Hypothesis: Laparoscopic Roux-en-Y gastric bypass is a complex procedure performed on a high-risk patient population. Good results can be attained with experience and volume.

Design: Retrospective study.

Setting: Tertiary care academic hospital.


Interventions: All patients underwent laparoscopic Roux-en-Y gastric bypass.

Main Outcome Measures: Perioperative deaths and complications.

Results: The patient population was 85% women and had a mean body mass index of 47 kg/m² (range, 32-86 kg/m²). The overall complication rate was 15% and the mortality was 0.3%. For the first 100 cases, the overall complication rate was 26% with a mortality of 1%. This complication rate decreased to approximately 13% and was stable for the next 650 patients. The incidence of major complications has also decreased since the first 100 cases. Leak decreased from 3% to 1.1%. Small-bowel obstruction decreased from 5% to 1.1%. Overall mean operating time was 138 minutes (range, 65-310 minutes). It decreased from 212 minutes for the first 100 cases to 132 minutes for the next 650 and 105 minutes (range, 65-200 minutes) for the last 100 cases.

Conclusions: Laparoscopic Roux-en-Y gastric bypass is a technically difficult operation. This review of a large series in a high-volume program demonstrated that the morbidity and mortality could be reduced by 50% with experience. The results are similar to those reported from other major centers. In addition, as reported elsewhere, the learning curve for this procedure may be 100 cases.

Arch Surg. 2005;140:362-367

Over the past 20 years, the United States and the world at large have seen a staggering increase in the prevalence of obesity. Recent surveys by the Centers for Disease Control and Prevention (Atlanta, Ga) suggest that more than 64% of US adults are overweight and 5% are morbidly obese, defined as having a body mass index (BMI) greater than or equal to 40 kg/m².¹ Obesity is associated with health-affecting comorbidities such as diabetes mellitus, hyperlipidemia, hypertension, and obstructive sleep apnea. These adverse conditions contribute to the increased risk for premature death and disability for persons with BMIs greater than 25.² Commonly refractory to conservative weight loss treatments, morbid obesity has become a surgical disease. Operations to treat obesity are the most effective interventions for achieving meaningful and sustainable weight loss.³ Mirroring the rise in prevalence of obesity has been the dramatic increase in the number of bariatric procedures performed. In fact, the number of procedures performed yearly in the United States has increased a staggering 644% in the last decade.⁴ This increase can be attributed to the increased public awareness of the health risk associations of obesity and its staggering societal cost and the greater acceptance of surgery as a legitimate treatment. Equally significant is the adaptation of minimally invasive techniques to the field of bariatric surgery.

Laparoscopic and minimally invasive surgery have now extended into almost all surgical disciplines. The benefits of decreased postoperative pain, length of hospital stay, wound morbidity, and even improved cosmesis are particularly appealing for this complex patient population.

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Roux-en-Y gastric bypass (RYGBP) is currently the procedure of choice in the United States for intractable morbid obesity. However, it has traditionally been a formidable operative procedure with the potential for catastrophic complications. In 1994, Wittgrove and Clark described the first successful laparoscopic gastric bypass procedure. Since that time, the number of laparoscopic gastric bypass procedures has increased dramatically as the equipment has improved and surgeons across the country have undergone extensive training. However, the laparoscopic Roux-en-Y gastric bypass (LRYGBP) remains a more technically challenging operation compared with its open counterpart. Some surgeons have reported that the learning curve is approximately 75 to 100 cases. In addition, other studies have suggested that the operative morbidity and mortality were somewhat dependent on case volume. The purpose of this study was to evaluate the role of technical experience and patient volume in reducing the rate of perioperative and postoperative complications in patients who underwent LRYGBP.

METHODS

To be considered for surgery, all patients had to satisfy the criteria for gastric bypass surgery as stated in the 1991 National Institutes of Health Consensus Development Conference Statement on obesity. All patients also had to successfully complete the interdisciplinary screening and preparatory process for bariatric surgery by the various health care professionals of the Obesity Consult Center of Tufts-New England Medical Center in Boston, Mass.

