Surg Endosc (2006) 20: 859–863
DOI: 10.1007/s00464-005-0134-5

SURGICAL ENDOSCOPY
and Other Interventional Techniques

Laparoscopic sleeve gastrectomy as an initial weight-loss procedure for high-risk patients with morbid obesity

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Received: 7 March 2005/Accepted: 7 September 2005/Online publication: 22 April 2006

Abstract
Background: The surgical treatment of obesity in the high-risk, high-body-mass-index (BMI) (>60) patient remains a challenge. Major morbidity and mortality in these patients can approach 38% and 6%, respectively. In an effort to achieve more favorable outcomes, we have employed a two-stage approach to such high-risk patients. This study evaluates our initial outcomes with this technique.
Methods: In this study, patients underwent laparoscopic sleeve gastrectomy (LSG) as a first stage during the period January 2002–February 2004. After achieving significant weight loss and reduction in co-morbidities, these patients then proceeded with the second stage, laparoscopic Roux-en-Y gastric bypass (LRYGBP).
Results: During this time, 126 patients underwent LSG (53% female). The mean age was 49.5 ± 0.9 years, and the mean BMI was 65.3 ± 0.8 (range 45–91). Operative risk assessment determined that 42% were American Society of Anesthesiologists physical status score (ASA) III and 52% were ASA IV. The mean number of co-morbid conditions per patient was 9.3 ± 0.3 with a median of 10 (range 3–17). There was one distant mortality and the incidence of major complications was 13%. Mean excess weight after LSG at 1 year was 46%. Thirty-six patients with a mean BMI of 49.1 ± 1.3 (excess weight loss, EWL, 38%) had the second-stage LRYGBP. The mean number of co-morbidities in this group was 6.4 ± 0.1 (reduced from 9). The ASA class of the majority of patients had been downstaged at the time of LRYGB. The mean time interval between the first and second stages was 12.6 ± 0.8 months. The mean and median hospital stays were 3 ± 1.7 and 2.5 (range 2–7) days, respectively. There were no deaths, and the incidence of major complications was 8%.
Conclusion: The staging concept of LSG followed by LRYGBP is a safe and effective surgical approach for high-risk patients seeking bariatric surgery.

Key words: Laparoscopy — Morbid obesity — Bariatric surgery — Gastric bypass — Sleeve gastrectomy — High-risk

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Severely obese patients with high body mass index (BMI) (>60), life-threatening co-morbidity, and extremely poor quality of life have the greatest potential of direct benefit from bariatric surgery. However, they often carry an operative risk of morbidity and mortality that is two to three times greater than the typical morbidly obese patient, often rendering them ineligible for bariatric surgery [10].

Recognizing that surgically induced weight loss is the most effective method of improving co-morbidity and, consequently, operative risk, we have proposed a two-stage approach to laparoscopic Roux-en-Y gastric bypass (LRYGBP). The first stage involves laparoscopic sleeve gastrectomy (LSG) and the second stage is conversion to LRYGBP. LSG is associated with much less surgical intervention than LRYGBP, and was therefore considered a suitable selection as a preliminary stage. This study reports our early experience with this approach.

Materials and methods

This study was performed at the University of Pittsburgh Medical Center and was approved by the University of Pittsburgh Institutional Review Board. The study was also compliant with all HIPPA regulations. We evaluated outcomes of patients undergoing LSG (stage I) followed by LRYGBP (stage II) between January 2002 and June 2005. Patients were selected for this staged approach if they met National Institutes of Health (NIH) criteria for bariatric surgery and were considered to be especially high-risk by exhibiting excessive

BMI (>60 kg/m^2) or severe co-morbidity, or advanced age (>60 years), or a combination of these factors. In some patients, the decision to proceed with either the LSG + LRYGBP (two-stage procedure) or the complete LRYGBP (single-stage procedure) was made at the onset of the operation depending on initial operative findings. The possibility of performing a staged approach dependent on intraoperative findings was discussed preoperatively with the patient. LSG was selected if cirrhosis, profuse visceral fat, poor exposure, or severe adhesions were identified, because these conditions were thought to be unfavorable for safely performing the single-stage LRYGBP. Following LSG, patients became eligible for the second stage after at least 6 months of convalescence and after significant reduction in operative risk. Before surgery, all patients received extensive educational preparation in the form of written material, video, and workshops regarding the risks, benefits, and alternatives of LSG and LRYGBP. Informed consent was obtained in all cases. Comprehensive preoperative medical evaluation, venous prophylaxis, bowel preparation, and antibiotic prophylaxis were executed as described previously [11].

