



Clinical Efficacy of Jejunojejunostomy Leak Test Using Methylene Blue During Laparoscopic Roux-en-Y Gastric Bypass on Post-Operative Leak Rate

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Abstract

Background: Obesity is becoming a worldwide health problem. Recently, bariatric surgeries are developing to combat with this problem. However, these surgical methods themselves have risks.

Objectives: The present study investigated the preventive effect of routine leak test of both gastrojejunal and jejunojejunal anastomoses immediately after laparoscopic Roux-en-Y gastric bypass (LRYGB) surgery against post-operative leak by inexperienced surgeons.

Methods: In a prospective interventional study, this research enrolled 52 morbid obese patients with LRYGB from September 2014 to October 2016. After anastomoses, methylene blue and air leak tests were performed and the section line and both anastomosis sites for patency and inspected for air and dye leaks were examined.

Results: Mean body mass index of patients was $48.84 \pm 6.8 \text{ kg/m}^2$. Twelve patients had positive leak test and the anastomoses were reinforced by additional sutures. All patients were discharged with no leak and no patient had leak during the routine follow-up period.

Conclusions: Intraoperative leak test of both gastrojejunal and jejunojejunal anastomoses is a valuable test in the assessment of leak during LRYGB surgery, especially in unskilled surgeons.

Keywords: Obesity, Gastric Bypass, Leak Rate, Gastrojejunal Anastomosis, Jejunojejunal Anastomosis, Learning Curve

1. Background

Obesity is an increasingly prevalent disease worldwide and has become a pandemic problem (1). Bariatric surgery has the greatest efficacy among morbid obesity treatments (2). The laparoscopic Roux-en-Y gastric bypass (LRYGB) is used worldwide and known as the gold standard of bariatric surgery at certain centers (3). The mortality of this operation is variable with a reported incidence as less as 5% in one study to 0.13% to 0.18% in other studies (4). Post-operative leaks after LRYGB, increase the time of hospital and intensive care unit (ICU) stay. Also, these leaks cause mortality and morbidities (5, 6). The cause of leaks is multifactorial and depends on patient factors, surgical technique, and device malfunction (7). Source of Gastrointestinal (GI) leaks may be from the gastrojejunostomy (GJ), sta-

ple lines of gastric remnant and gastric pouch, and jejunojejunostomy (JJ). Gastrojejunal anastomosis leak is more prevalent than other sites, while JJ leak can cause greater mortality (8-10).

There are several interventions that can decrease leak rates after LRYGB, including over-sewing the staple line and use of certain materials, such as fibrin glue or other tissue sealants to reinforce the staple line (8-11). For detecting leaks, intra-operative assessment of anastomosis can be done using dye, air, or other gas by endoscopy or orogastric tube to distend the site. Thus, it can be repaired during the procedure (11-13). The aim of this study was to examine the preventive effect of routine intraoperative gastrojejunal and jejunojejunal leak tests on postoperative leak rates after LRYGB.

2. Methods

2.1. Subjects

All procedures were in accordance with the ethical standards of the Local Ethical Committee and with the 1964 Helsinki declaration. All individual participants read and signed the informed consent. This prospective interventional study was performed at the Mother and Child Hospital affiliated with Shiraz University of Medical Sciences, Shiraz, Iran, during a 24-month period, from September 2014 to October 2016. The inclusion criteria were age of more than 18 years, body mass index (BMI) of $> 35 \text{ kg/m}^2$ with associated comorbidities or BMI of $\geq 40 \text{ kg/m}^2$, and being unable to lose or maintain weight loss during diet, exercise or medical measures. Patients with severe medical disease, making anesthesia and surgery prohibitively risky, psychiatric instability, drug and alcohol use or other addictions, smoking, active problem of bulimia or other eating disorder, immobility, unsupportive home environment, and mentally incompetent to the procedure were not scheduled for LRYGB.

2.2. Preoperative Measures

Before surgery, all patients were evaluated by a team of surgeons, anesthesiologist, psychiatrists, nutritionist, and specialist in sport medicine. All operations were performed by fellowship-training bariatric surgeons and the same surgical team. All patients received varice stocking, intravenous ceftriaxone and metronidazole, and subcutaneous heparin prior to induction of general anesthesia. Bladder catheterization was used and the stomach was decompressed with orogastric tube-Fouchet 36 Fr.

