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and Other Interventional Techniques

Laparoscopic Roux-en-Y gastric bypass

Defining the learning curve

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Abstract

Background: Increasing numbers of laparoscopic surgeons are performing laparoscopic Roux-en-Y gastric bypass (LGB). Our aim was to determine the length of the learning curve for a skilled laparoscopic surgeon.

Methods: The study population consisted of the first 225 consecutive LGB procedures attempted by one laparoscopic surgeon (HJS). Outcome parameters included mortality, morbidity, operative time, and conversion to an open procedure.

Results: Average operative time decreased from 189 min (first 75 patients) to 125 minutes (last 75 patients). Most of the improvement in operative time occurred over the first 75 patients. The perioperative complication rate decreased from 32% (first 75 patients) to 15% (second and third groups of 75 patients). Complication rates did not significantly decrease after the first 75 patients. Low mortality and conversion rates were achieved early in the series.

Conclusion: Low mortality rates and low conversion rates can be achieved early in the learning curve for LGB. Complication rates plateau after approximately 75 LGBs, and operative times decrease substantially over the initial 75 cases. Operative times continue to decrease at a slower rate beyond 75 cases.

Key words: Bariatrics — Laparoscopic gastric bypass — Complications — Learning curve

Roux-en-Y gastric bypass is the most commonly performed bariatric operation done in the United States [4]. The laparoscopic approach to gastric bypass is a recent development, first described by Wittgrove et al. in 1994 [12]. Laparoscopic gastric bypass (LGB) has subsequently been shown to be associated with less pain, shorter hospital stays, better postoperative quality of life, and quicker convalescence than traditional open gastric bypass [7]. These benefits have driven patient demand and convinced laparoscopic surgeons to pursue LGB.

LGB, however, is a technically demanding procedure with a long learning curve. The learning curve results in elevated complication rates, excessive operative times, and high conversion rates [1, 5, 9, 10, 11]. The purpose of this study was to determine the length of the learning curve for a surgeon experienced in advanced laparoscopy.

Materials and methods

The study group consisted of the first 225 consecutive LGB procedures attempted at Hackensack University Medical Center by one surgeon (HJS) between 22 April 1999 and 27 August 2001. Patients having a history of previous bariatric procedures or previous gastric surgery were excluded. All patients met the minimal criteria for bariatric surgery proposed by the NIH Consensus Development Panel report of 1991 [6]. Patients were not selected based on upper BMI limits, history of previous abdominal operations, or gender. Preoperative workup and specialty medical consultations were dictated by individual patient need.

HJS, the surgeon who performed all the LGBs in this study, had previous advanced laparoscopic surgery experience. Although HJS did not complete a laparoscopic surgery fellowship, he worked for 3 years in a laparoscopic surgical practice and routinely performed laparoscopic cholecystectomy (>100 cases), laparoscopic inguinal (approximately 50 cases) and ventral hernia repair (approximately 15 cases), and laparoscopic Nissen fundoplication (approximately 30 cases). HJS also performed laparoscopic colectomy (approximately 10 cases), laparoscopic splenectomy (approximately 10 cases), and laparoscopic adrenalectomy (3 cases). Before performing LGB on humans, HJS performed 20 open gastric bypasses, completed a nationally recognized 2-day LGB course, and performed 10 LGBs on pigs.

Data were collected retrospectively by chart review. Parameters recorded include patient demographic factors, comorbidities, operative times, need for conversion to an open procedure, and perioperative complications. Operative times were recorded only for those patients who underwent LGB without other procedures, such as cholecystectomy. Operative times were defined as the time between the initial skin incision and the final skin suture. Significant comorbidities of obesity were considered to be hypertension, coronary artery disease, dyslipidemia, obstructive sleep apnea/hypoventilation syndrome of obesity, and diabetes. Perioperative complications were considered to be any adverse event occurring within 30 days of surgery. Gastrointestinal

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leaks, pulmonary emboli, bowel obstructions requiring operation, bleeding resulting in hemodynamic instability or blood transfusion, and any other complication requiring an operation or a significantly prolonged hospital stay were considered to be major complications. Minor complications were considered to be all other adverse events.

