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SURGICAL ENDOSCOPY and Other Interventional Techniques

Clinical predictors of leak after laparoscopic Roux-en-Y gastric bypass for morbid obesity

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Abstract

Background: Gastrointestinal leak is a complication of laparoscopic Roux-en-Y gastric bypass (LRYGB). Contrast studies may underdiagnose leaks, forcing surgeons to rely solely on clinical data. This study was designed to evaluate various clinical signs for detecting leakage after LRYGB.

Methods: We retrospectively reviewed 210 consecutive patients who underwent LRYGB between April 1999 and September 2001. There were nine documented leaks (4.3%). Clinical signs between patients with leaks (group 1) and those without leaks (group 2) were compared using univariate and multivariate logistic regression analysis.

Results: Evidence of respiratory distress and a heart rate exceeding 120 beats per min were the two most sensitive indicators of gastrointestinal leak. Routine upper gastrointestinal contrast imaging detected only two of nine leaks (22%).

Conclusion: Leak after LRYGB may be difficult to detect. Evidence of respiratory distress and tachycardia exceeding 120 beats per min may be the most useful clinical indicators of leak after laparoscopic Roux-en-Y gastric bypass.

Key words: Gastrointestinal leak — Contrast study — Laparoscopic Roux-en-Y gastric bypass — Clinical predictors — Morbid obesity

Obesity, a serious public health problem in the United States, is increasing in prevalence among both adults and children [8]. Diabetes mellitus, dyslipidemia, hypertension, and coronary heart disease contribute to significant morbidity in this population [1]. Medical treatment fails to achieve sustained weight loss in the majority of patients [6]. As a result, a variety of operations designed to achieve large-scale weight loss and eradicate obesity-related comorbidities have been devised and used since the 1960s.

The Roux-en-Y gastric bypass (RYGB) is currently the most commonly performed "weight loss" operation in the United States accounting for 70% of all bariatric operations [10]. It is currently considered the gold standard and has surpassed vertical banded gastroplasty and malabsorptive operations such as biliopancreatic diversion in frequency [10]. Although effective at achieving sustained weight reduction, RYGB is not without morbidity. Complications including hemorrhage, bowel obstruction, gastrointestinal leak, wound infections, and ventral hernias have been reported [13].

As with other procedures, RYGB currently is performed laparoscopically to capitalize on the presumed advantages of the minimally invasive approach. However, the operation is complex and requires the surgeon to be adept at both advanced laparoscopic and bariatric surgical techniques. Despite the potential benefits of the minimally invasive approach, complications occur [10]. One of the most serious is a gastrointestinal leak.

Many centers use routine upper gastrointestinal (UGI) contrast studies to detect leakage in the early postoperative period. However, contrast studies may not identify all leaks, forcing surgeons to rely largely on clinical data. The purpose of this study was to evaluate the usefulness of clinical signs in determining the presence of leak after laparoscopic Roux-en-Y gastric bypass (LRYGB).

Methods

We analyzed the records of 210 consecutive patients (data were collected prospectively for 60 of these patients) who underwent LRYGB at the University of Texas Southwestern Medical Center between April 1999 and September 2001. All the patients met the National Institute of Health (NIH) and the Society of American Gastrointestinal and

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Endoscopic Surgeons (SAGES) 2000 guidelines for the surgical treatment of obesity. These patients represent the first 210 LRYGB operations performed in our series.