2.3. Surgical Technique

The operation was performed by the double loop technique. After insertion of five trocars in the upper abdomen, entrance to the abdomen was achieved. After dissection of the His angle with perigastric dissection, 5 cm below the gastroesophageal junction (GEJ), the researchers created a gastric pouch by two to three 60-mm linear stapler. Then, the middle portion of the greater omentum was divided in the longitudinal direction. Next, about 30 to 50 cm from the Treitz ligament, the proximal loop of jejunum was brought to the upper abdomen in an antecolic/antegastric fashion without tension. Furthermore, GJ was stapled to the posterior pouch with 45-mm blue cartridge. The aperture was sutured. After obstruction of proximal and distal loop, GJ leak test was done by methylene blue with air. If leakage was seen, it was repaired and retested. From the GJ, a segment of the jejunum (about 120 to 150 cm) was measured to anastomose to the biliopancreatic loop on

the afferent portion of the GJ. The JJ was performed with a 60-mm white cartridge stapler. The opening was sutured. The mesenteric and Peterson defects were closed with a 2-0 Prolen. The JJ leak test was done using 250 mL of 4% methylene blue in normal saline, which was introduced through an orogastric tube. Then, forced injection of air was done by obstruction of alimentary and biliopancreatic limbs, distal and proximal loop of JJ anastomosis (Figure 1).

If the test was positive, the anastomosis was over-sewn with a PDS 2-0 and then retested. Then, with 60-mm of white cartridge stapler, the jejunum was divided between the GJ and JJ. One Jackson Pratt (JP) drain was inserted in the left upper abdomen. The skins were sutured. The orogastric tube was removed at the end of surgery.

2.4. Postoperative Management

After extubating and stabilizing in the recovery room, patients were transferred to the surgical ward. After 24 hours, the patients underwent upper GI series for evaluation of gastric pouch, stenosis or leak. If it was normal, the patient started sips of water. The next day, if there was no problem, the intake was advanced to dilute juice. The patients, which tolerated the liquid diet, had ambulation, were afebrile and with absence of post-op ileous and uncontrolled pain, were discharged with ranitidine and cephalexin. Outpatient assessment was done seven days after discharge, on a monthly basis for the first three months, then, quarterly during the first year, and half-yearly thereafter. Any symptoms suggesting leakage, such as post-operative pain, fever, tachycardia, abdominal pain, hiccups, nausea, and vomiting were investigated by upper gastrointestinal (UGI) series, abdominal CT-scan or laparoscopy.

2.5. Statistical Analysis

The IBM SPSS statistical software version 23 was used and results were considered significant at $P\text{-value} < 0.05$. Quantitative and qualitative variables were extracted and the mean, maximum, minimum, and standard deviation was calculated. Chi-square for comparison between categorical variables and the student t test for comparison between continuous data were used.

3. Results

During the study, the researchers performed 52 LRYGB cases. Pre, intra and post-operative patients' characteristics are shown in Table 1.

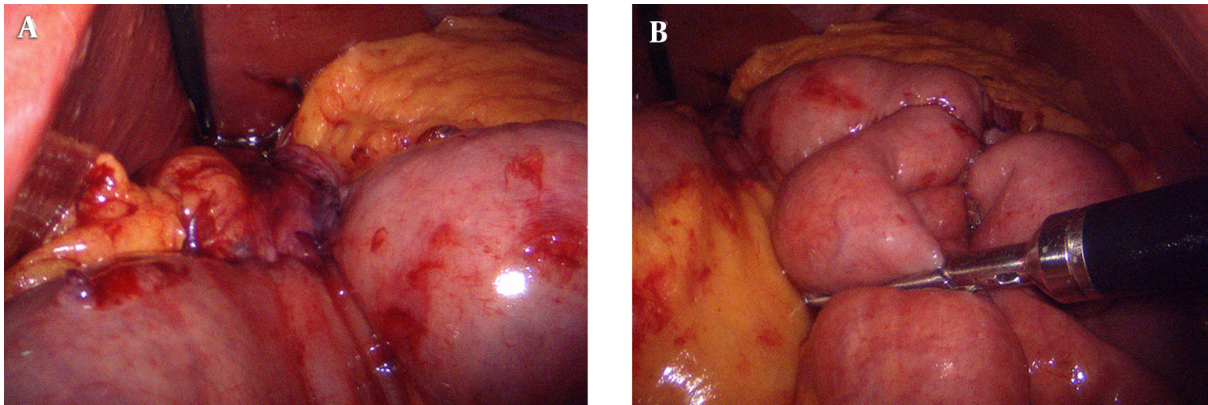


Figure 1. Performing of leak tests. A, gastrojejunal anastomosis; B, jejunojejunal anastomosis

