



Direct visual insertion of primary trocar and avoidance of fascial closure with laparoscopic Roux-en-Y gastric bypass

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Abstract

Background: Laparoscopic Roux-en-Y gastric bypass (RYGBP) has been used increasingly more often in the past 10 years. The authors summarize their experience and safety/complications data based on 849 laparoscopic RYGBP procedures. They also evaluate the use of the Endopath trocar in terms of trocar-site hernias, bowel obstruction, and elimination of time-consuming fascial closure.

Methods: From July 2000 to December 2003, 849 laparoscopic RYGBP procedures were performed using a bladeless, 12-mm, visual entry trocar. The patients' average body mass index (BMI) was 53.2 kg/m². The trocar ports ($n = 3,744$) were not closed. Perioperative and postoperative assessments were performed.

Results: In this study, 74% of the patients were retained for follow-up evaluation (mean, 10 months). Among these patients, no intraoperative bowel or vascular injuries, no mortality, and two trocar-site hernias (0.2%) were found. At 1 year, the mean excess weight loss was 73.4%.

Conclusions: The Endopath trocar system shows a trend toward reducing trocar-site hernias, decreasing bowel obstruction, and eliminating the need for time-consuming fascial closure, although further studies are needed to confirm these findings.

Key words: Laparoscopic surgery — Morbid obesity — Optically guided trocar insertion — Roux-en-Y gastric bypass — Trocar — Trocar-site closure

selected complications, including wound infection and abdominal wall hernia [1, 8]. However, problems inherent in obtaining access to the peritoneal cavity are amplified with obese patients, increasing complication rates in this patient population [15]. Consequently, specialized instruments, procedures, and bariatric surgery centers are designed to accommodate the obese patient.

Among laparoscopic entry approaches, the Hasson or open method is difficult to perform for the morbidly obese patient because an incision large enough for the various tissue planes to be traversed is likely to be associated with inadequate pneumoperitoneum and difficult closure [15, 19]. Another entry option, blind insertion of a Veress needle (then establishment of pneumoperitoneum, followed by trocar insertion), is correlated with potentially life-threatening bowel and major vascular injury [10, 15, 19]. Randomized trials have failed to demonstrate that either the Hasson or the Veress needle technique is associated with fewer complications than the other [15]. In contrast, studies suggest that the optical-tip trocars may permit timely and safe visually guided entry into the peritoneal cavity, without insufflation, even for the obese patient [3, 10, 20]. Visual guidance also permits immediate visualization, and thus repair of bowel or vascular injury that may occur during entry or during the procedure [5, 10].

Whereas cutting trocars create wounds in the fascia and muscle and can result in vascular injury and trocar-site hernia [15], the blunt-tipped obturator of the optical trocar separates muscle and fascia as the device is inserted, which helps to prevent hernias and generally eliminates the need for suturing. The trocar is inserted with a steady, downward, twisting motion that helps to prevent cutting of tissue and bleeding. After release of the pneumoperitoneum and trocar removal, oblique muscle fibers have been observed to retract and approximate their presurgical position [7]. Because anterior and posterior fascial defects do not align,

Minimally invasive, laparoscopic abdominal surgery is associated with more rapid wound recovery and convalescence than open surgery, as well as lower rates of

wound suturing is rarely required [7, 9, 10, 18], except at midline/umbilical port sites, where closure may be necessary due to lack of musculature [7, 18]. A report involving seven patients undergoing laparoscopic Roux-en-Y gastric bypass (RYGBP) surgery without fascial closure indicates that no bleeding or hernia occurred at any of the five port sites needed for each patient. This suggests that the blunt-tipped trocar and lack of closure are just as effective for the obese patient [7].

The primary rationale for wound closure is the risk of hernia. Commonly reported trocar-site hernia rates for the general population for all types of laparoscopic procedures range from 0.2% to 3%, although reported rates may be lower than the actual incidence [18]. Trocar-site incisional hernias, although rare, remain a concern because they may become Richter hernias. A Richter hernia (named after August Richter, who in 1785 offered the first complete medical description of the condition) is formed when only a portion of the bowel circumference becomes entrapped [8]. Because of vague and varied symptoms, including nausea, vomiting, and abdominal pain, Richter hernias may be difficult to diagnose. However, if the bowel becomes gangrenous or perforates, the situation is severe, possibly leading to death.

