Hypothesis: A technique of the laparoscopic Roux-en-Y gastric bypass can be developed that is safe, effective, and practical in the community setting.

Design: A case series of 400 morbidly obese and super-obese individuals who underwent the laparoscopic Roux-en-Y gastric bypass over a 22-month period.

Setting: Community private practice in Fresno, Calif.

Patients: A consecutive sample of 400 patients (70 males and 330 females) who met National Institutes of Health criteria for recommendation of a bariatric procedure. Only patients who had a previous gastric or bariatric procedure were excluded from this sample.


Main Outcome Measures: Weight loss, complications, length of hospital stay, successful completion of the operation, and operative times were measured.

Results: Open conversion was required in 12 patients (6 males and 6 females) and a secondary operation for incomplete division of the stomach was required in 2 patients early in the case series. Alternative exposure and fixation techniques greatly reduced these occurrences. There were 6 staple-line failures owing to a change in the manufacture of the instrument. There were no leaks at the gastrojejunal anastomosis, but 21 patients required endoscopic balloon dilation for significant stenosis. The average hospital stay was 1.6 days for the patients who underwent laparoscopy and 2.7 days for patients requiring open conversion. Average excessive weight loss was 69% at 12 months. Operative times are between 60 and 90 minutes. Other complications are described.

Conclusion: The Roux-en-Y gastric bypass can be safely and effectively performed in the community setting using advanced laparoscopic techniques.

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The procedure was completed laparoscopically in 388 patients over a 22-month period. Of the 12 patients who required open conversion, 6 were males (average BMI, 47) and 6 were females (average BMI, 57). Incomplete division of the gastric pouch occurred in 2 patients requiring reoperation for inadequate weight loss. This early experience forced us to adopt the present means of liver retraction with a 10-mm rod placed in the subxiphoid position. Traditional fan-type retractors were either too malleable or would lacerate the fatty liver parenchyma. Also greater use of the Harmonic scalpel (Ethicon Endo-Surgery Inc)

The laparoscopic Roux-en-Y gastric bypass was first reported by Wittgrove et al in 1994. Although ingenious in the design of their operation, the use and the endoscopic placement of the 21-mm circular stapler (model ECS21 Endopath Stealth Endoscopic/Conventional Circular Stapler; Ethicon Endo-Surgery Inc, Cincinnati, Ohio) was a significant departure from our standard open technique. In addition, anastomotic gastrojejunostomy leak rates of 4% have been reported and parallel the experiences of Fazio et al with colorectal anastomosis using similar stapling devices. We chose to design a surgical procedure that more closely emulates our open procedure both in configuration and formation of the gastric pouch and the gastroenteric anastomosis.

Minimally invasive surgery has significant advantages over traditional surgery. However, these procedures “must be shown to be at least as effective and safe as the open procedures.” This study evaluates our experience with this procedure for efficacy and complications.
PATIENTS AND METHODS

PATIENTS

All patients (70 males and 330 females, aged between 13 and 70 years) were evaluated for surgery using National Institutes of Health guidelines. Each patient was counseled by the operative surgeon (K.D.H.) and advised of other bariatric surgical procedures and bariatric surgical programs. All patients were considered candidates for the laparoscopic procedure regardless of weight, body mass index (BMI), (weight, in kilograms, divided by height, in meters squared) or the presence of previous operations (except for gastric or bariatric procedures). It was our intention to determine exclusion criteria as early as possible.

The operative technique evolved to compensate for occurrences we had not experienced with the open surgery, such as internal hernias. Exposure and retraction methods developed that allowed a higher success rate and shorter operative times.

This case series represents patients operated on by a single surgeon (K.D.H.). Although one of us (K.B.B.) has performed over 200 such procedures, these are not included in this case series to simplify comparative data.

SURGICAL TECHNIQUE

The patient is placed supine in a gentle reverse-Trendelenburg position. Standard perioperative antibiotics and subcutaneous heparin sodium are administered and antiembolism devices are used. Bowel preparation consists of clear liquids for 24 hours prior to surgery.

