

Laparoscopic Gastric Bypass, Roux en-Y – 500 Patients: Technique and Results, with 3-60 month follow-up

Alan C. Wittgrove, MD, FACS; G. Wesley Clark, MD

Private Practice, Alvarado Hospital and Medical Center, San Diego, CA, USA

Background: The authors have performed the laparoscopic gastric bypass since 1993 and perform about one-half of bariatric cases laparoscopically. Since our initial report, several groups throughout the world have performed the gastric bypass laparoscopically, with various modifications.

Method: Prospectively, we followed and recorded the results of our laparoscopic patients. A detailed pre- and post-operative analysis of the patient's co-morbidities is performed as well as complete weight and laboratory data evaluation.

Results: With > 80% follow-up, we found an excess weight loss of about 80% by the first year. This degree of loss is well sustained. Over 95% of the significant pre-operative co-morbidities are controlled.

Conclusion: The laparoscopic gastric bypass has been refined over 5 years of use. Though we have not changed the basic operation as we originally described, others have modified the various anastomotic techniques. The weight loss results are very good to excellent, with patients now out to "long-term" follow-up. Resolution of the co-morbidities is documented. The operation has an adequate track record to show effectiveness, and training programs should be established to maximize safety.

Key words: Morbid obesity, gastric bypass, laparoscopy

Introduction

Roux en-Y gastric bypass is an accepted and established method for the management of clinically severe obesity. It is our impression that the procedure achieves optimum alteration of physiology, combining restriction of intake with a profound early sensation of satiety. Patients can achieve long-term alteration of caloric intake and of eating

patterns, with minimal nutritional risk, and with powerful physiological support for behavior modification.

Since 1993, we have progressively refined the open gastric bypass technique, as developed and performed by R. Catlin, to a technique which we believe optimizes the effects of this operation, as we observe them. Its essential features include:

- **Gastric Division**

Gastric partition without division has repeatedly been shown to be associated with a high incidence of gastro-gastric fistulization, and consequent failure of weight control.

- **Lesser Curvature Based Pouch**

The lesser curvature is the least elastic portion of the stomach, and is less susceptible than a fundic pouch, to stretching and pouch dilatation over time. Increased capacitance appears to be an important mechanism of long-term weight control failure.

- **Minimal Pouch Size**

The proximal gastric pouch is made as small as is technically feasible, at a measured 15 cc volume. A very small pouch which dilates even 100% will remain small.

- **Retro-Colic, Retro-Gastric Roux Limb**

This pathway provides by far the shortest route, and minimizes compromise of the bowel circulation, and anastomotic tension. We measure the limb to be at least 75 cm in length, to preclude reflux into the gastric pouch.

- **Calibrated Anastomosis**

All gastroenterostomy anastomoses are calibrated to a diameter of 12 mm. During celiotomy, this is accomplished by use of an

Reprint requests to: Alan C. Wittgrove, MD, FACS, 6719 Alvarado Road, Suite 308, San Diego, CA, USA. Tel: 619-229-3940; fax: 619-229-3951; Email: acwmd@gastricbypass.com

intra-luminal dilator, while with laparoscopic surgery, we rely upon the internal diameter of the circular stapler.

- **Intensive Long-Term Follow-up**

Although not usually regarded as integral to a surgical procedure, we consider long-term follow-up to be of the essence of successful bariatric surgery.

Laparoscopic general surgery has become a widely accepted alternative surgical technique only within the past decade, permitting the performance of major abdominal surgical procedures with marked decrease in peri-operative discomfort, reduced hospital stay and costs, and earlier return to full, productive lifestyle. Advanced techniques and instruments have been developed to permit intracorporeal transection and anastomosis of bowel and division of vascular structures. Limited access techniques have now been adapted to performance of most surgical procedures.