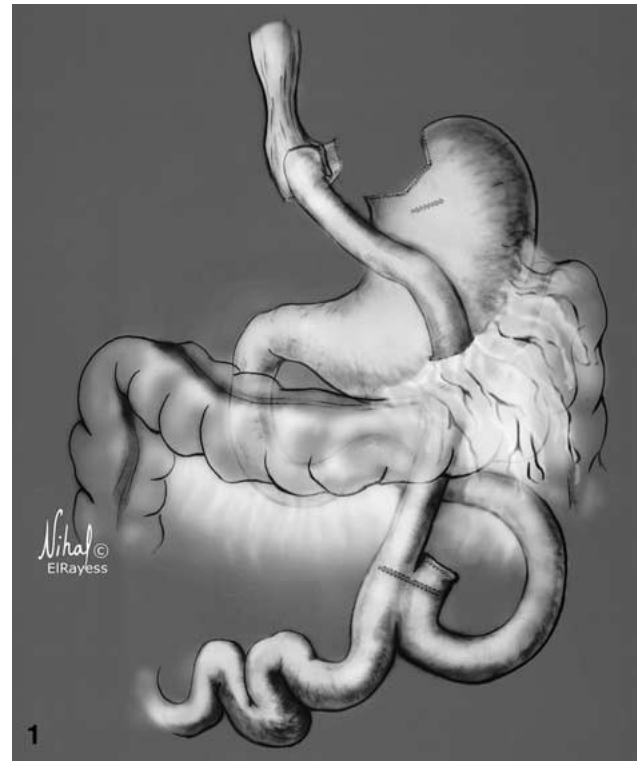
Leaks were defined as evidence of extravasation of contrast material on an upper gastrointestinal contrast study or abdominal computed tomography (CT) scan, or by identification of enteric spill from a gastrointestinal anastomosis, staple line, or enteric lumen at the time of laparotomy. Early leaks were defined as those occurring before the patient was discharged from the hospital. Leaks were classified as late when they occurred after discharge. Contained leaks (i.e., controlled fistulas after drainage) were defined as those in which a small amount of contrast material or enteric contents was identified external to its normal confines but in a localized area. Patients with controlled fistulas were hemodynamically stable and treated conservatively with existing drains, nothing by mouth status, antibiotics, and proper fluid management. Free leaks were defined as those in which contrast material or enteric contents were detected leaking freely into the abdominal cavity in the presence of hemodynamic instability. Free leaks were managed with prompt open repair and drainage.

Patients were considered to be free of leaks if they had negative postoperative day 1 contrast results remained hemodynamically normal with no unexpected problems at the time of discharge, and appeared well at their first postoperative follow-up visit. No further evaluation was done to confirm the absence of leaking.

The same surgical team performed all the operations. Postoperative care of uncomplicated cases was standardized and coordinated by a clinical pathway. Each operation and its subsequent routine postoperative care were executed in a similar fashion, according to the following description.

Operative procedure

With the patient under general anesthesia, the surgeon uses six laparoscopic ports to transect the jejunum 45 cm distally to the ligament of Treitz. The distal end of the jejunum is marked with a Penrose drain and advanced into the upper abdomen through a window created in the transverse mesocolon. A 75-cm Roux limb is measured, and distal intestinal continuity is reestablished with a side-to-side jejunojejunostomy. A 20-cc isolated gastric pouch is created along the lesser curvature of the proximal stomach using a series of linear gastrointestinal anastomosis (GIA) staplers. A gastrojejunostomy is fashioned between the pouch and the retrocolic antegastric Roux limb, using a 21-mm circular end-to-end anastomosis (EEA) stapler and three reinforcing Lembert sutures. The distal gastric remnant is left in its normal anatomic position (Fig. 1). The jejunal mesenteric, transverse mesocolic, and the Peterson hernia defects are repaired with a nonabsorbable suture. Before the abdomen is closed, the anesthesiologist rapidly infuses a 60 ml bolus of saline through the nasogastric tube into the gastric pouch (with the proximal Roux limb occluded to distend the pouch) to exclude leak. If no leak is visualized, the nasogastric tube is left in the pouch and screened until output from the tube is minimal (rarely more than 12 h). If the result of the saline test is equivocal, 60 ml of dilute methylene blue is bolused through the nasogastric tube as a secondary measure. We no longer place closed suction drains at the operative site as a matter of routine. Port sites are closed with #1 vicryl, using a fascial closure device followed by infusion of local anesthesia. To maintain an adequate fluid balance, the anesthesiologist infuses 4 to 5 liters of crystalloid during each case. Intravenous resuscitation is continued at a rate of 200 ml for the first 24 h postoperatively.