The pneumoperitoneum and abdominal entry is established with an 11-mm trocar (ENDOPATH Optiview 11-mm Optical Trocar; Ethicon Endo-Surgery Inc). Three more blunt 12-mm ports were created using a 12-mm trocar (ENDOPATH Optiview 12-mm Optical Trocar; Ethicon Endo-Surgery Inc) and a single 5-mm or 10-mm port for liver retraction is placed Figure 1. Adhesions from previous surgical procedures are mobilized to allow displacement of the omentum to the upper abdomen. If the adhesions are too dense or the omentum bulky, the lesser sac is entered through the gastrocolic ligament. The ligament of Treitz is visualized by creating an opening through the transverse mesocolon. The proximal jejunum is divided 5 to 10 cm distal to the ligament of Treitz with a 45-mm linear cutter, 2.5-mm stapler (ENDOPATH Endoscopic Linear Cutter 45 mm; Ethicon Endo-Surgery Inc). The mesentery is divided with the same stapler and the Roux limb is measured. For patients whose BMI is less than 50, a 100-cm limb is measured; for those whose BMI is greater than 50, we use a 150-cm limb. A side-to-side jejunojejunostomy is performed using the 45-mm linear cutter, 2.5-mm stapler. The enterotomy is closed with interrupted 3-0 polyglyactin (Vicryl) sutures. The mesenteric defect is closed with 3-0 silk sutures.

The gastric pouch is estimated at 20 mL and created by repeated application of the 35-mm linear cutter, 3.5-mm stapler (ENDOPATH Endoscopic Linear Cutter 35 mm; Ethicon Endo-Surgery Inc). The vagus nerves are preserved. The pouch is based on the lesser curve and oriented vertically with the exclusion of the gastric fundus. We believe, as does MacLean et al, this configuration improves emptying and prevents subsequent dilation of the pouch.

The Roux limb is brought up in a retrocolic position and lies anterior to the stomach remnant. The mesocolon is attached to the Roux limb with three 3-0 silk interrupted sutures to prevent migration of the limb. The gastrojejunostomy is a standard 2-layer, hand-sewn anastomosis performed with 3-0 polyglyactin sutures, running and interrupted, and sized with an intraluminal 32F tube (Figure 2).

The skin is closed with staples. The trocar fascial openings are not closed.

Rather than blunt dissection allowed for better visualization and safer dissection of the gastric cardia. With these modifications, failure to complete the procedure via the laparoscopic approach has occurred only 3 times in the last 12 months (0.8%).

There were 70 male and 330 female patients. The average age was 43 years (age range, 13-70 years). The average BMI was 46 (range 35-78). Twenty-one patients were in the suprasuperobese category (BMI, >60). There was no operative mortality, leakage from the hand-sewn gastrojejunostomy, or clinical deep vein thromboses in this case series. There has been no trocar site hernia identified for the duration of this study. One patient developed bleeding from 1 of the anastomoses and required a 4-U blood transfusion. One patient developed an intragastric hematoma, presumably from the gastric staple line. Reoperation or transfusion was unnecessary in this patient.

Migration of the Roux limb through the mesocolon created internal hernias in 13 patients. Internal herniation through the small-bowel mesentry occurred in 1 patient. Although these areas were secured from the onset, the use of absorbable material proved to be inadequate. All patients were successfully reexplored laparoscopically except for 2 who required open decompression. We now use nonabsorbable sutures in these critical areas. The incidence of postoperative internal hernias is now less than 1%.

Stenosis at the gastrojejunostomy anastomosis occurred in 21 patients (5.25%). All were successfully treated with endoscopic balloon dilation. One patient developed stenosis of the Roux limb due to constriction at the mesocolon. This required laparoscopic exploration to enlarge this opening.

There were 6 occurrences of staple-line failures. These were either detected at the time of surgery or within 12 to 24 hours after surgery. In all cases, they were repaired laparoscopically and although the patients stayed an average of 2 days longer, they suffered no long-term sequelae. As this occurred well into our case series, it was difficult to explain until the manufacturer disclosed having recently modified the 45-mm linear cutter, 3.5-mm stapler. In retrospect, the staple-line failures only occurred with the improved version; we have not seen this problem since we returned to using the 35-mm linear cutter with 3.5-mm stapler for gastric partitioning.
One patient developed lower extremity weakness requiring readmission to the hospital. Magnetic resonance imaging and neurologic consultation diagnosed the problem as central pontine myelolysis. This rare disorder is usually seen in alcoholic and malnourished patients associated with hyponatremia. This patient lost 26.1 kg in 2 months and had normal electrolyte levels and nutritional values. The problem spontaneously resolved over the course of several months.

There were 2 major complications involving perforation. One occurred in an elderly patient with diabetes mellitus. On reexploration, a gastric perforation was found proximal to the gastrojejunostomy. We hypothesize a thermal injury from the Harmonic scalpel weakened this area. The other was a staple-line disruption owing to severe gastric distension secondary to meat the patient ingested the night prior to surgery. The meat bezoar became impacted at the jejunojejunostomy and caused the obstruction. This patient also suffered from severe gastrograffin aspiration pneumonitis at the time of induction of anesthesia. Both patients have done well following a hospital stay of 17 and 30 days, respectively (Table 1).

