

Gastric leaks after sleeve gastrectomy: a multicenter experience with 2,834 patients

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Abstract

Background Laparoscopic sleeve gastrectomy (LSG) remains under scrutiny as a stand-alone bariatric procedure. The most feared complication after LSG is staple line leak. **Methods** Eight bariatric centers in Israel participated in this study. A retrospective analysis was performed by querying all the LSG cases performed between June 2006 and June 2010. The data collected included patient demographics, anthropometrics, and operative and perioperative parameters.

Results Among the 2,834 patients who underwent LSG, 44 (1.5 %) with gastric leaks were identified. Of these 44 patients, 30 (68 %) were women. The patients had a mean

age of 41.5 years and a body mass index (BMI) of 45.4 kg/m². Intraoperative leak tests and routine postoperative swallow studies were performed with 33 patients, and all but one patient (3 %) failed to detect the leaks. Leaks were diagnosed at a median of 7 days postoperatively: early (0–2 days) in nine cases (20 %), intermediately (3–14 days) in 32 cases (73 %), and late (>14 days) in three cases (7 %). For 38 patients (86 %), there was clinical suspicion, later confirmed by imaging or operative findings. Computed tomography, swallow studies, and methylene blue tests were performed for 37, 21, and 15 patients, respectively, and the results were positive, respectively, for 31 (84 %), 11 (50 %), and 9 (60 %) of these patients. Reoperation was performed for 27 of the patients (61 %). Other treatment methods included percutaneous drainage ($n = 28$, 63.6 %), endoscopic placement of stents ($n = 11$, 25 %), clips ($n = 1$, 2.3 %), and fibrin glue ($n = 1$, 2.3 %). In 33 of the patients (75 %), the leak site was found in the upper sleeve near the gastroesophageal junction. The median time to leak closure

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was 40 days (range, 2–270 days), and the overall leak-related mortality rate was 0.14 % (4/2,834).

Conclusion Gastric leak is the most common cause of major morbidity and mortality after LSG. Routine tests to rule out leaks seem to be superfluous. Rather, selective utilization is recommended. Management options vary, depending mainly on patient disposition. An accepted algorithm for the diagnosis and treatment of gastric leak has yet to be proposed.

Keywords Gastric leak · Laparoscopic sleeve gastrectomy · Morbid obesity · Morbidity · Mortality

Laparoscopic sleeve gastrectomy (LSG) is rapidly gaining momentum, both as a stand-alone and as a putative first-stage procedure in bariatric surgery. Since its introduction into the bariatric armamentarium [4, 13], LSG has become the most popular procedure in Israel. Its major advantages are its relative operative simplicity, lack of anastomoses, absence of a malabsorptive component, and induction of a favorable hormonal change facilitating weight loss through restriction and appetite suppression. It has reported lower morbidity and mortality rates than Roux-Y gastric bypass (RYGB) or biliopancreatic diversion with or without duodenal switch (BPD or BPD-DS), thereby making it more appealing [1, 4, 34]. It also has been used as a revisional option for patients with failed bariatric procedures such as vertical banded gastroplasty, silastic ring vertical gastroplasty, laparoscopic adjustable gastric banding, and previous sleeve gastrectomy [5, 17, 21, 22, 26].

One of the dreaded complications after LSG is a gastric leak, most commonly occurring at the upper staple line near the gastroesophageal junction [9, 20, 24]. This complication, if not identified and treated quickly and aggressively, may lead to abdominal sepsis, which might progress either to chronic gastric fistula or to multiorgan failure and patient demise.

This retrospective study reports 2,834 patients who underwent sleeve gastrectomy at one of eight bariatric centers in Israel. The study aimed to report on the clinical factors associated with leakage and to evaluate methods for early detection and management of gastric leak.

Methods

Eight bariatric centers in Israel participated in this study, each maintaining a prospectively collected database of all the bariatric procedures performed. Local ethical committee approval for database management was obtained at each center. Retrospective analysis of these databases was carried out by querying all the LSG cases managed between June 2006 and June 2010.