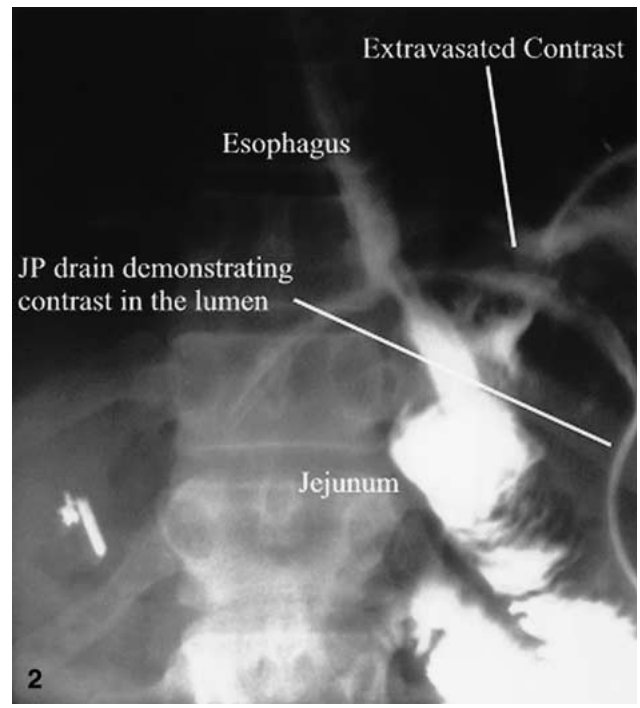


Fig. 1. Completed Roux-en-Y gastric bypass.

Fig. 2. Postoperative contrast study showing leak at gastrojejunostomy.

Postoperative UGI contrast imaging

An upper gastrointestinal contrast study is performed on postoperative day 1 for all patients undergoing laparoscopic Roux-en-Y gastric bypass. A standard protocol is used for the postoperative swallow study, with emphasis placed on early detection of clinically significant stricture, obstruction, or gastrointestinal leak (Fig. 2). An initial scout film of the abdomen is taken to include, at a minimum, the left upper quadrant and the surgical site. The patient then is placed in a semiupright position on the fluoroscopy table. Approximately 60 ml of Gastrografin (diatrizoate meglumine and diatrizoate sodium; Bracco Diagnostics, Princeton, NJ, USA) is administered orally. Fluoroscopy is performed as the contrast is administered, and fluoroscopic spot films are obtained. Overhead films then are made in the anteroposterior (AP), and right and left posterior oblique (RPO and LPO) positions to evaluate passage of contrast through the esophagus and gastric pouch. Then 15 min later, an additional AP film is taken to assess emptying of the pouch, passage of contrast through the jejunum, reflux

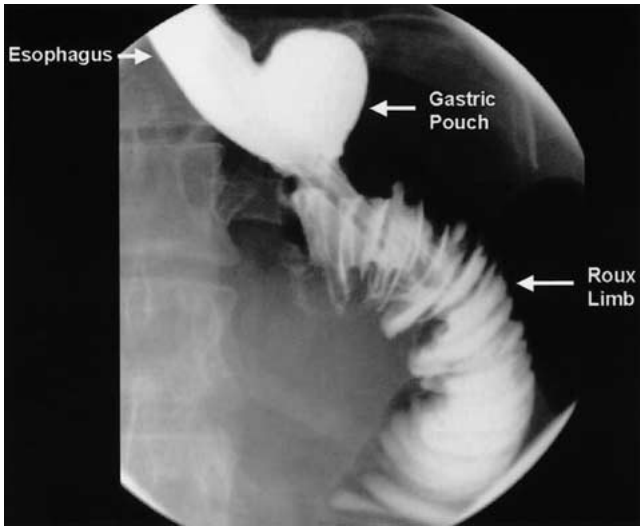


Fig. 3. Normal postoperative upper gastrointestinal contrast study.

into the duodenum, and possible delayed leak. The radiologist and the operative surgeon of record review all films. If contrast passes through the bowel and there is no evidence of leak or obstruction (Fig. 3), the patient's diet is advanced.

Data collection

Basic demographic and clinical data were collected from the medical records of all 210 patients. Recorded parameters included heart rate, systolic blood pressure, urine output, fluid requirements, administration of blood products, temperature, and signs of respiratory distress.