Four patients developed marginal ulcers. The use of nonsteroidal anti-inflammatory drugs likely played a role even though patients are routinely counseled against their use. Two patients presented with pain, 1 patient developed hematemesis but did not require transfusion, and 1 patient presented with perforation requiring exploration and revision of the gastrojejunostomy.

Operative times varied greatly at first as we developed and improved on our retraction and dissection techniques. Currently, the operation can be performed reliably in 60 to 90 minutes, comparing favorably with our open procedure (Figure 3).

Average hospital stay without major complications for the patient who underwent laparoscopy was 1.6 days. The average hospital stay for those patients requiring open conversion was 2.7 days.

Nine patients developed symptomatic cholelithiasis. All patients underwent successful laparoscopic cholecystectomy.
Average excessive weight loss was 69% at 12 months but varied according to initial BMI (Figure 4 and Table 2). There were 3 patients who were lighter than their ideal body weight at 1 year. The average BMI of this group was 21 (not clinically underweight). In addition, there were no nutritional deficiencies identified in these 3 patients. (Measured values at 1 year included complete blood cell count and the levels of serum protein, albumin, vitamin B₆, vitamin B₁₂, folate, iron, and iron-binding capacity.)

As with many advanced laparoscopic procedures, the learning curve can be a long and arduous journey. We did not select only ideal patients, as we wanted to determine who was not a candidate for the laparoscopic procedure as early as possible. We discovered the additional challenges of the larger patients required that we develop exposure techniques that were beneficial to all patients. We used only standard length trocars and instruments. Operative times have gradually improved as our experience and development of techniques has allowed more directed and safer dissection. Operative times considerably at first as different exposure and retraction techniques were developed. Operative times include patients who have had previous abdominal procedures and who required concomitant cholecystectomy. Operative times varied according to initial BMI (Table 2). There were 3 patients who were lighter than their ideal body weight at 1 year. The average BMI of this group was 21. In addition, there were no nutritional deficiencies identified in these 3 patients. (Measured values at 1 year included complete blood cell count and the levels of serum protein, albumin, vitamin B₆, vitamin B₁₂, folate, iron, and iron-binding capacity.)

We have seen 2 life-threatening complications that we have not as yet experienced with the open procedures: that of staple-line disruption secondary to meat bezoar and gastric perforation from thermal injury. Although similar complications have been described, counseling patients about their “last meal” and more careful dissection with the Harmonic scalpel should eliminate these complications.

Internal hernias have only occurred in the laparoscopic case series, apparently due to decreased intra-abdominal adhesions. By using nonabsorbable sutures for fixation of the Roux limb at the mesocolon and at the small-bowel mesentery, this now occurs with a frequency of less than 1%.

Stenosis of the gastrojejunostomy was a significant problem requiring endoscopic balloon dilation in 5.25% of our patients. Our experience compares favorably with the 9% to 20% stenosis rate reported in a recent review.

With any mechanical stapling device, one can expect a certain failure rate. It was fortunate that a sufficient volume of cases revealed an early problem with the improved 45-mm linear cutter with 3.5-mm stapler. The manufacturer responded in a professional and expeditious manner that helped us to identify and correct this problem.

The laparoscopic Roux-en-Y gastric bypass has been shown to be safe and effective for the nonsuper obese patient (BMI < 50) by Wittgrove et al. More recently, using similar techniques, Nguyen et al were able to perform this procedure on a patient with a BMI of 61. We have not found absolute patient size, BMI, or the presence of previous operations to be prohibitive in our case series. Actually, it is advantageous to dissect low pelvic adhesions laparoscopically rather than extend the traditional upper midline incision. In 1 patient who had an incarcerated ventral hernia that had failed previous attempts at repair, we were able to perform the laparoscopic Roux-en-Y gastric bypass without disruption of the hernia. Subsequent repair will hopefully have a higher degree of success after significant weight loss has occurred.

Symptomatic cholelithiasis occurred in only 2.25% of our patients. Our data does not support concomitant routine cholecystectomy. However, all patients with symptoms suggestive of gallstones were evaluated preoperatively and laparoscopic cholecystectomy was performed prior to or during the gastric bypass. Other patients were prescribed ursodiol for 6 months following surgery.
The pediatric age group (aged < 18 years) deserves special consideration. We have performed this procedure on 2 pediatric patients (aged 13 and 17 years), but only after extensive counseling and cooperation with the local pediatric weight management program and their pediatricians. These patients were essentially “physiological adults.” We do not advocate surgical weight loss in the pediatric age group as a routine.