Table 1. Pre, Intra and Post-Operative Patient Characteristics During the Study Period

Baseline Characteristics	Value
Male: female	16:36
Age (y)	
Mean \pm SD	36.27 \pm 9.56
Range	18 - 57
BMI (kg/m²)	
Mean \pm SD	48.84 \pm 6.80
Range	38.20 - 65.00
Comorbidity disease, No. (%)	17 (32.69)
Central obesity, No. (%)	16 (30.77)
Operation time (min)	
Mean \pm SD	271.63 \pm 63.46
Range	150 - 390
Time of GJ leak test (min)	
Mean \pm SD	2.50 \pm 0.50
Range	2 - 3
Time of JJ leak test (min)	
Mean \pm SD	4.82 \pm 0.80
Range	3 - 6
Admission time (d)	
Mean \pm SD	3.17 \pm 0.61
Range	3 - 7

All gastric bypass was performed successfully in all 52 patients with no conversions to open surgery. The researchers were able to perform the leak test for all patients. The clinical leak rate, GJ stenosis, venous thromboembolism, and bleeding requiring blood transfusion

were zero. Intraoperative leak test showed a positive result in 12 LRYGB cases (23.1%). In two of the cases, both gastrojejunal anastomosis and jejunojejunal anastomosis leak tests were positive. In two patients, leak was not through the sutures. One leak was in the biliopancreatic limb before JJ anastomosis due to small tearing by retraction that was detected by injection of methylene blue with air. Another leak was found in the posterior aspect of the bowel, near JJ anastomosis during passing the cartridges for JJ anastomosis by tips of linear stapler, which resolved after reinforcement by a multiple simple stitch. All cured positive leak patients had no clinical leak after surgery. Finally, 16 patients (30.76%) had central obesity, seven of whom had a positive leak test (Table 2).

There were no intraoperative complications and no significant intra or postoperative blood loss. There was no mortality in this series. One patient admission was longer than others due to wound infection.

There was one case of acute bowel obstruction due to internal hernia after less than two years of operation. The patient referred to the center after five days of symptoms. In explorative laparotomy, gangrenous bowel was resected and then the patient was transferred to the intensive care unit (ICU). After stabilization, gastric bypass was revised with about a 70-cm viable small bowel and maintenance of terminal ileum. Fortunately, the patient did not develop short bowel syndrome. Wound infection was seen in one patient, who was treated with intravenous antibiotics and irrigation of wound. Significant differences were seen between leak of GJ and JJ ($P = 0.05$). There were no significant differences between the GJ leak and BMI and time of operation. No significant differences were seen between leak of JJ and BMI and time of operation. In analysis of association of JJ and GJ leaks with age, gender, metabolic disease, and central obesity, a significant association was only found be-

Table 2. Patient Characteristics of JJ Leak Test During LRYGB Procedure

Case	Age	Sex	BMI (Kg/M ²)	Comorbidity	Central Obesity
1	23	M	57	-	+
2	36	F	38.3	+	-
3	28	M	51.5	-	+
4	53	F	45.3	-	-
5	31	F	43.33	-	-
6	47	F	50.4	+	+
7	38	F	61.7	+	+
8	28	M	58	-	+
9	45	F	65	+	+
10	49	F	48	-	-
11	54	F	56.6	+	-
12	45	F	45.2	-	+

tween JJ leak and central obesity ($P = 0.018$).

4. Discussion

The most serious complication of LRYGB was anastomotic leak, with incidence of 1% to 8.3% (14). Although leak rate was decreased over time (15), leak remained an important cause of morbidity, mortality, and a potential complication after LRYGB. In obese patients, GI leak may have delayed clinical presentation or may be more subtle in management of leaks. The main principle is early diagnosis and treatment, which is an important issue for decreasing the occurrence of morbidity and mortality (16). Leak is a multifactorial condition. Technique-related factors, include excessive tension on the anastomosis, the presence of staple-line bleeding, and the presence of tissue ischemia. Furthermore, patient-related variables include poor nutrition, smoking history, liver cirrhosis, and renal failure (8). However, most GI leaks occur without a known technical error (16).