We have maintained a prospective database for all patients undergoing LRYGBP at Tufts-New England Medical Center since March 1998. Baseline patient characteristics, including age, sex, height, weight, BMI, percentage excess weight, and comorbid conditions, were recorded in the program’s bariatric database. At the time of surgery, operating time, blood loss, length of stay, and operative complications were recorded. Following surgery, patients were monitored for complications including signs of staple line leak (signs of peritonitis or abnormal output from the drain), hemorrhage, obstruction, and infections. After hospital discharge, all patients were followed up as per the protocol for surgical follow-up established by the Obesity Consult Center. Although postoperative radiographic or endoscopic studies were not routinely performed, there was a low threshold to study any patient who returned for a follow-up appointment with any gastrointestinal symptoms such as pain, vomiting, or inadequate weight loss.

For this investigation, a retrospective analysis was performed on the database of the first 750 consecutive morbidly obese patients undergoing LRYGBP from March 1998 to April 2004. Operative time, blood loss, length of hospitalization, and 30-day morbidity and mortality were analyzed. The data were analyzed after segregation into 5 different categories based on chronology: the first 100 cases (1-100), the second 100 cases (101-200), all cases after the first 100 cases (101-750), the last 100 cases (651-750), and all cases (1-750).

Except for some minor alterations, all patients underwent LRYGBP performed in a similar fashion. The gastric pouch was created with the Endo GIA linear cutting stapler with 60-mm long, 2.5-mm cartridges (US Surgical Corp) with the stapler’s anvil placed into the pouch via a transabdominal technique. The pouch’s staple line and the gastrojejunostomy were checked for leakage by inflating the pouch and proximal Roux limb with 2 L of oxygen and flooding the left upper quadrant of the abdomen with saline. Bubbling observed in the saline pool would identify a leak. This would then be corrected with sutures until normal air test results were achieved. A closed suction drain was placed between the staple lines of the pouch and excluded stomach in all patients.

The jejunoojejunostomy was created in a side-side fashion between the biliopancreatic limb and the Roux limb. The Endo GIA linear cutting stapler with a 60-mm long, 2.5-mm cartridge was passed distally into each limb of bowel through small enterotomies created on the antimesenteric borders. After firing the stapler, it was reintroduced with a 30-mm long, 2.5-mm cartridge proximally through the now common enterotomy. After firing, the common enterotomy was closed transversely with a 60-mm long, 2.5-mm cartridge. The mesenteric defect was closed initially with interrupted silk sutures (first 440 cases) but has since been closed with running silk suture. At the conclusion of the gastric bypass, the internal hernia spaces were closed. The Petersen space was obliterated by tacking the proximal Roux and biliopancreatic limbs together. The mesocolic defect was controlled by tacking the Roux limb to the cut edges of the mesocolon. Twelve-millimeter port wounds were closed at the level of the fascia, and all port sites were closed with subcuticular running suture.

RESULTS

From March 1998 to April 2004, 750 patients underwent LRYGBP at Tufts-New England Medical Center. The patients were predominantly female (85%) with a mean age of 41 years (range, 14-69 years). Body mass index spanned the range of 32 kg/m² to 86 kg/m², with an average BMI of 47 kg/m² and a median BMI of 46 kg/m². The Figure shows the breakdown of the different case types since the first LRYGBP was performed. Over the ensuing 6 years, the total number of bariatric cases performed annually increased from 166 to 370 per year. The number of LRYGBPs increased from 16 in the first year...
to 303 the last year. Similarly, the number of open RYGBPs dramatically decreased over the same period. The number of open cases peaked in the second year at 169 but decreased to only 6 in the last year. The LRYGBP made up only 10% of the practice in year 1 but was 91% of the practice in year 5. It decreased to 82% in year 6 because of the increasing popularity of the laparoscopic band. Other bariatric cases included revisional procedures and laparoscopic adjustable gastric bands. The striking increase in the number of other bariatric cases performed in year 6 also represents the more liberal offering of the laparoscopic band.