The information collected included patient demographics, anthropometrics, operative and perioperative data, and the presence or absence of leaks. The methods used to detect and manage leaks and to determine the interval between surgery and diagnosis as well as the interval between detection and leak closure were recorded. The patients who underwent LSG and experienced a diagnosed gastric leak were the study group, whereas those who did not have a leak were designated as the control group.

The surgical technique varied slightly between centers with regard to various parameters including stapler manufacturer choice, staple height, bougie size, use of buttressing materials and/or oversuturing of the staple line, and choice of energy source. All surgeons performed LSG by dividing the greater curvature vessels first and resecting the stomach later.

Statistical analysis

Analysis of data was performed using SPSS 11.0 statistical analysis software (SPSS Inc., Chicago, IL, USA). Distributions of continuous variables were assessed for normality using the Kolmogorov–Smirnov test (cutoff at $p = 0.01$). Normally distributed continuous variables were described using mean \pm standard deviation, whereas continuous variables with distributions significantly deviating from normal were described using median (minimum–maximum). Continuous variables were compared using Student's t test for independent samples or the Mann–Whitney U test as appropriate. Categorical variables were described using frequency distributions and are presented as frequency (%). Categorical variables were compared by leakage using Chi-square or Fisher's exact test as necessary. All tests were two-tailed and considered significant at a p value lower than 0.05.

Results

During the study period, 2,834 patients underwent LSG for the treatment of morbid obesity at eight bariatric centers. We identified 44 patients (1.5 %; range, 0.8–3.9 %) with a gastric leak. Of these 44 patients, 30 (68 %) were women. The patients had a mean age of 41.5 years and a body mass index (BMI) of 45.4 kg/m². The 2,790 patients who underwent LSG without a leak served as a control group.

Of 11 patients (25 %) who had previous bariatric operations, six had undergone laparoscopic adjustable gastric banding and five had undergone silastic ring vertical gastroplasty. In the control group, 285 (10 %) of 2,790 patients had undergone previous bariatric interventions. This difference in proportion was highly significant ($p < 0.005$; odds ratio, 2.8; 95 % confidence interval,

Table 1 Patient demographics, body mass index (BMI), and comorbidities

| Parameters | Controls (<i>n</i> = 2,790) | Leak (<i>n</i> = 44) | <i>p</i> value |
|--------------------------|---------------------------------|--------------------------|----------------|
| Mean age (years) | 41.5 ± 17 | 41.5 ± 10 | 0.9 |
| % Females | 71 | 68 | 0.7 |
| BMI (kg/m ²) | 43.7 ± 12 | 45.4 ± 8.5 | 0.4 |
| Hypertension (%) | 37 | 43.2 | 0.4 |
| Dyslipidemia (%) | 34 | 40.9 | 0.3 |
| Sleep apnea (%) | 32 | 29.5 | 0.7 |
| Type 2 diabetes (%) | 10 | 18.2 | 0.07 |

1.4–5.6), implying a threefold risk for leak in patients with previous bariatric surgery. Previous abdominal surgeries had been performed for 10 of the patients (22.7 %). This was similar to 574 patients (20 %) in the control group.

Comorbidities were present in 23 patients (52 %) including hypertension in 19 patients (43.2 %), dyslipidemia in 18 patients (40.9 %), obstructive sleep apnea in 12 patients (29.5 %), and type 2 diabetes in eight patients (18.2 %) (Table 1). Of 38 leaks, 29 (76 %) occurred after the management of 50 cases per surgeon. An intraoperative leak test was performed during the original surgery for 33 patients (75 %): using blue dye injection in 25 patients and air testing in eight patients. All but one patient (3 %) experienced failure to detect the leak. The one case in which the leak was identified by blue dye injection had experienced a stapler misfire. The leak was identified and sutured, with a consequent negative intraoperative dye test. Unfortunately, the patient leaked postoperatively and required percutaneous drainage.

Intraoperative mishaps were encountered in 14 cases (31.8 %). Five of the patients underwent conversion to an open procedure due to poor exposure (oversized liver in three patients and adhesions from previous surgeries in two patients). Two of the patients had bleeding from the stapler line, necessitating unplanned suturing. Stapler misfire was oversewn in four of the patients. In one of the patients, an orogastric tube used for stomach decompression was accidentally left alongside the bougie and cut through, causing stapler failure. The tube was freed, and the area was oversewn. In two of the patients, a thermal injury (1 by an ultrasonic scalpel [Harmonic scalpel] and 1 by a vessel-sealing device [Liga-Sure]) was reported, both in the posterior fundus, caused by freeing of posterior connective tissue attachments. In both cases, the small area was imbricated with an absorbable suture, but the leak site was later identified in that area.