Heart rate (beats per minute [bpm]) was classified according to the following categories based on the highest recorded rate: less than 100 bpm (normal); 100 to 109 bpm (mild tachycardia); 110 to 119 bpm (moderate tachycardia), or more than 120 bpm (severe tachycardia). Systolic blood pressure lower than 100 mmHg was considered systolic hypotension. Temperature readings were divided into the following groups: 38.0°C or lower (normal), 38.1° to 38.4°C (low-grade fever), 38.5° to 38.9°C (moderate fever), and 39.0°C or higher (high-grade fever). Postoperative fluid boluses were noted, as was the presence of marginal urine output (< 1000 ml / 24 h). Patients with at least one of the following conditions were considered to have respiratory distress: respiratory rate of 24 bpm or faster, arterial hemoglobin (Hb) oxygen saturation of 92% or less on room air, or increasing oxygen requirements after discharge from the recovery room. The rate of oxygen delivery (either by nasal cannula or face mask, if any) at the time of discharge from the recovery room was considered the baseline postoperative state. Any increase in the rate of oxygen supplementation above that amount (as ordered by the physician because of tachypnea, decreasing hemoglobin saturation, or subjective shortness of breath) was considered increasing oxygen requirements. Abnormal clinical signs were compared with each patient's preoperative vital signs to determine whether the abnormality was present at baseline. In addition, the result of each patient's upper gastrointestinal contrast study was reviewed.

Statistical analysis

Clinical data from the cohort of 201 patients without leaks were compared with data from nine patients with documented gastrointestinal leaks, A between-group comparison of clinical indicators was performed using Student's *t*-test for continuous variables and Chi-square for discreet variables (SAS Institute, Cary, North Carolina, USA). Those indicators found by univariate analysis to be different between groups at the 95% confidence level then were entered into a step wise, multivariate, logistic regression model. Statistical significance was assumed for p values less than 0.05.

Results

Of the 210 patients in the study, 9(4.3%) had documented gastrointestinal leaks. As Table 1 shows there were no significant differences in the mean age, body mass index (BMI), or distribution of American Society of Anesthesiologists (ASA) scores between the groups. There were no notable differences in the number or type of prior abdominal/pelvic operations between the groups.

Patients who developed leaks had significantly longer stays in the hospital and in the intensive care unit than patients without leaks (Table 1). Leak complications included septic shock, multiple-system organ dysfunction, prolonged ventilator dependence, pneumonia, intraabdominal abscess, central venous catheter–related sepsis, and persistent controlled fistulas.

All of the patients in group 1 (leaks) and more than half of those in group 2 (no leaks) were tachycardic (heart rate > 100 bpm) postoperatively (Table 2). Almost 90% of the group 1 patients, however, demonstrated severe tachycardia (> 120 bpm.) Only 16% of the group 2 patients experienced this sign. Of the patients in group 2, 42% had low-grade postoperative temperatures (38.0–38.4°C). Fewer than 10% experienced a temperature above 39.0°C. In contrast, fewer than one-fourth of the patients in group 1 had any temperature elevation at all. When temperature was present, it was low-grade in all cases (Table 2).

Twice the number of group 1 patients experienced systolic hypotension than those in group 2. However, this was an infrequent finding in both groups. Respiratory distress was six times more common in group 1. Similarly, more patients with leaks experienced marginal urine output than patients without leaks, by a factor of almost 5 to 1 (Table 2). Severe abdominal pain or peritonitis was noted on examination in three of nine patients (33%). Abnormal clinical signs and symptoms in group 2 patients (no leak) were attributed to a variety of normal postoperative complications, including the following: atelectasis, pneumonia, urinary tract infections, pulmonary embolism, bleeding, pain, and volume depletion.

Postoperative day 1 contrast studies showed two of nine (22%) clinically significant gastrointestinal leaks. Seven of nine (78%) were not identified. At reexploration, leaks were identified in the following areas: anterior gastrojejunostomy anastomosis (3/9), distal gastric remnant (2/9), jejunojejunostomy (2/9), efferent Roux limb (1/9), and the gastric pouch (1/9). Two patients went on to develop controlled fistulas (both subsequently closed) after repair of their initial leaks. A single patient with a distal gastric remnant leak died of refractory septic shock on postoperative day 5 (mortality rate, 0.5%).