Since the introduction of laparoscopic surgery, trocar port sites have been recognized as another location with the potential for Richter hernia development. Therefore, it has become a common procedure to close trocar wounds that are 10mm or larger [8, 18]. As indicated, noncutting, blunt-tip trocars reduce the risk of hernias forming at trocar sites [7]. During laparoscopic RYGBP surgery, Richter hernias may occur not only at port sites, but also in the area of the fatty preperitoneum [8]. Early visualization of these sites avoids undiagnosed complications. For the laparoscopic RYGBP procedures performed in this study, we used the 12-mm Endopath trocar (Ethicon Endo-Surgery, Inc., Cincinnati, OH, USA) because it is a bladeless trocar that permits tissue separation (instead of cutting) and has an optical tip. The latter feature eliminates blind entry and allows visualization and immediate repair of injuries, thus facilitating a decrease in complications.

Although bariatric surgery was developed approximately 40 years ago, it has gained recognition in the past 10 years with the escalation of laparoscopically performed procedures [1]. Laparoscopic RYGBP is a complex procedure, with complication rates that decrease as the surgeon's experience increases. One study reported a perioperative complication rate of 32% for a surgeon's first 75 RYGBP procedures, with the complication rate dropping to 15% for the surgeon's second and third groups of 75 patients [14]. The overall complication rates with laparoscopic RYGBP are reported to be approximately 15%, with mortality rates at 1% [4, 14, 17]. We report our experience with 849 laparoscopic RYGBP procedures using the Endopath. Our findings show a low risk of port-site hernias, significantly reduced bowel obstruction, and elimination of time-consuming fascial closure associated with this device.

Materials and methods

Patients

Between July 2000 and December 2003, 849 patients (171 men and 678 women) qualified for RYGBP. Of these patients, 844 (99.4%) were able to undergo the procedure laparoscopically, whereas the 5 remaining patients (0.6%) required conversion to open procedures. The surgeries were performed at The Bariatric Institute, Cleveland Clinic Florida. All the procedures were performed by two surgeons.

In accordance with the National Institutes of Health (NIH) guidelines, the inclusion criteria specified patients 18 years of age or older with a body mass index (BMI) of 35 kg/m² or more and two or more comorbid conditions or a BMI of 40 kg/m² or more and no obesity-related comorbidities [11]. The patients had an average BMI of 53.2, but the BMI range was quite wide (35–97). All the patients met the NIH guidelines for bariatric surgery. Deviating from traditional age limits for RYGBP surgery, patients older than 65 years were accepted for the surgical procedure. The patients ranged in age from 19 to 75 years (mean, 48 years).

Operative technique for Roux-en-Y Gastric bypass

Patients are placed in the supine position, in slight reverse Trendelenburg and right lateral decubitus. The customary antibiotics and subcutaneous heparin (5,000 U) are administered preoperatively. Abdominal cavity access is established with a 12-mm Endopath bladeless, direct visual access trocar using a supraumbilical approach. Once pneumoperitoneum CO₂ at 15mmHg is established, four additional 12-mm bladeless trocars and two 5-mm blunt-tip trocars are inserted, all under direct visualization (Fig. 1).

Dissection of the angle of His is made to visualize the left crus and the gastroesophageal junction (GEJ). On the lesser curvature 7.5 cm below the GEJ (typically between the second and third vascular pedicles), a window is dissected into the lesser sac. The rationale for dissection at the edge of the stomach, on the lesser curve, is to avoid injury to the nerves of Latarjet and major vessels. With two firings of the 45-mm linear cutter, 2.5-mm triple-row stapler (Ethicon Endo-Surgery, Inc.), followed by three or four firings of the 45-mm, 3.5-mm stapler reinforced with bovine pericardium (Peri-Strips Dry; Synovis Surgical Innovations, St. Paul, MN, USA), a 15- to 30-ml, 7.5 × 1.5-cm gastric pouch is created around a 32-Fr gastric lavage tube. The pouch is small and easily manipulated during surgery.