As depicted in Table 1, the percentage of women who underwent surgery decreased from 98% in the first 100 cases to 81% for the last 100. Men were rarely offered the LRYGBP during the first 100 cases but were rarely denied the LRYGBP thereafter. Mean age and BMI increased slightly over time. Of note, while the mean BMI seems to have only risen slightly from the first 100 to last 100 cases (from 44 kg/m² to 47 kg/m²), no patients with a BMI greater than 55 kg/m² were offered the LRYGBP in the first 100 cases. Estimated blood loss, operative time, and hospital length of stay consistently dropped. Mean operating time was 212 minutes for the first 100 cases, 163 minutes for the next 100 cases, 132 minutes for all cases after the 100th, and only 105 minutes per case for the last 100 cases.

The overall mortality for the patient population was 0.3% with a complication rate of 1.1%. This rate was rather stable for the rest of the series. The complication rate was 13.4% for all patients operated on after the 100th case and 11% for the last 100 patients in the series. In addition, complications possibly related to technique, such as trocar site wound infection (8% vs 2%), splenic injury (1% vs 0%), bowel obstruction (5% vs 0%), and gastrointestinal tract leak (3% vs 0%), decreased while others such as intraluminal bleeding and anastomotic stricture and thromboembolism remained essentially unchanged.

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The RYGBP was first described by Mason and Ito in 1967. For more than 30 years, it has been the “gold standard” operative procedure for the treatment of intractable morbid obesity. The recent dramatic increase in the number of RYGBPs performed yearly can be attributed to many factors, most significantly, the growing public awareness of the disease of obesity and the successful evolution of the procedure from open to laparoscopic. The procedure has never been safer owing not only to the introduction of minimally invasive technologies but also to the improvements in patient preparation, anesthetic management, and postoperative care.

Yet despite the advances in bariatric surgery in the last 30 years, the procedure remains a technically difficult operation performed on high-risk patients. As most bariatric surgeons are well aware, morbidly obese patients do...
not tolerate complications. Complications, such as leaks, often result in catastrophic outcomes for these patients.

The introduction of laparoscopy into bariatric surgery has been of tremendous overall benefit but also a “double-edged sword.” As with other abdominal procedures, laparoscopy dramatically reduces wound complications. With RYGBP, the risk of wound infection, said to be as high as 20% to 25% with open surgery,16 is reduced to approximately 1% with laparoscopy.17 Most significantly, a prospective, randomized trial by Nguyen et al,18 comparing open RYGBP with LRYGBP, found that with laparoscopy there are decreases in postoperative fluid shifts, pulmonary derangements, cytokine release, and temperature changes.19

Despite the potential overwhelming benefits of performing LRYGBP, the technical challenges cannot be overstated. The procedure is performed in deep abdominal cavities and requires exposure of the gastroesophageal junction. The liver is often steatotic and enlarged, limiting exposure and light penetration. Massive abdominal adiposity also compromises exposure to the viscera. Despite these hazards, the operation requires proximal gastric staple division and the creation of 2 anastomoses. As with other complex procedures, there is strong opinion that these procedures have a long and steep learning curve.

In surgery, the learning curve is defined as the number of cases performed necessary to acquire a familiarity with the operative technique. This also implies the point in training where technical complications should not occur more often than accepted frequencies. The concept of a learning curve became more relevant with the introduction of a major breakthrough in surgical technique, the ability to perform traditional surgery laparoscopically. This paradigm shift required the training of an entire surgical community to completely new techniques and totally new dexterities. For cholecystectomy, the first common open procedure adapted for laparoscopic surgery, the learning curve was assumed to be the number of cases a surgeon should perform to reduce the incidence of common bile duct injury to that of the open procedure. As more procedures were adapted, learning curves were suggested for them as well. The more complex the procedure, the greater the number of cases the surgeon must perform to master the learning curve. For laparoscopic inguinal herniorrhaphy, more than 50 cases are thought to be required.20 At least 20 cases were found necessary in 1 study to lower complications after laparoscopic splenectomy.21 Similar findings have been described for laparoscopic fundoplication and colectomy.22,23

The LRYGBP is generally considered to be one of the more technically challenging laparoscopic procedures. As previously described, the patient size and the complexity of the procedure contribute to the major challenges. Consistent with this is the support that the learning curve is as high as 100 cases. Schauer et al19 reviewed their first 150 LRYGBP procedures and reported that the operative complications halved after their 100th case. Operative time and the incidence of wound infections and leaks also decreased. Oliak et al20 found dramatic reductions in operating time (from 189 to 125 minutes) and perioperative complications from 32% to 15% after the 75th case. In a follow-up study, Oliak et al21 reported that advanced laparoscopic training could reduce this long, steep learning curve.