We began to explore techniques for laparoscopic performance of the gastric bypass in 1993, adhering to the fundamental principle that essential features of the open operation must not be modified or compromised, to achieve the limited access technique. After laboratory verification of the instrument techniques, we performed our first procedure in late 1993. We have striven to maintain long-term follow-up and surveillance, in order to validate the efficacy of the technique, as an alternative to the open operation.

We have now performed over 700 laparoscopic gastric bypass procedures, and have maintained long-term follow-up in over 80% of patients. We report here the results of our first 500 procedures, including peri-operative management, technical refinements, weight loss, morbidity, and the effects on co-morbidities.

Methods

Qualification for Surgery

Patients are considered for surgery based upon satisfaction of the minimal criteria for bariatric surgical treatment, as determined by the Consensus Development Panel of the National Institutes of Health,¹ which are consistent with the recommended criteria of the American Society for Bariatric Surgery and the International Federation for the

Surgery of Obesity. In brief, surgery may be considered in those persons with body mass index (BMI) greater than 40 kg/m², or greater than 35 kg/m², when there are co-morbidities which are life-threatening or detrimental to activities of daily living.

All patients participate in a multistage educational and informational program, to accomplish full disclosure pre-operatively, and to engage them in compliance with bariatric management post-operatively. Patients attend an informational lecture, view a video, or read the extensive information published on our web site, which addresses the etiology and risks of the disease of morbid obesity as well as the medical and surgical treatments. The various surgical options are outlined with their results and risks.

Medical history information, including dietary history, is gathered by our nurse practitioner, during detailed patient interviews. Co-morbidities of each patient are identified and graded for severity.

Pre-operative diagnostic and consultative evaluations are tailored to the needs of the individual patient, based upon their medical history. Pre-operative psychological consultation is obtained in all cases, to be sure that the patient understands the concept of the surgery and its risks, has realistic expectations, the ability and commitment to comply with recommendations, and no psychological contraindications to the planned surgery. Concurrent with the final pre-operative history and physical examination, the patient's knowledge and understanding are evaluated with a true/false examination pertaining to the operation, its risks, complications, and long-term sequelae. The importance of regular follow-up is repeatedly emphasized.

Study Group

This study includes the first 500 consecutive patients undergoing Laparoscopic Roux en-Y gastric bypass (LapRYGBP), between October 1993 and January 1999. Patients whose operations were converted to open laparotomy are excluded. Patients have been followed prospectively for 3 to 60 months, including current follow-up of over 80% of patients, by office examination or telephone evaluation.

Post-operative morbidity is recorded at the time of occurrence. The status of co-morbidities is re-evaluated during regular post-operative follow-up.

Procedure

Gastric bypass is comprised of gastric division, with Roux en-Y reconstruction by gastroenterostomy and enteroenterostomy. The complete laparoscopic technique has been previously described,² and modifications have subsequently been reported.³ Figure 1 summarizes our technique.

Post-Operative Management

Patients undergo radiographic examination of the gastroenterostomy on the first post-operative day, using water-soluble contrast media, after which they begin a clear liquid diet immediately. Typically, patients are discharged on a clear liquid diet on the second post-operative day, and begin a soft solid diet 1 week later, emphasizing high protein and low fat intake.

Our comprehensive surgical weight management program emphasizes the importance of active patient involvement, using the new physiological tool created through surgery to achieve permanent dietary and behavioral change. This begins with educational sessions on nutrition, exercise and psychological adaptation, during the immediate post-operative period. Patients are given a comprehensive "Gastric Bypass Owner's Manual" regarding their surgery and the expected effects, and are required to maintain regular follow-up, at least bi-monthly, for the first year following surgery, during the rapid phase of weight loss. Thereafter, at least yearly follow-up is recommended.

- Proximal Bypass with a 15 cc Measured Pouch
- Divided Stomach
- 75 cm Roux Limb
- Retro-colic/Retro-gastric Limb
- 1.2 cm Gastric Opening for Anastomosis
- Intracorporeal Anastomoses

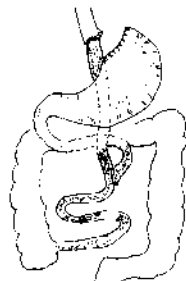


Figure 1. Summation of authors' technique of the laparoscopic gastric bypass.