Once the ligament of Treitz is identified, the small bowel is divided 50cm distally to create the biliopancreatic and alimentary limbs. The mesentery is not divided unless tension is noted at the gastrojejunal anastomosis. The length of the alimentary limb is determined by the patient's BMI: a 100-cm limb for a BMI of 40 to 50 kg/m², a 150-cm limb for a BMI of 51 to 60 kg/m², or a 200-cm limb for a BMI of 60 kg/m² or more. With the alimentary Roux limb positioned in an antecolic antegastric location, the gastrojejunostomy is fashioned by using half of a single firing of a 45-mm linear cutter, 2.5-mm stapler between the posterior wall of the pouch and the jejunum. The anterior wall of the anastomosis is hand sewn with two crossing, running 2-0 monofilament (Vicryl) sutures, then tested for leaks with both air and methylene blue. The jejunoj jejunal anastomosis is created by using two sequential firings of the 45-mm linear cutter, 2.5-mm stapler. The enterotomy is closed with two to three firings of the 45-mm linear stapler. Routinely, one 19-Fr Blake drain then is placed proximal to the gastrojejunostomy, and another is situated in the midabdomen proximal to the jejunoj jejunal anastomosis. The trocar ports ($n = 3,744$) are not closed.

In our study, the patients were monitored overnight in an intermediate care unit and administered intravenous antibiotics for 48 h. Patients with a history of preoperative deep venous thrombosis, pulmonary embolism, or lymphedema had a Greenfield filter placed in the inferior vena cava. The 5,000 U of subcutaneous heparin that all patients received before surgery was continued every 8 h after surgery (along with sequential compression devices applied to both legs) to avoid deep venous thrombosis. On postoperative day 1, the patients underwent a routine sodium amidotrizoate and meglumine (Gastrog-rafin) upper gastrointestinal series for assessment of patency and testing for leaks. The patients without complications were transferred

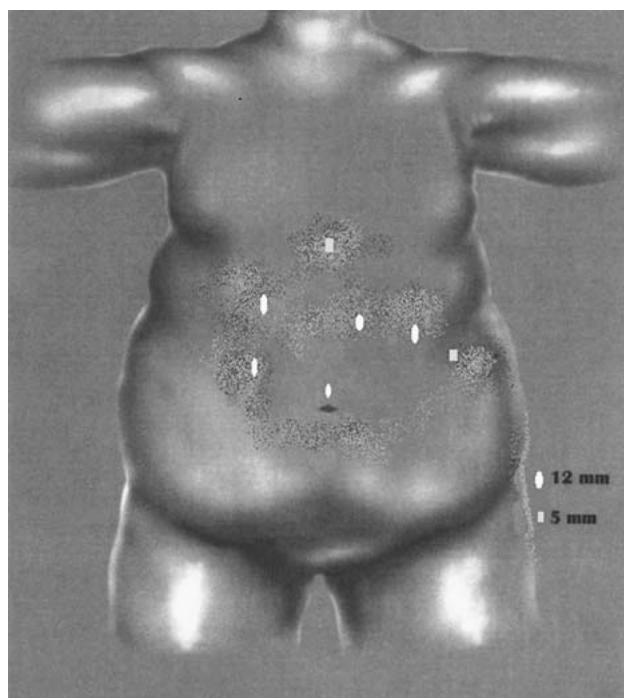


Fig. 1. Port-site locations for laparoscopic Roux-en-Y gastric bypass procedures.

to a standard room until discharged from the hospital after passage of flatus, typically on postoperative days 2 to 4. Drains were removed immediately before the hospital discharge.

The patients initiated a liquid diet 2 weeks before the procedure and continued it for 2 weeks postoperatively. After the RYGBP procedure, proton pump inhibitors were administered for 3 months. Multivitamins, vitamin B₁₂, vitamin B complex, calcium citrate, and iron were prescribed for 2 weeks. However, the patients were advised to continue their use indefinitely. Nutritional counseling was provided, and every 6 months, blood was drawn for a laboratory workup. Follow-up visits with one of the two surgeons occurred at 2 weeks, 6 weeks, 6 months, and 1 year, then annually thereafter.

Results

Of the 849 patients who underwent bariatric surgery, 844 (99.4%) had laparoscopic surgery. The rationale for converting 5 patients (0.6%) to open procedures was that the laparoscopic RYGBP surgery could not be performed safely because of the patients' high BMI and the lack of adequately sized instruments. Preoperative comorbidities included diabetes mellitus, hypertension, sleep apnea, and coronary artery disease.