Another point of controversy is whether LRYGBP surgery should only be performed at high-volume centers. Many bariatric surgeons believe that the degree of difficulty of the procedure and the unique high-risk nature of the patient population mandates limiting this field to centers that specialize in it and perform it on a regular basis. Theoretically, high volume enables the surgeon to develop a significant experience with the procedure in a shorter period. High frequency leads to the acquisition of a comfort level with the nuances of the technique and the ability to modify the procedure based on trial-and-error learning. The result is to perform the operation with fewer technical problems and in less time. This comfort extends beyond the surgeon to all health care professionals involved with the care of these patients. All become comfortable with the unique aspects of the physiologic characteristics of the postoperative morbidly obese patient. Clinical pathways can be developed and implemented. Resources can be directed to the high-volume programs. Complications, even when occurring at a low frequency, will be seen more often because of the volume of cases. This allows the care team to better recognize these complications and therefore better prepared to address them.

Numerous publications in several surgical disciplines support the notion that high volume leads to better patient outcome. For pancreatic cancer, the literature is clear that high-volume programs improved outcome for both curative as well as palliative surgery. Sosa et al25 found that increased hospital volume of all pancreatic surgery for cancer was associated with decreased in-hospital mortality rates and length of stay. Birkmeyer et al26 found that late survival after pancreaticoduodenectomy was markedly better for patients undergoing surgery at high-volume centers. Similarly, Parks et al27 reported better results for patients undergoing surgery by surgeons specializing in pancreatic cancer and with higher case loads. For carotid surgery, both stroke rate and mortality were lower for high-volume surgeons.28 Similar results have been reported for primary colon cancer resection.29

The association between case volume and outcome has also been reported for bariatric surgery. Courcoulas et al30 analyzed the 3-year outcome results of gastric bypass surgery in Pennsylvania from 1993 to 2000. They found that surgeons who performed fewer than 10 procedures per year had a statistically significantly higher risk of adverse outcome (28% vs 14%; P = .05) and risk of death (5% vs 0.3%; P = .06) than higher-volume surgeons. They further found that while hospital volume differences did not reach significance, surgeons who performed only 10 to 50 cases per year in low-volume hospitals had a 55% risk of adverse outcome (P < .01). Hospital volume differences did reach statistical significance in a study by Liu et al.11 Using the California inpatient hospital discharge database, they analyzed all gastric bypasses performed between 1996 and 2000. They found that complications were more likely to occur in patients who had surgery at very low-volume (<50 cases per year) and low-volume hospitals (50–99 cases per year) with odds ratios of 2.72 and 2.70, respectively, when compared with higher-volume hospitals performing more than 200 cases annually.
Our data seem to support both premises that the learning curve is approximately 100 cases and a high-volume program may achieve better patient outcome than a low-volume program. With regard to learning curve, our data are consistent with those published by Schauer et al. Despite an increasing tendency to offer LRYGBP to more complex patients (ie, male patients and those with higher BMIs, previous abdominal surgery, higher comorbidity), we were able to simultaneously reduce our complication rate and operative time by 50%. Operating time did not level out after the first 100 cases but continued to fall. This may reflect that while the learning curve may be approximately 100 cases, learning and improvements in operating efficiency may continue beyond that point.