A leak was clinically suspected in 39 patients (88.6 %) and later confirmed by imaging or operative findings.

Computed tomography (CT) was performed for 31 patients and swallow studies (SS) for 21 patients to investigate clinically suspected leaks. The results were positive for 37 (84 %) and 11 (25 %) patients, respectively.

Leaks were diagnosed at a median of 7 days (range, 1–120 days) postoperatively: 9 (20 %) early (in 0–2 days), 32 (73 %) intermediately (in 2–14 days), and 3 (7 %) late (in >14 days).

Early surgical intervention was performed for 27 patients (61.4 %). All the interventions included a thorough washout and drainage of the abdomen. Leak-site suture was attempted in nine cases (20.5 %), all during laparoscopic exploration for washout and drainage. A gastrostomy tube was placed through the leak site in two patients, and a feeding jejunostomy was placed in two additional patients.

Nonoperative management was used for the remaining 17 patients (38.6 %), all without clinical signs of hemodynamic instability or uncontrolled sepsis. Of these 17 patients, four required no further intervention other than maintenance of the closed suction drainage placed during surgery. For the remaining 13 patients, other interventions included percutaneous drainage (*n* = 28, 63.6 %), Endoclips (*n* = 1, 2.3 %), and fibrin glue (*n* = 1, 2.3 %). An endoscopic stent was placed 13 times in nine patients (20.4 %) and reported to be successful in five patients (55 %). A nasojejunal feeding tube was placed in two patients to facilitate enteral feeding. A gastrostomy tube through the leak site was placed in two other patients. Total parenteral nutrition was used with 15 patients.

In the majority of cases (*n* = 33, 75 %), the leak site was in the gastroesophageal junction area. The leak occurred in the midsleeve in three cases (6.8 %), the antral area in three cases (6.8 %), and the posterior wall of the sleeve in two cases (4.5 %). The leak was not located in an additional three cases (6.8 %).

The median time to leak closure was 40 days (range, 2–270 days). At the time of this writing, one patient still harbors an unresolved chronic gastrocutaneous fistula.

A trend for longer leak resolution could be detected in the patients managed nonoperatively (50 days) than in those who underwent an early operation (20 days). This difference, however, was not statistically significant (*p* = 0.51).

Seven patients underwent additional surgical intervention for treatment of late complications. These included supradiaphragmatic manifestations in two patients (empyema and gastrobronchial fistula) and nonresolving intra-abdominal abscesses necessitating operative washout and drainage in five patients. Four of these seven patients underwent total gastrectomy with Roux-en-Y esophagojejunostomy as a last resort for leak termination.

Four patients did not survive this complication, succumbing to uncontrolled sepsis, multisystem organ failure, and death. All four patients leaked in the intermediate time frame: two on postoperative day (POD) 3, one on POD 5, and one on POD 6. The overall leak-related mortality was 0.14 % (4/2,834). However, the mortality rate was 9.1 % for the patients who had leakage. No other causes of death were identified.

Discussion

Sleeve gastrectomy is gaining popularity as a bariatric option, with short- and midterm results similar to those for the “gold standard” laparoscopic Roux-en-Y gastric bypass but with lower morbidity and mortality rates [20, 24, 27]. With increasing use of sleeve gastrectomy, both its technical nuances and drawbacks are accumulating, and its mechanisms of action will be better understood.

The American Society for Metabolic and Bariatric Surgery (ASMBS) Clinical Issues Committee statement quotes an overall complication rate for LSG of 0–24 % and a mortality rate of 0.39 % [11].

Leaks after LSG are reported to occur in 1.4–5.3 % of cases (Table 2). Clinically, they may range from mild micro leaks that present from weeks to months after surgery as the cause of perisleeve abscesses and chronic fistula to an abdominal catastrophe with sepsis, hemodynamic instability, multisystem organ failure, and rarely, patient demise [9, 10, 31].