No perioperative mortality occurred. Data on rates and types of complication were divided into two periods: early (during the procedure or within the initial postoperative hospitalization) and late (after discharge from the hospital). Complication rates were compiled for each of the early and late periods, then divided into major and minor events. There were 103 major complications (12.1% for both early and late major complications), including 21 bleeds (2.5%), 16 leaks (1.9%), 12 small bowel obstructions (1.4%), and 53 strictures (6.3%). With minor complications included in the overall number, 269 total events were found, giving an overall

Table 1. Early complications

Minor <i>n</i> (%)	Major <i>n</i> (%)
Atelectasis: 98 (11.6)	Gastrointestinal bleeding: 21 (2.5)
Wound infection: 31 (3.7)	Anastomotic leak: 16 (1.9)
Hypertensive crisis: 16 (1.9)	Pneumothorax: 1 (0.1)
Deep venous thrombosis: 7 (0.8)	
Total: 152 (18.0)	Total: 38 (4.5)

Table 2. Late complications

Minor <i>n</i> (%)	Major <i>n</i> (%)
Marginal ulcer: 12 (1.4)	Anastomotic stricture: 53 (6.3)
Trocar-site hernia: 2 (0.2)	Small bowel obstruction: 12 (1.4)
Total: 14 (1.7)	Total: 65 (7.7)

complication rate of 31.8%. Among the 269 patients with complications, 190 (22.5%) had early complications (Table 1), and 79 (9.4%) had late complications, with anastomotic stricture being the most common (Table 2).

Nonclosure of fascia, using the Endopath trocar, did not increase the trocar-site hernia rate. Our 0.2% rate is at the lowest end of the rates commonly reported in the literature. Furthermore, the Endopath trocar provided a safe and quick technique for placement of the primary trocar and subsequent trocars for the obese patient. At 1 year, the mean excess weight loss was 73.4%.

Discussion

Efficacy of laparoscopic RYGBP

Recently published reports on excess weight loss range from 58.7% to 78.3% at 1 year and from 60% to 84.4% at 2 years [2, 6, 12]. At 1 year, the mean excess weight loss in our series was 73.4%, putting our patients at the upper end of the weight loss range. The average excessive weight loss at 1 year for the supermorbidly obese patient (i.e., BMI ≥ 60 kg/m²) is reported to be slightly lower (e.g., 53%) at 1 year [2]. In our series, the average BMI was 53.2 kg/m² (range, 35–97 kg/m²). Therefore, the mean excess weight loss of 73.4% likely indicates that the procedure was effective not only for the morbidly obese, but also for the supermorbidly obese patient.

Comparison of complication rates

Complication rates frequently are reported in the literature as a comparison between open and laparoscopic RYGBP. Podnos et al. [16] evaluated 3,463 laparoscopic procedures reported in 10 trials and compared them with 2,771 open procedures reported in 8 trials. These authors found that selected morbidity (e.g., iatrogenic splenectomy, wound infection, incisional hernia, and mortality) is reduced with laparoscopic RYGBP, whereas other types of complications (e.g., frequency of early and late bowel obstruction, gastrointestinal tract hemorrhage, and stomal stenosis) are increased, with no

significant differences for anastomotic leak, pulmonary embolism, or pneumonia rates [16]. Another study concluded that the major difference in complication type between the laparoscopic and open approaches is that reduced tissue injury is a key advantage for the laparoscopic procedure, and that CO₂ pneumoperitoneum is its major disadvantage [1].

Although our results generally are comparable with those of the open RYGBP procedure for weight loss and major morbidity, as compared with the Podnos et al. [16] metaanalysis, our data indicate a significant reduction in bowel obstruction ($p = 0.01$), suggesting that a trocar providing direct visualization may be helpful in reducing these injuries. In addition, we had no mortality and only a 0.2% trocar herniation rate, which are lower than the compiled rates specified in the study of Podnos et al. [16]. However, because of the disparity in sample size, both findings indicate only a trend toward a statistically significant difference.

Studies also have focused on a reduction in complication and mortality rates correlated with surgeon experience. As discussed, one report indicated that complication rates were reduced by more than half between the surgeon's first 75 procedures (32% complication rate) and subsequent procedures (15% complication rate). Although typical for this procedure, this reduction represents a long learning curve [14]. The surgeons in our study had performed more than 75 procedures before trial initiation. As indicated, the overall complication rates reported in the literature for laparoscopic RYGBP are estimated at 15%, and mortality rates at 1% [4, 14, 17]. However, the events included in the category of overall complication rates and a breakdown of major and minor complications or early and late occurrences frequently are not provided. A need exists in the field to standardize complication rates for laparoscopic RYGBP.

Factors contributing to successful surgical outcome

Given the comorbidities associated with obesity, laparoscopic RYGBP is a safe approach for the surgical treatment of morbid obesity. However, laparoscopic RYGBP is a technically challenging procedure, associated with a concern for patient mortality. Recently reported mortality rates range from 0% [6] to as high as 5% among the supermorbidly obese patient population (i.e., BMI ≥ 60 kg/m²) [13]. Compilation of the findings for the 10 laparoscopic trials reported by Podnos et al. [16] produced a mortality rate of 0.23%, with pulmonary embolism (50%) and anastomotic leaks (37.5%) shown as the leading causes of death.