Further support for the steep and protracted learning curve can be seen in the pattern of morbidity reduction achieved in our series. Complications that could be attributed to technique or patient management demonstrated the greatest improvements with experience. Most notably, the gastrointestinal track leak rate was 3% for the first 100 cases, 1% for the next 100, and 1.1% overall. Trocar wound infections occurred in 8% of the first 100 cases and prompted a technique change from transesophageal passage of the circular stapler anvil to a totally abdominal approach. This is consistent with the results reported by Schauer et al. Similarly, improvements in technique led to decreases in splenic injuries, gastrointestinal fistula, internal hernias, and early postoperative bowel obstructions due to stricture or kinking of the jejunojejunostomy. On the contrary, complications that are less likely the result of technique or management errors, such as intraluminal bleeding, thromboembolism, and anastomotic strictures, did not decrease in incidence.

Our program is a very high-volume program that is currently performing more than 400 bariatric procedures yearly, approximately 80% of which are LRYGBPs, although only 16 LRYGBPs were performed in the first year of the study. Overall, 166 bariatric procedures were performed (the majority were open RYGBPs). By the next year, total case volume was more than 200. At approximately 3 to 4 cases weekly, the volume was sufficient to provide the necessary experience for all health care professionals involved. Even while we were climbing the learning curve for the LRYGBP (100 cases were not reached until after year 3), patient management experience was being gained from the open cases. The finding that the complications seen in the first 100 LRYGBP cases were operative and technique related and not due to patient care supports this premise. This study was limited in scope. It was a retrospective observational analysis of a bariatric program. Many other factors could also have influenced the results. The operative data did change slightly over the course of the study period. Case volume increased at the same time as the learning curve was being climbed. Were the improvements due more to conquering the learning curve, increasing the weekly case volume, or both? Furthermore, the true number of cases performed to conquer the learning curve was not proven nor was the necessary yearly volume.

Despite the limitations of a retrospective review, there is no dispute that the complications associated with the LRYGBP were dramatically reduced after approximately 100 cases were performed at a high-volume bariatric program.

Accepted for Publication: December 13, 2004.

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Previous Presentation: This study was presented at the New England Surgical Society annual meeting; October 2, 2004; Montreal, Quebec; and is published after peer review and revision. The discussions that follow this article are based on the originally submitted manuscript and not the revised manuscript.
John Kelly, MD, Worcester, Mass: Your statistics have improved as you have gone through and yet you have had many fellows, you have young attendings that are starting with you, and by all rights they should have problems during their 100 or their first 50 that would drag down your statistics. I wonder if you could comment on what you think keeps them safe.

Dr Shikora: Well, first of all, we keep these folks on a very tight leash in the operating room. When we have somebody who is training with us, we often will scrub 2 attendings with the trainee so that if the trainee is starting to get into difficulty, the attending can switch places from holding the camera to operating. Remember that the number 1 priority, even though we are all very interested in training, is keeping our patients safe.

The explanation I have for the fact that our complication rate has stabilized at about 12% or 13% is that we have liberalized our patient selection. We are no longer denying the higher-risk patient, for example, the larger BMI, the older patient with more comorbidity, or the patient with significant previous abdominal surgery. It also may take into account that we have been more liberal with who we are training. William Laycock, MD, Lebanon, NH: My question really is, I heard about fellows. I have heard about minifellowships, young attendings. I have not heard about residents. Currently I imagine at Tufts this has to be the highest-volume abdominal operation you do. At Dartmouth, it is more common than laparoscopic cholecystectomy. In our environment, I do all these with either a fourth- or a second-year resident. At the second-year resident level it is a little bit painful, but by the end of a specific laparoscopic rotation of 3 months, our fourth-year residents are doing the case. Now the problem is our time. We have not seen that diminution of time to the level that you have, but at the end of the day, I think we have to get this to the resident level at some point given the volume and the likely impact this is going to have on the general surgeon. I would like you to comment on how you are incorporating residents into the program.