Results

Weight loss results with LapRYGBP in our series are comparable to those reported with open surgical technique:^{4,5} the average weight lost exceeds 60% of excess body weight (XSBW) within 6 months of surgery, and rises steadily to a mean of 77% XSBW at 12 months following surgery. Figure 2 demonstrates average percent of XSBW lost at various increments post-operatively.

Table 1 shows the distribution of percentage of XSBW lost, versus time, for 36 to 60 months post-operatively: about 80% of patients lost 50% or more of excess body weight. This loss persisted through 60 months postoperatively.

Total numbers of co-morbidities were reduced overall by 96%, from 1752 pre-operatively to 71 post-operatively. Post-operative co-morbidities, even when persisting, tended to be markedly reduced in severity. Gastro-esophageal reflux disease (GERD) was symptomatically eliminated in over 98% of patients afflicted pre-operatively. Clinical parameters of diabetes mellitus were eliminated in 98%, and reduced in the remaining patients. Sleep apnea was clinically resolved in 98% of afflicted patients. Of 118 hypertensive patients, 92% experienced clinical remission.

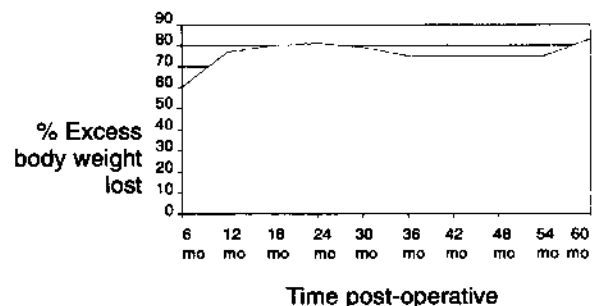


Figure 2. Laparoscopic gastric bypass: average % excess body weight lost per time post-operative.

Table 1. Distribution of % excess body weight lost following LapRYGBP over time. % of patients who lost <50% up to >75% of their XSBW over 36 to 60 months

Time Post-op	% of XSBW Lost			# of Pats
	<50%	50-75%	>75%	
36 mo	15% of pats	30% of pats	55% of pats	92
42 mo	20%	22%	58%	57
48 mo	22%	19%	59%	36
54 mo	15%	23%	62%	16
60 mo	0	25%	75%	4

Comparison of pre-operative and post-operative co-morbidities are shown in Table 2.

Occurrence of diabetes, and its severity, are summarized in Table 3. Post-operative status for these patients is shown in Table 4. Pre-operatively, 64 of the 85 diabetic patients manifested elevated values of hemoglobin A1C, while only three had elevated Hgb-A1C levels after the operation.

Our results demonstrate less weight loss in diabetic patients than in non-diabetic patients (Figure 3) although clinical parameters of diabetes are normalized. We speculate that this effect is related to long-ingrained dietary patterns of frequent small feedings.

There has been no mortality in this series. Complications from the entire series, some previously described, are included in this report for completeness. There have been no incisional hernias. Wound infections have occurred in 5%. They tend to be minor, and typically affect only one of the several trochar sites. Respiratory problems were generally minor and transient, despite the high-risk of this patient group. Intra-abdominal

hemorrhage requiring re-operation occurred in four patients, and tended to be at the staple-lines, not associated with anastomotic breakdown. Pyelonephritis occurred in a patient with known stone disease, who had a history of multiple prior similar infections. The types and incidence of post-operative complications are shown in Table 5.

All anastomotic leaks occurred at the gastrorrhaphy/gastroenterostomy site. Though the first 300 patients had a leak rate of 3%, the last 200 patients had a leak rate, requiring re-operation, of only 1%.