The LSG (stage I) involves a longitudinal resection of the fundus, body, and antrum (approximately two-thirds gastrectomy), leaving a tubularized stomach conduit based on the lesser curve as described previously [1, 7]. Briefly, after port sites are placed similar to our standard LRYGBP, a laparoscopic stapler, Endo GIA (Autosuture, Norwalk, CT, USA), with a 60-mm cartridge (3.5-mm staple height, blue load) is used to divide the stomach parallel to and alongside a 46–50 French bougie (placed against the lesser curve of the stomach). The resection extends from the distal antrum (5 cm proximal to the pylorus) to the angle of His. The short gastric vessels and the greater-curvature ligaments (gastrosplenic and gastrocolic) are divided using ultrasonic dissection to complete the resection. The resected portion of the stomach is extracted from the right upper abdominal 1-mm port site by widening the skin incision from 12 mm to approximately 20 mm. Fibrin glue (Tisseel VH, Baxter, Deerfield, IL, USA) is applied to the staple line (3 ml) as a sealant as well as to the anterior surface of the tabularized stomach (2 ml) as an antiadhesive to prevent adhesions to the liver [2]. A round, 15 French drain is placed alongside the staple line and removed 2–7 days after surgery. The fascia at all port sites >12 mm is closed with absorbable suture. Postoperatively, LSG patients were managed similarly to our LRYGBP patients [12]. A thin barium swallow study was performed on postoperative day 1, and the patients were advanced to liquids if the study was normal. The patients were then evaluated in the bariatric surgery clinic at 7 days postoperatively, then at 1, 3, 6, 9, and 12 months postoperatively. Patients were considered eligible for stage II, LRYGBP after 6 months or approximately ≥100 lb weight loss and significant operative risk reduction.

The stage II LRYGBP was performed in similar fashion as previously described, resulting in a 15-ml gastric pouch, a stapled end-side gastrojejunosotmy (Endo GIA, 60-mm cartridge, 3.5-mm staple height), and an antecolic, antegastric 150-cm Roux limb.(12) The excluded tubular gastric remnant was sutured to the abdominal wall for access by a gastrostomy tube, if desired.

Outcome assessment for this study included demographics, past medical history, operative time, time interval between procedures, morbidity, mortality, hospital length of stay, weight loss, and changes in co-morbidity. Descriptive statistics included mean, standard deviation, and range.

Results

From January 2002 to June 2005, 126 patients underwent a laparoscopic sleeve gastrectomy (LSG) at the University of Pittsburgh Bariatric Surgery Center as the first stage of a staged laparoscopic Roux-en-Y gastric bypass. Although most of the procedures had been planned preoperatively, some LSGs were performed after intraoperative abdominal evaluation (<10%). Of the patients, 53% were women, with a mean age of 49.5 ± 10 years (range 20–74 years) and mean BMI of 65.4 ± 9 (range 45–91). Among the patients, 42% were ASA III and 52% were ASA IV. Most patients had significant co-morbid conditions, with the average number being 9.4 ± 3 per patient with a median of 10 (range 3–17, Table 1).

Table 1. Preoperative co-morbid conditions in patients undergoing laparoscopic sleeve gastrectomy[a]

Condition	Percentage of population
Fatty liver disease	100%
Sleep apnea	82%
Peripheral edema	59%
Hypertension	68%
Degenerative joint disease	69%
Type II diabetes	59%
Low back pain	42%
Gastroesophageal reflux disease	36%
Elevated triglycerides	52%
Depression	36%
Asthma	25%
Coronary artery disease	18%

[a] As can be seen here, most of our patients who underwent laparoscopic sleeve gastrectomy as the first stage toward a Roux-en-Y gastric bypass had significant co-morbid conditions. Fatty liver disease was confirmed by intraoperative biopsy. Sleep apnea was diagnosed by sleep study. Coronary arterial disease was diagnosed by preoperative angiogram or stress test

Table 2. Effect of LSG on co-morbid conditions: co-morbid conditions in patients who underwent completion Roux-en-Y gastric bypass[a]

Condition	Resolved	Improved
Sleep apnea	80%	7%
Peripheral edema	91%	3%
Hypertension	78%	7%
Degenerative joint disease	85%	6%
Type II Diabetes	81%	11%
Low back pain	44%	10%
Gastroesophageal reflux disease	70%	8%
Elevated triglycerides	73%	5%
Depression	67%	9%

[a] As can be seen, there was significant reduction in the co-morbid conditions 6 months after stage II gastric bypass (n = 20)

The mean operative time for a LSG was 143 ± 28 min (range 90–210 min). The mean hospital stay was 3 ± 1.7 days, median 3 (range 2–12) days. There were no deaths in the perioperative period; however, there was one late death. This occurred in the only conversion to open sleeve gastrectomy in a 62-year-old woman, who had had previous abdominal surgeries. She developed postoperative decubiti ulcers and was discharged to a skilled nursing facility. She developed a pulmonary embolus 3 months after surgery and did not recover. There were a total of 18 (14%) post-operative complications,including five strictures, two leaks, two pulmonary embolisms, five patients requiring >24 h ventilator support, and four patients who developed renal insufficiency not requiring dialysis. Only the patients with strictures returned to the operating room for dilatation several weeks after LSG.