As depicted in Table 3, stepwise multivariate logistic regression modeling identified severe tachycardia (heart rate > 120 bpm) and respiratory distress as independent clinical indicators of leak. Epidemiologic statistics for these and other clinical signs are displayed in Table 4.

Table 1. Demographics

	Group 1: leak ($n = 9$)	Group 2: no leak ($n = 201$)	p
Gender (F/M)[a]	9/0 (100%)	183/18 (91%)	NS
Age (years)	42.3 ± 7.7	39.6 ± 8.8	NS
BMI (kg/m^2)	48.5 ± 5.8	48.2 ± 6.1	NS
Operative time (min)	188 ± 74	162 ± 61	NS
Hospital stay (days)	24.8 ± 17.5	3.0 ± 1.3	<0.05
ICU stay (days)	12.1 ± 13.3	0 ± 0	<0.05

Note: Data expressed as mean ± SD unless indicated
[a] Percentage female gender in parentheses
BMI, body mass index; ICU, intensive care unit; NS, not significant

Table 2. Univariate analysis of clinical indicators in leak and nonleak groups

Indicator	Group 1: leak ($n = 9$) n (%)	Group 2: no leak ($n = 201$) n (%)	p
Tachycardia[a]			
Mild	0/9 (0)	61/201 (30.3)	<0.05
Moderate	1/9 (11)	49/201 (24.4)	NS
Severe	8/9 (89)	32/201 (15.9)	<0.01
Temperature (°C)			
38.0–38.4	2/9 (22)	57/201 (28.4)	NS
38.5–38.9	0/9 (0)	23/201 (11.4)	NS
≥39.0	0/9 (0)	6/201 (3)	NS
SBP ≤ 100 mmHg	2/9 (22)	23/201 (11.4)	NS
Respiratory distress[b]	6/9 (67)	21/201 (10.5)	<0.01
Marginal urine output[c]	3/9 (33)	14/201 (7%)	<0.01
Positive UGI contrast study[d]	2/9 (22)	0/201 (0)	<0.05

[a] Tachycardia was defined as mild (heart rate 100–109 bpm), moderate (heart rate 110–119 bpm), or severe (heart rate ≥ 120 bpm)
[b] Respiratory distress was defined as the development of increasing oxygen requirement after discharge from the postanesthetic care unit (PACU), SaO_2 <92% on room air, or respiratory rate ≥ 24
[c] Marginal urine output was defined as <1000 ml of urine output in a 24-h period
[d] A positive UGI contrast study was defined as an initial routine postoperative study unequivocally identifying an anastomotic leak. A third study identified a proximal obstruction in a patient who later developed a leak from the gastrojejunostomy
SBP, systolic blood pressure; NS, not significant

Table 3. Results of multivariate logistic regression model

Clinical sign	Group 1: leak ($n = 9$) n (%)	Group 2: no leak ($n = 201$) n (%)	Odds ratio	95% Confindence interval	p
Severe tachycardia[a]	8/9 (89)	32/201 (15.9)	23.2	2.57–208.5	<0.01
Respiratory distress[b]	6/9 (67)	21/201 (10.5)	6.0	1.2–29.4	<0.05

[a] Severe tachycardia was defined as a sustained heart rate greater than 120 beats/min
[b] Respiratory distress was defined as the development of an increasing oxygen requirement after discharge from the postanesthetic care unit (PACU) SaO_2 <92% on room air, or respiratory rate ≥ 24

Discussion

Our leak rate of 4.3% is consistent with that of other studies reported in the literature [6]. There were no leaks among the initial 35 patients. Four of the leaks in our study occurred during the first 70 operations (4/70, 5.7%). The remaining five leaks occurred in the subsequent 140 patients (5/140, 3.6%), suggesting that a learning curve exists [8, 11].