Early in the series, operative times averaged approximately 4 hours. With refinement of techniques, and increased operating efficiency, operating time has approached that for the open gastric procedure. Current operative times are approaching 90 minutes and the length of stay is no longer compiled, as it has remained stable at 2.5 days.

Table 2. Co-morbidity comparison in laparoscopic gastric bypass

CONDITION	PRE-OP	POST-OP
GERD	269	4
HYPERCHOLESTEROL	275	8
HYPERTRIGLYCERIDE	158	1
DIABETES	85	1
GLUCOSE INTOLERANCE	50	0
STRESS INCONTINENCE	201	6
SLEEP APNEA	225	5
HYPERTENSION	118	10
ARTHRITIS (symptomatic)	371	36
TOTAL	1752	71%

Table 3. Type II diabetic patients before laparoscopic gastric bypass

85 out of first 500 Patients	
-CHEMICAL 46	27 had elevated HgbA1C
-ORAL AGENTS 30	29 had elevated HgbA1C
-INSULIN 9	8 had elevated HgbA1C
50 More patients were Glucose Intolerant	

Table 4. Diabetes mellitus type II before and after laparoscopic gastric bypass

DIABETES TYPE II (85 OF 500)	PRE-OP	POST-OP
MEDICATION	39	0
ELEVATED HgbA1C	64	3*

*2 of the 3 were "near normal" range

Technical Observations

General

Laparoscopic instruments were developed for the normal-sized patient. The basic physics of the lever

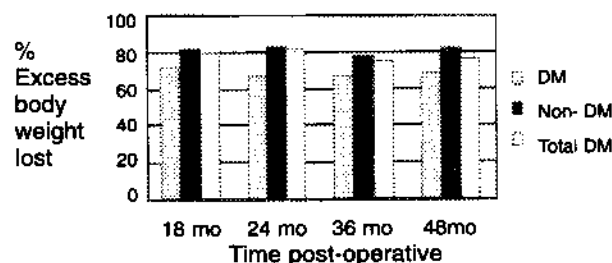


Figure 3. Laparoscopic gastric bypass: average % excess body weight lost per time post-operative for Diabetics vs. non-Diabetics.

Table 5. Complications from laparoscopic gastric bypass by frequency and type

TYPE	FREQUENCY	
	FIRST 300	301-500
LEAK (Re-Op: 2 Open, 7 Lap)	9	2
INFECTION (MINOR)	15	9
INFECTION (MAJOR)	2	2
RESPIRATORY	5	2
"STENOSIS"	3	5
SMALL BOWEL OBSTRUCTION (>1 MO)	3	0
HEMORRHAGE (1 Open, 3 Lap)	4	0
PYELONEPHRITIS (Hx OF STONES)	1	0
STROKE	1	0

implies that maximum precision and maneuverability is accomplished when the length of the instrument inside the abdomen is approximately equal to that outside. Use of these instruments in the obese patient is limited both by loss of reach and by loss of precision, due to the depth of the abdominal wall, which reduces the mechanical advantage and increases movement at the tip, while simultaneously increasing the side forces on the abdominal port and on the grip of the instrument.

The maximum feasible size of the patient is affected by body weight, configuration (android vs. gynecoid pattern), depth of the chest, and the experience of the operating surgeon. We have performed the procedure successfully, in suitable patients over 180 kg (400 lb) in weight. Table 6 shows the distribution of patients in various BMI categories pre-operatively.

We have used linear staplers from each of the major manufacturers. Each instrument requires variation in technique to achieve satisfactory results. We find that the ET45B (Ethicon Endosurgery, Cincinnati, OH) instrument⁶ offers the most satisfactory quality, reliability and security of the currently available instruments.

Gastric Transection

The proximal stomach is divided with successive applications of a 45-mm linear stapler, starting at the proximal lesser curvature, and following a "hockey-stick" configuration, to reach the angle of His. Application of the stapler across a previously formed staple-line can lead to distortion and tear-out of staples, and localized leakage at the junction of linear staple lines. In general, we have learned to be skeptical of the security of staple-lines, which also are susceptible to breakdown in the presence of any extra-luminal collection. We frequently oversuture staple-lines to provide a serosal covering.