Of our patients, 46% reported for follow-up at 1 year after LSG and had a mean excess weight loss of

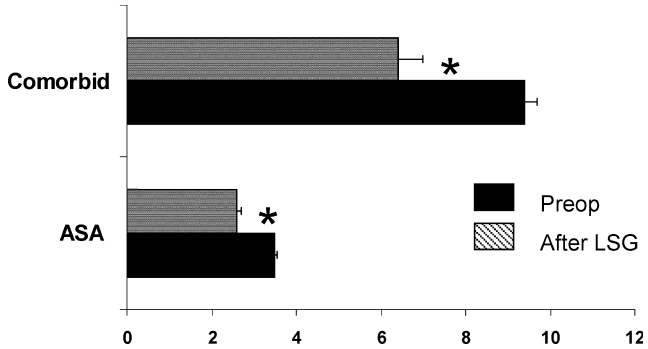

Fig. 1. Effect of LSG on co-morbid conditions and ASA class in superobese patients. A total of 36 patients proceeded to stage II completion Roux-en-Y gastric bypass. As can be seen, LSG resulted in a reduction of co-morbid conditions from 9.4 ± 3 to 6.4 ± 3 prior to stage II. Similarly, the ASA class dropped significantly, from 3.5 ± 0.5 to 2.6 ± 0.7 (*$p < 0.05$).

Table 3. Co-morbid conditions in patients who underwent completion roux-en-Y gastric bypass at 6 months' follow-up[a]

Condition	Percentage unresolved
Sleep apnea	27%
Peripheral edema	8%
Hypertension	14%
Degenerative joint disease	12%
Type II diabetes	14%
Low back pain	40%
Gastroesophageal reflux disease	20%
Elevated triglycerides	38%
Depression	27%

[a]As can be seen, in patients who had persistent co-morbid conditions after LSG, most resolved after stage II gastric bypass ($n = 20$).

Table 4. Summary of weight, co-morbidities, and ASA after each stage[a]

	Preop	12 mo after stage I	6 mo after stage II	*p* value
Mean weight (kg)	177	131	109	< 0.05
Body mass index	65 ± 9	49 ± 8	39 ± 8	< 0.05
Co-morbidities	9 ± 3	6 ± 3	2 ± 1	< 0.05
ASA ≥ 3	94%	44%	NA	< 0.05

[a] As can be seen, stage I significantly reduced weight, co-morbid conditions, and ASA class. Completion LRYGBP further reduced these categories

45 ± 17% (range 23–79). As can be seen in Table 2, LSG had a significant impact on the co-morbid conditions, with either resolution or improvement in > 75% of the patients at 1 year.

In this series, 36 patients proceeded to stage II completion LRYGBP with a mean interval of 12 ± 5 months (range 4–22 months) between the two stages. As can be seen in Fig. 1, LSG had a significant effect on the number of co-morbid conditions (9.4 ± 3 to 6.4 ± 3) and ASA class (≥3, reducing from 94% to 44%, or a mean of 3.5 ± 0.5 to 2.6 ± 0.7) prior to stage II. Of the patients who proceeded to state II, 61% were women, with a mean age of 50.5 ± 10 years. Their BMI had reduced significantly to 49.5 ± 8 (range 34–65), with a mean weight loss of 43.6 kg. The mean follow-up for this group of patients was 7.1 ± 5 months (range 1–24 months). The mean operative time for the 36 patients who underwent the LRYGBP was 229 ± 65 min. The mean hospital stay was 3 days (range 2–7) days. There were no deaths, and there were six (17%) complications. These included three patients with postoperative bleeding, one leak, one acute cholecystitis, and one marginal ulcer. Only the patient with acute cholecystitis had to be taken back to surgery.

Although 27 patients have reached at least the 6-month mark, only 20 patients have kept their 6-month appointment. The mean BMI at 6 months' follow-up is 40 ± 6, with a mean excess weight loss of 33%. The mean excess weight loss in this subgroup after both stage I and II is 55%. The number of co-morbid conditions has further diminished to 2.6 ± 1 at 6 months' follow-up (Table 3). As can be seen, there was a significant improvement in the number of serious co-morbid conditions after completion LRYGBP. Table 4 highlights the reduction in weight, BMI, co-morbid conditions, and ASA after each stage.