Operative technique

Our operative technique is a modification of the technique described by Wittgrove et al. [12]. We have periodically made changes in our technique over the course of our experience. Our current technique involves first establishing pneumoperitoneum by using the Veress needle technique in the left upper quadrant. Five ports are routinely used. We divide the jejunum 40 cm from the ligament of Trietz, and perform a stapled jejunojejunostomy using a linear stapler (Ethicon Endo-Surgery Inc, Cincinnati, OH). Our convention has been to construct the roux limb to be twice the BMI in centimeters. The roux limb is passed through a retrocolic, retrogastric tunnel. A divided 20-30 cc pouch is created and the gastrojejunostomy is performed using a 21-mm circular stapler (Ethicon Endo-Surgery Inc.). A #10 Jackson-Pratt drain is left adjacent to the gastrojejunostomy. Changes made in the operative technique over the course of this study include changing from transoral to transabdominal passage of the circular stapler anvil (after 30 cases), changing from an antecolic to retrocolic roux limb course (after 30 cases), and making a more careful effort to completely close the transverse mesocolic defect using nonabsorbable sutures.

Postoperative care

Patients begin ambulating the day of surgery. Radiologic examination of the gastrojejunostomy using water-soluble contrast was obtained the morning after surgery in the first 100 patients. Since then, routine contrast studies have not been obtained. Clear liquids are begun at a rate of 2 oz/h the day after surgery. Patients are typically discharged 2 or 3 days after surgery. The drain is routinely removed before discharge. Follow-up visits are scheduled after discharge at 1 week, 3 weeks, 3 months, 6 months, and then yearly. Complete 30-day follow-up was available for 95% of the patient population.

Data analysis

Outcome parameters assessed include mortality, operative time, conversion to an open procedure, and complications (total and major). We defined the learning curve to be the number of procedures until the outcome parameters assumed a statistically constant value or rate. The learning curve therefore varied depending on the outcome parameter evaluated. We analyzed the study population as three groups of 50 patients. Each outcome parameter was compared between the groups. The length of the learning curve was the number of groups (of 75 patients) after which the outcome variable no longer changed significantly. Data were analyzed using analysis of variance for groups of continuous variables and the chi-square analysis, or Fisher's exact test, when appropriate, for categorical variables. A probability of <0.05 was accepted as statistically significant.

Results

Of our study population of 225, 78% were women and 22% were men. The average age was 40 years with a range of 21–69 years. The average BMI was 51 with a range of 36–86. Severe comorbidities of obesity were present in 55% of the patients, and a history of previous abdominal or pelvic operations was present in 49%. For the analysis of outcomes, the patient population was divided into groups of 75 patients. Demographic details of the patient population divided into groups of 75 are shown in Table 1. Age, gender ratio, BMI, and comorbidity rates were similar between the groups.

Table 1. Demographics of the patients

| Group (<i>n</i>) | A (1–75) | B (76–150) | C (151–225) |
|---|--|--|--|
| Age (yrs) (range) ^a Female ^a BMI (range) ^a Comorbidity ^a | 40 (24–65) 77% 49 (37–86) 53% | 40 (21–69) 81% 50 (38–74) 57% | 41 (21–69) 75% 53 (36–80) 55% |

^a p = NS between groups

Two mortalities occurred in the first group of 75 patients. The first occurred in a 25-year-old female (patient 12) with a BMI of 46 who developed necrosis of her roux limb. She developed progressive sepsis and died on postoperative day 7. We hypothesize that this occurred due to tension on the roux limb in the antecolic, antegastric position. An autopsy showed no mechanical obstruction and no anastamotic leak. This event led us to subsequently change our technique and position the roux limb in a retrocolic, retrogastric position. The second death occurred in a 45-year-old male with a BMI of 69 (480 pounds) who developed a leak at the jejunojejunostomy. He presented to the emergency room 1 week after discharge with advanced sepsis. Difficulty during intubation on postoperative day 8 resulted in his death. The mortality rates were not significantly different between the groups.