Although the stomach is usually regarded as thicker than the small intestine, we find the very proximal stomach pouch may not be as thick-walled as the main body of the stomach. A 3.5-mm staple height recommended for intestinal anastomosis appears to improve security and hemostasis.

Table 6. Number of Lap RYGBP patients per pre-operative BMI category

BMI (kg/m ²)	NO. OF PATIENTS
35-40	151
40-45	162
45-55	169
>55	18
TOTAL	500

Entero-enterostomy

Laparoscopists frequently accomplish enteroenterostomy by exteriorizing the bowel, performing the anastomosis externally with conventional suture methods. This method has been explored experimentally in animals, as a potential bariatric technique. This approach is not feasible in the obese human patient, due to foreshortening of the bowel mesentery, and the thickening of the abdominal wall. Intracorporeal enteroenterostomy can be readily accomplished with available instruments.

Retro-Colic, Retro-Gastric Bowel Passage

The proximal Roux limb can be easily passed to the upper abdomen via an incision at the base of the transverse mesocolon. This route is direct, and is only 3-4 cm in length, from the ligament of Treitz to the proximal gastric pouch. No incision of the small bowel mesentery is necessary. Risk of internal hernia is minimal, compared to the antecolic and antegastric routes. The latter create more tension and a greater risk of ischemia. They require a much greater length of bowel and a lengthy mesenteric incision.

In practice, this passage is now accomplished through the lesser peritoneal sac readily, using a 1/4" penrose drain, which serves as a traction device, being tucked through an opening in the lesser omentum into the depth of the lesser sac. It is easily retrieved via a small incision in the mesocolon. The Roux limb is tacked to the drain, and passed into the upper abdomen by traction on the drain, drawing the bowel behind it.

Gastroenterostomy

Our desire to maintain the essential proximal pouch size of 15 cc, while accomplishing the necessary intracorporeal calibrated gastroenterostomy anastomosis, led to development of the technique of endoscopic peroral insertion of the circular stapler anvil. This method borrows the concept and materials used for Percutaneous Endoscopic Gastrostomy, to permit formation of a precise anastomosis in a gastric pouch of minimal size. Since our first procedure, we have used only one type of 21-mm circular stapler (ECS21 Stealth, Ethicon Endosurgery, Cincinnati, OH).

We have previously described construction of the gastroenterostomy using a "side-to-end" stomach to bowel anastomosis. Recently, one of the authors (GWC) has employed a side-to-side gastroenterostomy technique, using retrograde insertion of the circular stapler through the opened upper end of

the Roux limb, which is then re-closed after completion of the gastroenterostomy. The remaining short segment of proximal bowel is then applied to the gastric staple-line as a serosal covering.

The close conjunction of the linear gastric staple-line, and the linear enterorrhaphy of the Roux limb, with the circular gastroenterostomy, leads inevitably to formation of narrow angles between the multiple intersecting staple-lines. These should be closed, to protect against ischemic tissue loss and resultant leakage. We routinely oversuture these areas, covering the staple-line of the gastroenterostomy.

Drainage

We drain the vicinity of the gastroenterostomy, using a closed suction drain. While use of the drain has rarely been problematic, its presence may reduce the likelihood of leakage caused by intrusion of an extraluminal collection, and can greatly simplify management of a leak if it occurs – often obviating the need for re-operation.

Discussion

Since the introduction of minimally invasive general surgery just 10 years ago, a revolution in surgical techniques has occurred, as most surgical procedures have been adapted to limited access techniques. The demonstrated benefits of laparoscopic surgery include shorter hospital stay, earlier return to normal activity, superior cosmesis, and less pain. Incidence of incisional hernia is markedly diminished. Additional dividends include less systemic stress, less immunologic stress,⁷ reduced adhesion formation, and diminished incidence of ileus.