Discussion

With the rapid growth of bariatric surgery and heightened awareness of its beneficial outcomes, many physicians are referring increasingly complicated patients for operative therapy; a pattern that clearly represents an enhanced operative risk. In order to optimize clinical outcomes in this group, we have adopted a two-stage approach to the LRYGBP. This approach has been proven safe in small studies involving both the LRYGBP and the duodenal switch [1, 9]. We recommended this approach in a select group of patients based on large BMIs, prohibitive co-morbid conditions, advanced age, or history of previous multiple abdominal surgeries, with most patients having a combination of these factors [4, 6]. Some patients had a staged approach only after exploratory laparoscopy. As can be seen in our results, using these selection criteria, there were a higher number of male patients than is routinely encountered in a bariatric practice.

Although our morbidity rate for each of the individual stages appears high (14% for stage I and 17% for stage II), these complications did not result in significant long-term morbidity in most cases. The transient respiratory and renal failures were self-limiting. In fact, only those patients with stricture required additional opera-

tive (endoscopic dilatation) intervention. These strictures occurred early in our experience with LSG, when we were oversewing the staple line. We switched to the use of fibrin glue to protect the staple line and did not see any further strictures. Additionally, two of the four pulmonary emboli occurred in patients with a history of pulmonary embolism and were fully therapeutic on intravenous anticoagulants prior to being switched over to oral anticoagulants. Additionally, when we analyzed the combined the complications in stage I and stage II, there was no additional increase in the rate of complications. The low morbidity for the second stage of the procedure is clearly related to the interim improvement in the medical co-morbidities. Every patient with diabetes had improvement prior to the second-stage procedure, and almost all patients with sleep apnea had resolution or improvement in their condition. All cases of peripheral edema were resolved, and patients with DJD showed marked increase in activity levels prior to their second-stage procedure. Clearly, this contributed to the ambulation of all our patients on the day of surgery.

Another important outcome measure is mortality rate. Our overall mortality rate is less than 1%. Ren et al. have reported a mortality rate of 6.25% when performing laparoscopic duodenal switch on patients with BMI >65, and the rate for our staged approach is significantly lower [10].

With increased experience and improvements in technique, an argument can be made for proceeding directly with a LRYGBP. In fact, two recent reports have suggested that the overall morbidity and mortality rate in patients with BMI $>$ 60, undergoing laparoscopic Roux-en-Y gastric bypass directly without a staged approach, is no different than for those with BMI $<$ 60 [3, 14]. However, when comparing our population of patients to the studies by Tichansky et al. and Farkas et al., it can be seen that our population was at least 10 years older, comprised of more men, and overall had significantly greater number of co-morbid conditions ($>60\%$). Thus we feel that laparoscopic gastric bypass can and should be offered to a group of patients with BMI ≥ 60 if they are considered safe candidates for the procedure. However, in the case of the patients in this study, proceeding directly with a LRYGBP may not have been a safe option. A direct randomized comparison of staged vs unstaged laparoscopic gastric bypass is required in patients similar to our group to determine which method is superior.

Although arguments can be made for proceeding with open gastric bypass in the superobese patient, the known complication rate is comparable to our study and the safety and efficacy of laparoscopic vs open gastric bypass has been studied [8, 13]. Moreover, open gastric bypass is associated with an increased incidence of major perioperative complications, especially extra-intestinal complications, and greater perioperative mortality [8]. These rates may be increased in our population of patients with more co-morbid conditions. Again, a direct comparison of these two techniques would have to be performed to clearly demonstrate the superior technique.

One final area of concern is the financial aspects of a staged approach. With most insurance companies reluctant to approve unstaged gastric bypass, attempts at approval and reimbursement for a staged approach is likely to be met with great resistance. However, we feel that as this is a safer approach to sick, older, heavier patients, it is ultimately more cost effective.

Currently, we have completed the second stage in only 36 of 126 (28%) of all the patients that were enrolled for a two-stage approach and therefore do not have complete data on this approach. We have had 46% 1-year follow-up, and some patients have been lost to follow-up. There was a 45% EWL in this group of patients, and although this is significant, we feel that LSG does not sufficiently address the medical problems associated with morbid obesity. We and others therefore continue to recommend that each patient who underwent LSG be evaluated for a second-stage gastric bypass to ensure long-term weight loss [1].

Conclusion

As the prevalence of morbid obesity continues to escalate, the incidence of progressively complicated patients will rise. Clearly, a valid and effective strategy, beyond the current comprehensive evaluation measures, is needed for the optimal management of these patients. The staged approach to LRYGBP is a safe alternative for morbidly obese patients who are deemed too complicated to have the procedure performed in the traditional single method. Long-term follow-up of patients who have undergone a staged approach is necessary to determine durability and long term outcomes.

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