Routine upper gastrointestinal contrast studies (UGI) detected leaks in only two of nine (22%) patients with known leaks. These patients underwent prompt open repair and drainage. In a third patient, a significant proximal obstruction was suggested on the postoperative day 1 swallow study, but was attributed to postoperative edema. A planned repeated contrast evaluation on postoperative day 2 showed a leak at the gastrojejunostomy. This patient also underwent prompt open repair and drainage. In two other patients, worsening of the clinical signs including tachycardia, respiratory distress, declining urine output, and a base deficit despite vigorous fluid resuscitation and exclusion of other conditions in the differential diagnosis prompted the patients' return to the operating room for exploratory laparotomy to rule out intraabdominal catastrophe. In the final four leak patients, a computed tomography (CT) scan of the abdomen with intravenous and oral contrast was performed despite the negative

Table 4. Epidemiologic statistics of clinical indicators identified

Clinical/indicator	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Respiratory distress[a]	67	90	22	98
Marginal urine output[b]	33	93	18	97
SBP ≤ 100 mmHg	22	88	8	96
Tachycardia[c]				
Mild	0	70	0	94
Moderate	11	76	2	95
Severe	89	84	20	99
Positive UGI contrast study[d]	22	100	100	97
Temperature (°C)				
38.0–38.4	22	72	3	95
38.5–38.9	0	89	0	95
≥39.0	0	97	0	96

[a] Respiratory distress was defined as the development of an increasing oxygen requirement after discharge from the PACU, SaO_2 <92% on room air, or respiratory rate ≥ 24

[b] Marginal urine output was defined as <1000 ml of urine output in a 24-h period

[c] Tachycardia was defined as mild (heart rate, 100–109 bpm), moderate (heart rate, 110–119 bpm), or severe (heart rate ≥ 120 bpm)

[d] A positive UGI contrast study was defined as an initial routine postoperative study unequivocally identifying an anastomotic leak. A third study identified a proximal obstruction in a patient who later developed a leak from the gastrojejunostomy

PPV, positive pressure ventilation; NPV, negative pressure ventilation; SBP, systolic blood pressure; UGI, upper gastrointestinal

UGI results when the patients failed to respond to resuscitation efforts. The CT scans showed fluid collections or extravasation of contrast material, which prompted a return to the operating room. There were no nontherapeutic laparotomies. In all cases except one, the site of the leak was identified clearly at the time of reexploration. All reexplorations were done by open laparotomy, at which time the abdomen was irrigated, the leaks were repaired, a gastric feeding tube were placed, and closed suction drains were positioned. There were no false-positive upper gastrointestinal contrast studies.

Despite the apparent lack of sensitivity of routine postoperative radiologic contrast evaluation to detect all gastrointestinal leaks, we perform contrast studies routinely on postoperative day 1 for several reasons. First, leaks at the gastrojejunostomy, isolated gastric pouch, and proximal Roux limb are well visualized by radiologic contrasts and leaks can be detected in these areas. Second we believe the studies enable us to detect significant technical errors early. Third, patients who tolerate an oral liquid diet are typically discharged on postoperative day 2. Finally, the morbidity associated with a missed leak is significant, and therefore detecting even one otherwise unsuspected leak may justify its use.

Failure to identify leaks early has a measurable cost. The average length of hospital stay among patients in whom the initial contrast study was falsely negative was longer than among those in whom the leak was correctly identified on postoperative day 1 (27 days vs 8 days; $p < 0.05$). Additionally, there was a trend toward longer intensive care unit (ICU) stays (13 days vs 4 days; $p = 0.08\%$) when a leak was initially missed. This supports the notion that early detection of leaks is important.

The specific method we used for UGI examination was similar to that described in the literature [7, 9, 14]. The sensitivity of UGI described in these reports (primarily open RYGB) is better than that observed in our series. The reason for the lack of UGI sensitivity at our institution is unclear, but there are several possible explanations. We obtain the contrast study very early in the postoperative course, before the 5- to 7-day period when tissue strength is at its nadir and leaks are most likely to occur. Additionally, only three of nine leaks in our series occurred at the gastrojejunostomy. Upper gastrointestinal imaging, as described earlier, is limited to evaluation of the esophagus, pouch, gastrojejunostomy, and the Roux limb. Although delayed images are obtained routinely, the jejunojejunostomy and reflux into the duodenum and distal gastric remnant are frequently not identified. Therefore, contrast extravasation in these areas may not be visualized. We use a water-soluble contrast medium that is less opaque and more difficult to visualize than barium [5]. We also are aggressive in removing the nasogastric tube and beginning enteral feeding early. Small perforations that might otherwise have healed may therefore be stressed with early feeding. Finally, contrast studies are difficult to interpret given the physical limitations of the patients and the complex anatomic reconstruction involved [12]. A learning curve probably exists even for experienced radiologists. Whereas none of our first four leaks were detected, three of the five most recent leaks were identified or strongly suggested by early imaging.