Dr Shikora: It has always been a problem, and it continues to be a problem. Because of the new resident work hours, about a third of the residency goes home every morning so that there are a third less residents that would be potentially available to scrub with us. The ones that remain are divided up among the other surgeons who are operating that day. For many cases, we do not have a resident asking to scrub with us. We do welcome the residents and when they scrub, what we would do is have either myself and the fellow or myself and another attending operate along with the resident. We let the resident go as far as they can, keeping an eye on the clock and also to make sure that the technique is not being in any way, shape, or form compromised by the inexperience of the resident. We are willing to say, “okay, you could start now” and at a point where they get into trouble, switch places so that the more experienced set of hands can make progress. We then will get to another spot in the case where the resident can again contribute. That is how we have managed it. We would like to see residents with us more frequently than we do, but we are faced with the problems of the work hours and the other restrictions.

Steven Schwartzberg, MD, Boston, Mass: Having watched the development of the learning curve and all those people that you have trained, you and Phil Schauer and other people have been pioneers and even self-trained in a pioneering period. I think that we owe it to our surgical community to keep chippering away at this 100-case barrier and go back and look at the people that have been trained now that you have really refined this operation, really have gotten the techniques down, because this is going to become a political issue, a financial issue, a legislative issue, and those higher numbers have very high costs for surgeons who want to learn this and for institutions that want to initiate these programs. We don’t want to turn it into the “haves” and the “have nots” so I would encourage you to go back to your minifellows and look at their learning curves and see if we have knocked it down a bit over the next few years.

Dr Shikora: That is an excellent point. I alluded to that in the conclusion, that people who have had specialized training may have a lower learning curve than those who had to start from scratch. I did review an unpublished paper by somebody who had done some fellowship training in this and his suggestion was his own personal learning curve after 100 cases was 50 cases, but I agree with Steve that it is probably going to be less for those that had the opportunity to “jump on my back” and learn from my mistakes, because I can tell them “don’t do this,” “I did this and it didn’t work out,” or “here is a nice trick to keep you out of trouble.”

Dr Kevin Looser, MD, Portsmouth, NH: I am one of Scott’s minifellows, and our group of 3 surgeons started a program at Portsmouth and I think a learning curve number is difficult to come up with and varies obviously from surgeon to surgeon. I think if a surgeon has done a lot of laparoscopic surgery as we had to start out with and I of our surgeons did an advanced laparoscopic training for a year, I am not sure if that number of 100 holds up. Our program has been going for a little over a year now. We have done 75 cases, have not had any deaths, have had a number of complications, which you would expect, but I would certainly agree that a minifellowship is absolutely mandatory and important to do this procedure and that if you are just going to start off doing it without that kind of training you are going to have problems.

Dr Shikora: Well, Kevin, I agree with you in part. I still think that you and your partners benefited because I could tell you what I did wrong and how to prevent it. It does not necessarily have to do with how advanced your laparoscopic training was. It is some of the nuances of this particular operation. For example, it is learning a novel way to do the enterenterostomy that decreases bowel obstruction when the standard technique that I had been doing resulted in a few more bowel obstructions.

Jeremy Morton, MD, Portland, Me: We may have already gotten the answer to my question, but there are many hospitals that want to start programs like this and we are strapped with the responsibility of credentialing these folks. I mean they have to credential themselves within the hospital but those of us involved with insuring them from medical liability have to decide whether or not they are adequately trained, and my question is what is the minimum amount of training, say a minifellowship or whatever, that you consider represents adequate training in the process of retrofitting the previously trained surgeon?

Dr Shikora: That is a very difficult question to answer, and many of us have different opinions on it. In Massachusetts, you may or may not know, we just convened an expert panel that was sponsored by the Department of Public Health to come up with standards for Massachusetts. Certainly a year fellowship would be the best, but that is not practical for surgeons who are out beyond their residency and in practice. Phil Schauer talks about doing a 3-month fellowship as a minimum, but even that is not practical if you have a busy practice. Many of us offer a couple of weeks of advanced training with hands-on in the operating room at high-volume centers such as ours where in a week’s time you get to see 8 to 12 cases plus clinic and everything else that we do. That is probably the bare minimum for somebody who already has advanced laparoscopic skills. In addition, you should probably take certain courses put on by the ACS [American College of Surgeons] or the ACS in conjunction with the American Society of Bariatric Surgery, but I think we are still evolving what should be the appropriate training.