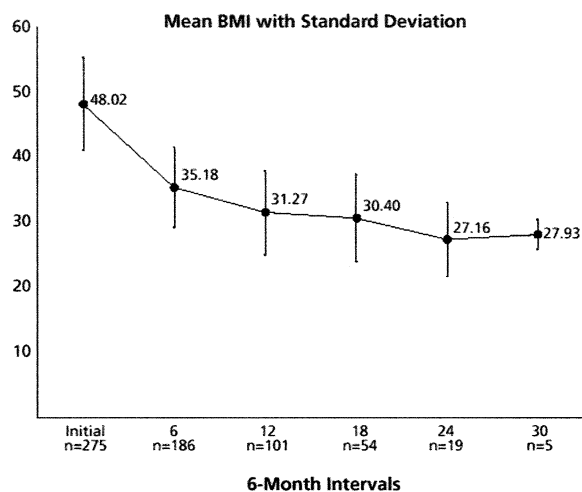


Fig. 7. Excess body weight loss after laparoscopic Roux-en-Y gastric bypass. Reprinted with permission from, Schauer PR, Ikramuddin S, Gourash W, Ramanathan R, Leketich J. Outcomes after laparoscopic Roux-en-Y gastric bypass for morbid obesity. *Ann Surg* 2000;232(4):515–529.

demand is rising steadily for the laparoscopic technique, and it probably accounts for at least some of the increase in patients seeking bariatric surgery. As more surgeons learn the laparoscopic technique, it should become the norm. Among the many challenges ahead are determining which operations are most suitable for specific patients, and whether expanding indications for surgery to include adolescents, the elderly, and those with moderate obesity (BMI less than 35) is appropriate and justifiable. In summary, the weight of recent evidence suggests that surgical management is the most effective therapy currently available for treating severe obesity, with a favorable risk/benefit ratio. Primary physicians should be obliged to discuss surgical options with all of their patients who suffer from morbid obesity.

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