Initially, very few patients opted for the open procedure despite extensive counseling and disclosure of our limited experience with the laparoscopic technique. This underscores the responsibility we have as surgeons to look at new technology critically. Patients seem too willing to accept an unknown and possibly higher complication rate to avoid the pain and/or problems associated with larger incisions. The question is not: Can we perform this procedure laparoscopically; rather, should we perform this procedure laparoscopically? Each surgeon must evaluate his or her own technical abilities in this regard. More importantly, each surgeon must evaluate his or her own commitment to the lifelong support required for the bariatric patient.

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REFERENCES


DISCUSSION

Mark A. Vierra, MD, Stanford, Calif: Dr Higa has presented today a remarkable single-surgeon experience of laparoscopic Roux-en-Y gastric bypass for morbid obesity including 400 patients operated on over only 22 months, and we were provided with data regarding a learning curve caring for these patients. During this series only 12 patients required conversion to laparotomy at the initial operation. Currently, the conversion rate is less than 1%. The operation is typically performed in 60 to 90 minutes using 4 disposable trocars and 5 abdominal puncture sites. Most patients are discharged within 1 to 2 days.

It is worth reviewing the complications although it is important to acknowledge that many of these are really complications of the development of the procedure, and I do not believe are likely to occur with the same frequency in the next series that we will hear about from Dr Higa. If I understand the presentation correctly, somewhere between 17 and 23 patients required reoperation. Most of these were performed by laparoscopy. There were 14 internal hernias, 1 stenosis of the roux limb at the mesocolon, 1 gastric perforation possibly related to thermal injury from the harmonic scalpel, 1 marginal ulcer with perforation, and 2 incomplete gastric divisions. There were 6 staple line failures on the stomach. All of these were recognized within 24 hours, and all occurred with one particular iteration of the stapling device. At least some of these were recognized intraoperatively. It is unclear to me from the presentation how many of these were actually cared for at the time of the initial procedure and how many were late complications which required later operation. Twenty-one patients underwent dilatation of the gastrojejunosomy for about 5%. There were no deaths in this series, no deep vein thromboses, no gas-trojejunosomy leaks except at the staple lines and, at least to date, no hernias.

This represents a remarkable series, and Dr Higa deserves tremendous credit for the hard work that it took to refine his current technique. Now that he is on the flat part of his learning curve, his outcomes and complication rates I think are clearly better than what has been achieved in most open series of gastric bypasses. I am personally convinced that the technique described is a legitimate extension of laparoscopy to bariatric surgery. The surgery that he has chosen to perform, the Roux-en-Y bypass, is that endorsed by National Institutes of Health Consensus Panel report of 1991, and I believe that it reproduces all of the essential elements of the procedure that we have come to expect in the open gastric bypass. Those essential elements include the creation of a very small gastric pouch, a small calibrated gastrojejunosomy stoma, complete division of the stomach, a Roux limb rather than a loop of the jejunojejunostomy, and though some might think this is not perhaps necessary, retrofitting of the limb.

Early weight loss results would appear to be comparable to the best series available for the Roux-en-Y gastric bypass, and I have no significant concerns about the anatomical result achieved by this procedure. For those of you who do not do bariatric surgery, the different weight loss, depending on the initial BMI of the patient, is something that has been demonstrated with virtually any type of bariatric procedure.

I do have a few observations and some questions. The first is the issue of the internal hernias. In our early experience with laparoscopic gastric bypass procedures at Stanford [University], we also had several internal hernias through the transverse mesocolon. This is a problem that was unique to us during the laparoscopic procedures, one that we had not seen with open surgery, and it clearly requires careful attention to fixation of the Roux limb. The second is that we also had several failures of the 45-mm 3.5-mm staple device. We have moved to the 45-mm device with 4.5-mm staples and have had no further staple line disruptions. At least a couple of these were seen intraoperatively, and, as with Dr Higa, all were picked up within the first 24 hours.

The third has to do with the length of stay of these patients. I note that the patients that were converted to open stayed an average of only 2.7 days in the hospital. Clearly Dr
Higa has a practice geared toward early discharge and it is im-
portant always to remember that many apparent improve-
ments in outcome attributed to laparoscopic procedures can
probably be achieved with open surgery as well if we just set
our minds to it.

My fourth comment is that there is clearly a learning curve
for these procedures. In Dr Higa's case this was undoubtedly
due to the development of a new technique and partly to the
acquisition of technical facility. His learning curve looks to be
about 150 cases, and, as I look back on my own, it looks to be
nearly perfectly superimposable on his. To some extent this curve
for future generations may be shorter as the technical details
of the procedure become better understood, but I think it is
always going to be a very long one. These are not easy proce-
dures to develop proficiency in.