On univariate analysis, several routinely monitored clinical signs correlated with leaks in the postoperative period. Marginal urine output, although present only in one-third of the patients with identified leaks, was almost five times more common than in the nonleak group. Similarly, hypotension, found in approximately 10% of nonleak patients, was twice as common in those with leakage. Interestingly, on review of the vital signs recorded in the 24 h before relaparotomy, many patients became hypertensive. The lack of fever in the leak patients is not surprising, because one of the criteria for the systemic inflammatory response syndrome (SIRS) is a temperature lower than 36°C. Notably, all the patients who eventually were found to have leaks demonstrated the aforementioned clinical signs before the leak was

detected, making recognition of their presence important.

On multivariate linear regression analysis, severe tachycardia (heart rate exceeding 120 beats/min) and respiratory distress, as defined in the Methods section, emerged as independent clinical indicators, and were by far the most sensitive indicators of leaking identified in this study. Despite this finding, most of the patients with no leaks also were tachycardic (pulse, 100–140) to some degree. This may reasonably be explained by the normal postoperative hypermetabolic state, or by large intraoperative fluid shifts and underresuscitation in the operating room despite the routine administration of 4 to 5l of crystalloid solutions. Interestingly, 16% of the patients without leaks were severely tachycardic (sustaining a heart rate greater than 120 beats/min), and 40% were moderately or severely tachycardic (sustaining a heart rate greater than 110 beats/min). This finding suggests that significant postoperative tachycardia alone is not an absolute indication for exploratory laparotomy.

As described in other reports, physical examination of the abdomen in this group of morbidly obese patients is an unreliable tool for identifying intraabdominal catastrophe. The reasons for the insensitivity of physical examination have been discussed at length by other authors, but may well be related to the large mass of subcutaneous tissue anterior to the peritoneum. The presence of other symptoms, such as shoulder pain and hiccoughs, were not specifically addressed in this study.

Conclusion

Gastrointestinal leak is the most serious complication associated with LRYGB operations, producing significant morbidity or even death in patients for whom the complication is not detected. Leaks may occur in up to 5.8% of patients, making it a more common postoperative complication than clinically apparent pulmonary embolism. Leaks after gastric bypass may be difficult to detect, however [3]. In our practice, we use early routine postoperative upper gastrointestinal contrast evaluation for the reasons stated earlier. Patients may still harbor leaks even though they are afebrile and normotensive, showing negative results on postoperative contrast studies. Clinical parameters recorded during the postoperative period may give more important clues to the presence of an occult leak than UGI contrast imaging alone. Tachycardia exceeding 120 beats/min and respiratory distress may be the two most useful clinical indicators, whereas hypotension and fever are less indicative.

On the basis of our clinical experience, we recommend initiating aggressive resuscitative efforts and attempts to rule out other potential postoperative complications (e.g., hemorrhage, pneumonia, atelectasis, pulmonary embolism, or volume depletion) when patients manifest worrisome clinical signs. However, attempts to rule out diagnoses other than gastrointestinal leak should not delay resuscitative efforts and return of the patient to the operating room to avert intraabdominal catastrophe. This opinion is supported by other authors [2–4].

In this study, patients with severe tachycardia and respiratory distress had a 20% chance of harboring a leak. In patients who do not respond appropriately to resuscitative efforts and in whom another plausible diagnosis is not identified, CT scan of the abdomen with oral and intravenous contrast may be obtained to rule out fluid collection and contrast extravasation. This may help to decrease the anticipated 80% nontherapeutic laparotomy rate for patients taken to the operating room on clinical signs alone. Again, repeated radiologic evaluation should not delay return of the patient to the operating room to rule out intraabdominal sepsis when the diagnosis of leakage remains in question. Further studies are needed to evaluate the optimal method for early detection of postoperative leaks in patients undergoing laparoscopic Roux-en-Y gastric bypass.

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