We converted three LGB procedures to open procedures (patient numbers 8, 47, 183). Patient number 8 was a 25-year-old female with a BMI of 41 who was converted emergently because of an injury to the inferior vena cava that occurred while dividing the gastrohepatic ligament with the harmonic scalpel (Ethicon Endo-Surgery Inc.). She underwent an open repair of the vena cava injury and underwent open gastric bypass later during the same hospitalization. Patient 47 was a 350pound 42-year-old female (BMI 57) who required conversion to an open procedure to revise a twisted roux limb. Patient 183 was a 565-pound 41-year-old male (BMI 77) in whom adequate laparoscopic exposure could not be achieved. The conversion rates were not significantly different between the groups.

Operative times varied between 71 min (patient 199) and 384 min (patient 47). The average operative times and the ranges of operative times for the patient population divided into groups of 75 are shown in Table 2. The majority of the decrease in operative times that occurred over the course of this study occurred during the initial 75 patients. Operative times continued to decrease beyond the first 75 patients, but at a slower rate. There was a statistically significant difference between the operative times for the first two groups of 75 patients (189 min vs 138 min; p < 0.001) and for the 2nd/3rd groups of 75 patients (138 min vs 125 min; p = 0.02). A plateau in operative times could not be demonstrated statistically to occur over the three groups of 75 patients in this study.

The major and minor complications that occurred in the patient population are listed in Tables 3 and 4. The number of complications that occurred in each of the three groups of 75 patients is shown in Table 2. It appears from the table that both major and total compli-

Table 2. Outcomes in consecutive groups of 75 patients

| Group (<i>n</i>) | A (1–75) | B (76–150) | C (151–225) | |
|----------------------------------|----------|------------|-------------|--|
| Mortality ^a | 2 | 0 | 0 | |
| Major complications ^b | 10 | 2 | 3 | |
| Total complications ^c | 24 | 11 | 11 | |
| OR time (min) ^d | 189 | 138 | 125 | |
| Conversion ^a | 2 | 0 | 1 | |

^a p = NS between groups

 $^{b}p = 0.02$ between groups A and B, p = 0.65 between groups B and C

 $^{c}p = 0.01$ between groups A and B

 $d^{r} p < 0.001$ between groups A and B, p = 0.02 between groups B and C

Table 3. Major complications in study population (n = 225)

| Major complications | n | 1 (0–75) | 2 (76–150) | 3 (151–225) |
|-------------------------|---|----------|------------|-------------|
| Wound infection | 1 | 1 | | |
| Roux limb necrosis | 1 | 1 | | |
| Vena cava injury | 1 | 1 | | |
| Bowel obstruction | 3 | 1 | 1 | 1 |
| Bleeding | 6 | 4 | 1 | 1 |
| Gastrointestinal leak | 1 | 1 | | |
| Necrotizing soft-tissue | | | | |
| infection | 1 | | | 1 |
| Pulmonary embolism | 1 | 1 | | |

cation rates become constant after 75 cases. Statistically there was a significant difference between the major complication rate of the first 75 patients and the second 75 patients (13% vs 3%; p = 0.02). There was not a difference between the complication rates (total and major) of the 2nd/3rd groups of 75 patients. A plateau in complication rates can be demonstrated statistically to occur after 75 cases.

Discussion

The learning curve poses a formidable challenge for surgeons wishing to perform LGB. In this study we were able to demonstrate a statistically significant association between inexperience and both major complication rates and operative times. We were not able to demonstrate an association between experience and either mortality or conversion rates.

This learning curve effect for LGB can be demonstrated from studies in the surgical literature (Table 5). Larger studies of LGB and studies of patient populations well beyond the learning curve demonstrate mortality rates of <1%, conversion rates of 1-3%, major morbidity rates of <5%, major leak rates of <2%, and operative times of <2 h [2, 3, 8, 13]. This contrasts with smaller studies evaluating the early patients undergoing LGB that show conversion rates of as high as 23%, major complication rates of as high as 13–20%, leak rates of 2–4%, and average operative times of over 3 h [1, 5, 9, 10, 11]. Wittgrove et al. report a decrease in their leak rate from 3% to 1% and a decrease in their operative times from 4 h to 90 min with experience [13]. Higa et al. demonstrate a plateau in operative times of 60-90 min after approximately 200 cases [2].