Bariatric surgical procedures are well-standardized, and very suitable to advanced laparoscopic methods. Exposure is actually enhanced in the very obese patient, when compared to that achieved with laparotomy. We have found the length of the instruments currently manufactured to be the limiting factor determining patient eligibility, not the actual size of the patient.

Successful long-term weight management is a function of intensive long-term patient support and follow-up, built upon a foundation of an effective surgical procedure. Bariatric surgery should only be performed in the context of a comprehensive

program of weight management.

To a much greater degree than with open procedures, technical success in limited access surgery depends heavily on the quality and reliability of the laparoscopic instrumentation. After progressive improvement in our anastomotic security and success for 2 years, we noted an increased frequency of gastroenterostomy leakage between July and September 1997, in association with the use of a different linear stapler. After eliminating usage of this device in September 1997, leak rates have been limited to one occurrence in the ensuing 93 procedures and a 1% leakage rate for our last 200 patients.

At this time, we perform over 50% of bariatric operations using minimally invasive technique. The operative times have decreased toward 90 minutes – only slightly longer than the equivalent open procedure. Average length of hospital stay has remained consistent at 2.6 days. As with the open procedure,⁸⁻¹⁰ reduction of co-morbidity is dramatic, with over 96% of the associated health risks being eliminated – the critical indication for performance of bariatric surgery.

We have shown in this report that LapRYGBP can be accomplished with minimal mortality, acceptable morbidity, and with reasonable operating times. When performed in the setting of a comprehensive surgical weight reduction program, weight loss results are very gratifying, and are sustained over the long-term. Over 96% of all co-morbidities are effectively treated.

Summary

More than 500 LapRYGBP have been performed, with acceptable morbidity and no mortality. Operating times approach those of the open operation. Weight loss averages 77% of excess body weight at 1 year, and is maintained through 60 months of post-operative follow-up. Concurrently, 96% of serious pre-operative co-morbidities were eliminated within 1 year of surgery. Diabetes mellitus is clinically reversed in 98% of afflicted patients. Laparoscopic Gastric Bypass is a safe and effective treatment for the serious health effects of clinically severe obesity.

References

1. Gastrointestinal Surgery for Severe Obesity. Consensus Development Conference Panel, National Institutes of Health. *Ann Intern Med* 1991; 115: 956-61.
2. Wittgrove AC, Clark GW, Tremblay LJ. Laparoscopic gastric bypass, Roux en-Y: preliminary report of five cases. *Obes Surg* 1994; 4:353-7.
3. Wittgrove AC, Clark GW. Laparoscopic gastric bypass: Technique and results in 75 cases with 3-30 months follow-up. *Obes Surg* 1996; 6:500-4.
4. Linner JH, Drew RL. Why the operation we prefer is the Roux-Y gastric bypass. *Obes Surg* 1991; 1:305-6.
5. Sugerman HR, Londrey GL, Kellum JM et al. Weight loss with vertical banded gastroplasty and Roux-Y gastric bypass for morbid obesity with selective vs random assignment. *Am J Surg* 1989; 157:93-102.
6. Ethicon Endosurgery, 4545 Creek Road, Cincinnati OH 45242-2839.
7. Vittimberga FJ, JR., Foley DP, Meyers WC et al. Laparoscopic surgery and the systemic immune response. *Ann Surg* 1998; 227:326-34.
8. Benotti PN, Forse A. The role of gastric surgery in the multidisciplinary management of severe obesity. *Am J Surg* 1995; 169:361-7.
9. Pories WJ, Swanson MS, MacDonald KG et al. Who would have thought it? An operation proves to be the most effective therapy for adult-onset Diabetes Mellitus. *Ann Surg* 1995; 222:339-52.
10. Carson JL, Ruddy ME, Duff AE et al. The effect of gastric bypass surgery on hypertension in morbidly obese patients. *Arch Intern Med* 1994; 154:193-200.

(Received December 19, 1999; accepted March 30, 2000)