Finally, this year Americans are going to spend some-
where between $30 and $50 billion on diet programs trying to
lose weight. Every bit of evidence that we have available to us
at the present time suggests that 1 year from now we will weigh
more than we do today. The only reasonable option at this time
for patients who are dangerously overweight is surgery, and if
Dr Higa's results can be widely reproduced, I believe that we
will see a substantial and justifiable increase in the perfor-
mance of bariatric surgery.

I have the following questions. Actually, you anticipated
my first and that is how you are selecting patients. My under-
standing is that you are excluding no one except for patients
with previous gastric operations. Have you seen any problems
with patients with advanced cardiomyopathy of obesity or sig-
nificant carbon dioxide retention? Second, what are you do-
ing for deep vein thrombosis prophylaxis? Four hundred bar-
iatric procedures without a single deep venous thrombosis or
pulmonary embolus is really quite remarkable.

The third is, how do you decide whether to dilate an anas-
tomosis? In talking with other surgeons who perform bariat-
ric surgery, it strikes me that the criteria for dilating anasto-
omoses vary tremendously and I wonder at what point you decide
that that is appropriate.

Finally, who should be doing these operations? My bias
is that these procedures must be performed only by surgeons
willing to make the commitment to learn bariatric surgery in-
cluding the critical elements of patient selection, and preop-
erative and postoperative care. On the other hand it is cer-
tainly the case that these operations require very advanced
technical skills in laparoscopy. I would like to hear your thoughts
on this topic.

Bruce Wolfe, MD, Sacramento, Calif: The key question
is not whether laparoscopic gastric bypass can be done or not,
but whether it is better. To this end, have you looked at your
previous experience with open gastric bypass and done a for-
mal data analysis to see if, in fact, the overall complications and
outcomes are comparable. My second question is that you showed
follow-up weight data on just 58 patients at 1 year. Are there only
58 patients who are 1-year postoperative, or is the follow-up rather
incomplete which might impact detection of late complica-
tions, particularly the problem of postoperative intestinal ob-
struction, which appears to be more common following laparo-
sopic gastric bypass compared with the open procedure?

Dr Higa: For patients who are ill, those with cardiomy-
opathy, sleep apnea, or severe medical problems, we approach
each patient individually. We are very intent on optimizing their
performance ahead of time, sometimes even admitting pa-
tients for diuresis and for evaluation with appropriate consul-
tation with cardiac and pulmonary specialists.

For deep vein thrombosis prophylaxis, we use antiembo-
lism compression devices and administer perioperative subcu-
taneous heparin. We also believe in early ambulation. Gastro-
jejunostomy stenosis is a recurring problem. It is one of our
most frequent complications, and I call it a complication be-
cause it requires a secondary procedure. Patients present with
progressive problems tolerating advancement of their diet, even
to the point of liquids. Fortunately, this anastomosis is dura-
ble and is amenable to endoscopic balloon dilation.

The next question is a very difficult one. Who should be
doing these procedures? The National Institutes of Health stan-
dards really call for a lifetime follow-up of these patients, and
there has to be a great commitment to these patients, more so
than just about any other procedure we do in general surgery.

I hope that the individuals who choose to do these are the
ones who have a real interest and a passion for bariatric sur-
ery. Then the question is, can everyone be trained in ad-
vanced laparoscopic techniques? There is a very long learning
curve as you can see with our data. So I do not have a real good
answer for that. I think that as time goes on individuals will
select themselves based on their interest, commitment, and de-
gree of laparoscopic skill.

Dr Wolfe asked a good question about formal data acqui-
sition looking back at our open experience and our present ex-
erience. In the ideal setting a prospective randomized study
of open vs laparoscopy would be of value, but patients really
won't stand for that. The idea of minimally invasive technol-
ogy is such a powerful tool that patients are willing to sacrifice
certainly a lot of things including an unknown safety factor. We are con-
vinced that our present laparoscopic experience is superior to
our personal open experience.

Follow-up is difficult in this group of patients. Third-
party payers do not recognize the need for lifetime follow-up,
so many patients are unwilling to pay for visits, especially if
they perceive there to be no problems. Our patients sign agree-
ments to be followed for at least 1 year in our office, but too
many do not. Although our first case was 2 years ago, we were
not as productive in the first year of this study. Therefore, most
of our patients have not been out of surgery for 12 months. I
agree with the need for long-term results.