With regard to prevention, some technical pitfalls seem to be important. A tight sleeve is created by dividing all connective tissue and vascular attachments of the stomach except the lesser curvature vessels. Use of the appropriate staple height for the resected segment of the stomach is mandatory, and care should be taken with heat-producing

instruments so as not to cause thermal injury to the created sleeve (as occurred with two patients in our series). If the dissection is too aggressive near the posterior aspect of the upper sleeve, devascularization may occur, making that area more susceptible to leakage. It is our impression that dissection of this area should be kept to the minimum required for mobilization and that the final firing should be away from the esophagus to the left of the gastroesophageal junction.

Bougie sizes ranging from 32 to 48 Fr have been used for sleeve calibration. The majority of surgeons in this study advocate the use of bougies smaller than 40 Fr without buttressing material or oversewing of the staple line. Atkins et al. [2] demonstrated that patients treated with the more restrictive 40-Fr bougie experienced a significantly greater weight loss and more comorbidities than those treated with a 50-Fr bougie. Two reports linking smaller bougie size to leak rates have been published recently, underscoring this issue [3, 23].

To date, no study has unequivocally supported or obviated the use of buttressing material or suture reinforcement for leak prevention [6, 14, 32, 39]. A recent systematic analysis showed that oversewing or buttressing of the staple line does not have a clinically significant effect on leakage [3]. However, Bellanger and Greenway [7] used a 34-Fr bougie without buttressing or oversewing of the staple line and saw a leak rate of 0 % in 529 cases. A recent consensus statement by an international sleeve gastrectomy expert panel deemed the optimal bougie size to be 32–36 Fr [38].

In our study group, one-third of the patients ($n = 16$) had reinforcement: 4 with biosyn membrane (Duet TRS; Covidien Surgical, Mansfield, MA, USA) and 12 with staple line oversewing. We cannot draw any strong recommendations regarding this issue.

Routine or selective use of intraoperative diagnostic methods is controversial. Intraoperative endoscopy, air leak testing, and transgastric dye injection have been used by some authors to detect a leak during initial surgery or in a patient returning after a suspected or proven leak [20, 24, 28, 33, 37]. The rationale behind the routine use of these tests intraoperatively is to detect “technical leaks” at a time when tissues are viable and most amenable to repair by restapling or suturing. A negative methylene blue test does not eliminate the possibility of a leak [10].

In the current study, an intraoperative test was performed for 33 of the patients (75 %), who eventually had leaks. The test was positive in only one case after a stapler misfire. We thus conclude that a selective rather than a routine use of this technique may be more appropriate.

Likewise, postoperative contrast-swallow tests, blue dye ingestion, and routine placement of closed suction drains have been advocated by several authors, whereas others

Table 2 Studies of staple line leaks after sleeve gastrectomy

| Author | No. of patients | Leaks n (%) | Years |
|----------------------------|-----------------|---------------|-------|
| Cottam et al. [13] | 126 | 2 (0.9) | 2006 |
| Serra et al. [40] | 993 | 6 (0.6) | 2007 |
| Burgos et al. [9] | 214 | 7 (3.2) | 2009 |
| Casella et al. [10] | 200 | 6 (3) | 2009 |
| Sanchez-Santos et al. [39] | 540 | 11 (2) | 2009 |
| Csendes et al. [15] | 343 | 16 (5) | 2010 |
| Dapri et al. [18] | 75 | 4 (5.3) | 2010 |
| Daskalakis et al. [19] | 230 | 10 (4.3) | 2010 |
| Lacy et al. [29] | 294 | 11 (4) | 2010 |
| Tan et al. [41] | 500–600 | 14 (2.5) | 2010 |
| Bellanger and Greenway [7] | 529 | 0 | 2011 |
| Current study | 2,834 | 44 (1.5) | |

claim that overtesting is unnecessary and that good clinical judgment suffices [16, 20, 24, 25, 33, 37]. Obviously, some patients will present with a clear clinical picture, making diagnosis simple, whereas for others, a more subtle clinical presentation may lead to a late diagnosis with potentially catastrophic consequences.