Several methods have been attempted to decrease leaks, which included choosing of open/laparoscopic operative technique, surgeon's experience, hand sewn/stapling technique of anastomosis, implementation of a well-constructed gastric pouch, staple line reinforcement by buttressing and over sewing, fibrin glue/ sealant application, meticulous dissection, hemodynamic stability, oxygenation, and intraoperative leak test (5, 6, 8, 11). However, no prospective randomized evidences are available to suggest any method as effective (8). Most bariatric surgeons used endoscopy and/or distention of anastomosis with blue dye and air by orogastric tube to detect leaks. After finding leaks, they can be repaired during the operation

and the leak test is repeated. However, these techniques cannot decrease the risk of post-operative leak (11, 13, 17).

Intra-operative endoscopy decreased post-operative leak and GJ stenosis in LRYGB. Endoscopy was operator-dependent and the operator must be familiar with the anatomy of LRYGB. Furthermore, all bariatric surgeons do not perform endoscopy after surgery (18). However, in the current study, there was no significant added operational cost for performing methylene blue with air leak test and no invasive than endoscopy and no operative dependent, too.

Importance of performing the JJ leak test can be attended due to low leak rate yet high mortality (5, 9, 10), difficult and delayed detection (9) and technical error. In the current study, JJ leak test was possible by not cutting biliopancreatic limb after GJ anastomosis and showed that routine diluted methylene blue with air leak test of both anastomosis led to detection of a persistent leak with safe and cheap procedure and can help lower the leak rate after LRYGB. The LRYGB surgery was one of the complex procedures that requires advanced skills, such as laparoscopic suturing, stapling, and dissection techniques. The learning curve was defined by complications and/or by duration of surgery. It has been reported that the learning curve of LRYGB was 50 to 100 procedures (19). In a study by Fernandez et al. (14), post-operative leak was 6.8 % in the first 102 cases. This dropped to 1.8 % in their next 164 patients. Sanchez-Santos et al. (20) found a complication rate of 18.1% without training in laparoscopic bariatric surgery versus 7.7% with training. In the study of Celio et al. (21), surgeons that performed fewer than 50 LRYGB per year were more likely to have 30-day readmissions and complications. In addition, performing LRYGB with inexperienced

operative assistants increased operative time and complications (22).

Therefore, greater skills in bariatric surgery of surgeons and assistants decrease post-operative complications and rates of hospital readmission and reoperation (23). In the current study, operations were done by fellowship-training bariatric surgeons that were not experts in LRYGB yet were under supervision of expert associate professor of surgery. In some cases, especially in patients with central obesity ($P = 0.018$), exposure and manipulation of tissues were very difficult and required more skilled surgeons and assistants. In two cases, leakage occurred in both GJ and JJ anastomosis and the cause of this problem was the low experience of the surgeon. Therefore, the researchers suggest that performing two anastomosis leak tests, especially in inexperienced surgeon, can help lower post-operative leaks.

4.1. Limitations

Despite of the current findings, this study had some limitations. First, the sample size of this study was relatively low. Second, the tissues were stained with methylene blue once the leak was detected. The current study used diluted methylene blue and air for leak test to lower this problem and increased sensitivity of the leak test. Furthermore, there was risk of aspiration of methylene blue. Future studies are needed with larger sample sizes and randomized trials for supporting the efficacy of intraoperative leak test of both anastomosis in postoperative leak rate. Other studies were performed for comparing sensitivity of endoscopy with methylene blue in intraoperative detection of leaks.

4.2. Conclusion

The result of this study showed that routine intraoperative diluted methylene blue with air leak test of both anastomosis led to detection of a persistent leak with a safe and cheap procedure and can help lower the leak rate after LRYGB, during the learning curve period.

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Footnotes

Conflict of Interests: All authors declare that they had no conflict of interest.

Ethical Approval: All procedures were in accordance with the ethical standards of the Local Ethical Committee and with the 1964 Helsinki declaration. All participants read and signed an informed consent.

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