Table 4. Minor complications in study population (n = 225)

| Minor Complications | п | 1 (0–75) | 2 (76–150) | 3 (151–225) |
|---------------------|----|----------|------------|-------------|
| Wound infection | 18 | 10 | 6 | 2 |
| Stricture | 5 | | 3 | 2 |
| SBO | | | | 1 |
| Ileus | | | | 1 |
| Hemolytic anemia | | | | 1 |
| Other infection | 2 | 2 | | |
| COPD exacerbation | 1 | 1 | | |
| Retained JP drain | 1 | 1 | | |
| Kidney stone | 1 | | | 1 |

We were not able to demonstrate an association between experience and mortality despite mortality being higher early in our experience. Our study did not have the power to demonstrate small differences in mortality between the groups. Other published studies suggest that low mortality rates can be achieved early in the learning curve [2, 5, 8, 9, 13].

We were also not able to demonstrate a relationship between experience and conversion rates. We achieved low conversion rates early in our series. This reflects HJS's previous experience with advanced laparoscopic procedures and limited experience with open gastric bypass. As can be seen in Table 5, conversion rates are highly variable among surgeons, depending on individual experience with open gastric bypass and laparoscopy. Because of these widely variable conversion rates, conversion is probably not a good outcome measure for the learning curve.

Our data demonstrated a statistically significant association between experience and operative times. We could not demonstrate a plateau in operative times over our initial 225 cases. Our data show that the majority of the decrease in operative time that occurred over the course of the study occurred during the initial 75 procedures. Beyond the initial group of 75 patients, operative times decrease at a much slower rate. Higa et al. [2] report operative times approaching 60 min after 400 cases and Wittgrove et al. [13] report average times of 90 min for patients 300–500 in their series. Our data suggest that, for surgeons experienced with laparoscopy, the majority of the decrease in operative times occurs during the first 75 LGB procedures.

Our data also demonstrate a statistically significant association between inexperience and perioperative complications. This is in agreement with other published studies (see Table 5), which suggest a decrease in major complications by at least 50% with experience. Many of our early major complications were clearly due to inexperience (see Table 3). We have shown that major complication rates (and total complication rates) plateau after 75 procedures. This suggests that the learning curve for LGB with respect to major complication rates for a surgeon trained in advanced laparoscopy is 75 cases.

In summary, the learning curve for LGB is long and subjects patients to increased major complication rates and prolonged operative times. Our study did not have the power to demonstrate an association between the learning curve and either elevated conversion rates or

Table 5. Outcomes for selected series in the literature^a

| Author | n | Mortality | Conversion | Major Cx | Leak | OR Time |
|-----------------|-----------|-----------|------------|----------|------|-----------|
| Teixeira [10] | 28 | | | | | 275 min |
| Westling [11] | 30 | | 23% | 20% | | |
| Scott [9] | 30 | 0 | 3% | | 3% | 234 min |
| Matthews [5] | 48 | 0 | 6% | | 2% | |
| de la Torre [1] | 50 | 0 | 2% | 2% | 2% | 199 min |
| Oliak | First 100 | 2 | 2% | 11% | 1% | 180 min |
| Oliak | Last 125 | 0 | 1% | 3% | 0 | 128 min |
| Schauer [8] | 275 | 1 | 1% | 3% | 1.5% | 260 min |
| Higa [2] | 400 | 0 | 3% | | | 60–90 min |
| Wittgrove [13] | Last 200 | 0 | | | 1% | 90 min |

^a Author arranged by the number of patients in their series and by their experience

mortality rates. Our data suggest that the learning curve for LGB is approximately 75 procedures when based on complication rates and operative times. For surgeons who do not have the prerequisite training in advanced laparoscopic techniques, the learning curve may be much longer.

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