In our series, swallow tests were performed for 21 patients who had clinical suspicion for leakage, with leakage detected in 11 of these patients (50 %). The leaks in our study were diagnosed after a median of 7 days postoperatively. It is logical to assume that leakage occurs later than POD 1, and we therefore propose that these tests should be performed selectively in cases with clinical suspicion for leakage.

Not surprisingly, the most sensitive method for leak detection is a high index of suspicion. This is consistent with similar observations in numerous reports [8, 16]. Tachycardia, fever, and abdominal pain (pain radiating to the left scapular region) are the most consistent signs for leakage in the described patient population. In general, laboratory examinations are rarely contributory, and as hinted earlier, contrast-swallow studies are notorious for showing “normal” results in the presence of leaks [8, 25]. Computed tomography scans had the highest rate of leak detection and confirmed the clinical diagnosis in 38 cases (86 %). Drain amylase levels have been proposed as a simple, low-cost adjunct with high sensitivity and specificity that can help to identify patients who may have a leak after gastric bypass surgery [30]. This, of course, mandates leaving a closed suction drain in all cases for at least 7–10 days, which arguably is not necessary in the majority of cases.

Management options are varied and dependent on the timing and clinical presentation of the leak. Immediate reoperation is the preferred course of action for the unstable patient, usually with washout, irrigation of the abdominal cavity, wide drainage, and an attempt at suturing of the leak if the tissue condition allows it [9]. Sound surgical judgment is imperative in deciding whether the tissues are amenable to suturing or whether further intervention will only impose further damage.

Stable patients and leaks presenting later in the postoperative course pose a yet unanswered dilemma regarding the best treatment algorithm. The methods used to date in attempts at leak closure have been percutaneous, endoscopic, or surgical.

Adequate drainage is of paramount importance and a mandatory adjunct for any endoscopic interventions. This can be achieved with a drain placed during initial surgery or with additional imaging-guided drains.

Percutaneous imaging-guided drainage and distal enteral or parenteral hyperalimentation together with systemic broad-spectrum antibiotics are the mainstay of the

nonoperative management. If the fistula does not heal after several weeks, endoscopic endoluminal placement of stents, various clips, and endoscopic suturing devices are an appealing option that allows direct visualization and treatment of the internal fistula opening but is fraught with poor success rates [12, 35]. Fibrin glue injection to the fistulous tract has been advocated by several authors and was used in our cohort as well [36].

Surgical options range from primary repair after a period of adequate drainage and patient stabilization to placement of gastrostomy tubes through the leak site, a serosal patch with the small intestine pulled up to the leak site, a Roux-en-Y pull-up of the small intestine anastomosed to the leak site, conversion from sleeve to gastric bypass with resection of the leak site (if sufficiently distal), or resection of the gastric sleeve with an esophagojejunostomy [6, 14, 32].

We were not able to find any accepted order in the application of these treatment methods nor one method with an overwhelming success rate. Some argue that the least invasive methods should be tried first, with advancement from percutaneous through endoscopic techniques, and with return to the operating room as a last resort. Others might opt for a more definite solution that will offer a quicker resolution, especially considering the poor efficacy of the nonsurgical approaches.

In summary, we conclude that LSG constitutes a reasonably safe bariatric procedure with acceptable postoperative morbidity and mortality rates. Gastric leak is the most common cause of major morbidity and mortality after LSG. The LSG procedure can be performed successfully with a leak rate of approximately 1.5 %.

Leak occurs near the gastroesophageal junction 75 % of the time, and the large majority of leaks occur after patient discharge. Routine tests to rule out leaks seem to be superfluous. Rather, selective utilization is recommended. Clinical suspicion and CT scan constitute the mainstay for the diagnosis. Management options vary, mainly depending on patient disposition. An accepted algorithm for the diagnosis and treatment of gastric leak has yet to be delineated.

Disclosures Nasser Sakran, David Goitein, Asnat Razieli, Andrei Keidar, Nahum Beglaibter, Ronit Grinbaum, Ibrahim Matter, Ricardo Alfici, Ahmad Mahajna, Igor Waksman, Mordechai Shimonov, and Ahmad Assalia have no conflicts of interest or financial ties to disclose.

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