Notably, in our series, no mortality was noted despite the inclusion of supermorbidly obese patients. In our view, the reason for the favorable outcomes is a balance of several factors that together help make the laparoscopic approach safer than an open RYGBP. We used an experienced surgical team skilled at detecting and managing potentially lethal complications early in the postoperative period. The use of drains during surgery permitted early recognition of bleeding. This was



Fig. 2. Laparoscopic Roux-en-Y gastric bypass using the Endopath bladeless, direct visual trocar.

combined with discontinuation of anticoagulation therapy when bleeding occurred. Our protocol for monitoring each of our patients for 24 h in the intermediate care unit of the hospital meant that 99% of all complications occurred in the setting most equipped to handle the adverse event. In addition, the use of laparoscopic surgery, as compared with an open procedure, decreased pain and thus narcotic administration, which improved postoperative results. Furthermore, it is our contention that features of the laparoscopic trocar device also favorably affected the morbidity and mortality outcomes.

Bladeless optical trocar

As described, abdominal cavity access was established with a 12-mm Endopath trocar (Fig. 2). In addition, four 12-mm bladeless trocars and two 5-mm blunt-tip trocars were inserted under direct visualization, the latter after pneumoperitoneum was established. The process of accessing the abdominal cavity is a critical step in the laparoscopic RYGBP procedure. The majority of complications occur during this step, either from blind access or from excessive downward pressure, typically resulting in bowel and vascular injuries. A visual access trocar shares the benefit of the open Hasson technique (direct visualization of the abdomen as it is transected), but avoids the danger of loss of pneumoperitoneum [5, 10, 19]. Furthermore, should an injury occur, it is at once evident and can be repaired immediately during the laparoscopic procedure itself.

Several studies have demonstrated that the optical-tip trocar allows safe and time-effective visually guided entry into the peritoneal cavity. In 2001, a series of 650 laparoscopic abdominal access procedures (the largest series published to date), performed for a variety of conditions, led to the conclusion that use of an optical access trocar provides safe and fast abdominal access [19]. The authors reported that only two complications were related to use of the optical trocar, both of which were noticed and repaired immediately. However, very few articles concern the use of an optical access trocar

with the obese patient. Published reports include only a small number of morbidly obese patients and involve surgeries other than bariatric procedures [3, 10, 20]. To our knowledge, this is the first series to investigate the use of the optical access technique with the morbidly obese patient. It is our assessment that the optical access technique allows safe and rapid placement of the primary and subsequent trocars with the morbidly obese patient. It has become our standard device for patients undergoing the laparoscopic RYGBP procedure.

In addition, the blunt-tipped obturator of the optical trocar separates muscle and tissue layers as the device is inserted, avoiding tears and cuts that occur with a sharp, cutting trocar. This feature obviates the need for time-consuming fascial closure and prevents herniation. The surgeon can observe the wound shrinking as the trocar is removed. The misalignment of the abdominal wall musculature and the fascia help to reduce the risk of a Richter hernia occurring at trocar port sites [7]. It will be recalled that midline/umbilical port sites should be closed due to the lack of musculature in this region. Although three other studies have reported that no herniation occurred during procedures that used the nonclosure technique and were performed with a non-blade trocar, only seven bariatric surgeries appear among a survey of all the subjects in these three studies [7, 9, 18]. Again, to our knowledge, ours is the first series to report on nonclosure and hernia rates associated with using a bladeless trocar in the treatment of the morbidly obese patient undergoing laparoscopic RYGBP. The hernia rate of 0.2% in our series is well under the reported rate of 1% to 3% for trocar-site hernias, and no Richter hernias occurred. However, further studies with the morbidly obese patient population are warranted.

In conclusion, the bladeless, optical-tip trocar is now part of our standard procedure for patients undergoing the laparoscopic RYGBP. We have found that visual entry prevents injury and permits wound repair in a timely manner. Visual entry may have played a key role in contributing to our mortality rate of 0%. The noncutting trocar facilitates wound healing and, as in our series, reduces the rate of trocar-site hernias, as compared with reported rates. Nonetheless, complications of laparoscopic RYGBP can be serious, if not life threatening, and vigilance regarding potential complications is a necessity.

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