

## Invagination sutures and intraoperative leak testing to prevention and management of sleeve gastrectomy anastomotic leaks

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### Abstract

**Background:** Laparoscopic sleeve gastrectomy (LSG) is one of the common bariatric procedures for the treatment of morbid obesity. One of the most serious complications of this procedure is leak.

**Objective:** This study compared sleeve gastrectomy (SG) staple-line leak rates of 2 prevalent surgical options: no reinforcement, and over sewing, no absorbable suture.

**Materials and Methods:** Analysis of the influence of technical adaptations on the outcome of LSG was performed in a nested case-control group of patients. The main modification adapted was performing invagination sutures over the staple line. The primary outcome was the occurrence of leak. The secondary outcomes were bleeding, operative time, prolonged hospital stay, and mortality.

**Results:** We included selected group of patients who underwent sleeve gastrectomy (SG) for treatment of morbid obesity between May 2014 and May 2016. The performance of intra operative leak testing (IOLT) by (methylene blue). The group who had invagination sutures (group 2) had a significantly lower frequency of leak (0%) than those without invagination sutures (7.3%; group 1). There was no significant difference in the occurrence of postoperative bleeding, hospital stay or mortality between the groups.

**Conclusions:** The procedure's safety overall is good; developing proven surgical strategies to minimize the risk of potentially life-threatening staple-line leak after LSG is of critical importance. Invagination sutures of the staple line have received great attention as prophylactic measures against leaks, and effective in reducing the incidence of leak.

**Keywords:** bariatric surgery, obesity, sleeve gastrectomy, staple line enforcement, suturing, leak, intraoperative leak test

### 1. Introduction

Bariatric surgery is widely accepted as the most effective treatment for morbid obesity. In recent years, the landscape of bariatric surgery has changed due to an increased use of the laparoscopic sleeve gastrectomy (LSG) relative to other procedures. In 2012, the LSG represented 36.3 % of all bariatric procedures performed at academic medical centers [1, 2].

When compared to gastric bypass procedures, the laparoscopic sleeve gastrectomy (LSG) has a relatively low risk and complications profile [3]. Nevertheless, a known complication of LSG is staple line leak, which usually occurs at the proximal portion of the staple line and has a reported incidence of 1.1–5.3 % [4]. Leaks can result in significant morbidity including sepsis, hemodynamic instability, multi-organ failure, and even mortality [4]. Early identification and treatment of leaks is critical, but the majority of leaks present days to weeks after the index operation, making early identification challenging [5].

Staple line leak after sleeve gastrectomy (SG) is a rare but dreaded complication with a reported incidence of 0% to 8%. Many surgeons routinely test the staple line with an intraoperative leak test (IOLT), but there is little evidence to validate this practice. In fact, there is a theoretical concern that

the leak test may weaken the staple line and increase the risk of a postoperative leak [6].

Sleeve gastrectomy (SG) is one of the more recently introduced interventions which are proved to induce a significant excess weight reduction [7]. Despite the successful outcomes reported, LSG, as any other bariatric surgery, is not without complications [8]. Leak is considered one of the most drastic complications after LSG [4]. Several strategies to prevent leak were utilized in many clinical studies. Staple line enforcement is one of the most tried protective methods against the leak [9]. Buttressing, over sewing, and roofing with fibrin glue of the staple line were used to address the prevention of leak [10]. Despite the efforts to minimize leaks after LSG [5], they still occur [11]. The reported leak rate in the literature is up to 3% [5] and is associated with significant morbidity and mortality [12]. The learning curve of the procedure could be an important factor determining the outcome [13]. Mentorship programs could effectively reduce the complications during the learning curve of LSG [14]. Mentorship programs, despite available, might not be achievable for every surgeon who wishes to treat his patients with LSG. The alternative solution is to have a clear description of the technique that explains the subtle differences and their influence on the course of the procedure.

The objective of this study was to describe the technical factors that might reduce the leak during or after SG. This review, discusses pre-, intra-, and postoperative interventions that can possibly decrease leak rate and their level of evidence.

### Physiology of Anastomotic Healing

These steps have traditionally been separated into three overlapping phases of wound healing to facilitate learning. The three phases are:

1. **Inflammation or “lag” phase:** The risk of anastomotic dehiscence and leak is greatest during this phase [15].
2. **Proliferation phase:** “Late” anastomotic leak can occur during impairment in this phase.
3. **Remodeling:** Leak does not usually occur during this phase [16, 17].

### Anatomy of Healing

All four layers of the gastrointestinal (GI) tract (mucosa, submucosa, muscularis propria, and serosa) play an important role in restoring continuity following anastomosis. Apposition of mucosa seals the gap and provides a barrier to luminal contents and bacteria. Submucosa contains the blood vessels, lymphatics, nerve fibers, and the bulk of collagen fibers. The stapled or sutured collagen fibers in this layer provide most of the tensile strength of the anastomosis. Decrease in numbers and the integrity of collagen fibers can lead to anastomotic disruption and leak; [16]

### Prevention of Leak

Although the incidence of anastomotic leak in bariatric surgery is low, it is still devastating. The cause is probably multifactorial but what can we do to decrease the incidence? Shows some interventions to reduce leak rate and their level of evidence.

#### a) Preoperative measures

Patients who undergo bariatric surgery usually have multiple comorbidities, such as diabetes, hypertension, poor nutrition, less exercise tolerance, and sleep apnea, should be replaced if there are deficiency.

#### b) Intraoperative measures

Choice of operative technique (open, laparoscopic), surgeon's experience, technique of anastomosis (hand sewn, stapling), implementation of a well-constructed gastric pouch, jejunojejunostomy or gastric sleeve, staple line reinforcement (buttressing, over sewing the staple line, fibrin sealant), hemodynamic stability, oxygenation, and intraoperative leak tests are factors that can be altered intra-operatively.

### Hand-sewn or stapled anastomosis

The speed, reproducibility, and ease of use of stapling devices have made them the most frequently utilized technique of anastomosis. Proposed benefits from a stapled technique include better blood supply, reduced tissue manipulation, less edema, uniformity of apposition, and adequate lumen at anastomotic site. These factors are believed to facilitate healing of the anastomosis. There are many systematic reviews showing that both hand-sewn and stapled anastomosis are equally effective in different parts of GI tract [18, 19].

While there are no significant differences in anastomotic complications between hand-sewn and stapled anastomosis

other than stricture, stapled anastomosis can be performed significantly faster, and while not reaching statistical significance, there is a decreasing trend in anastomotic complication rate as the surgeon gains experience [20, 21].

### Stapling and ischemic points

Staple lines reinforced with small intestinal submucosa have shown better durability with regards to leak rate and significantly higher anastomotic burst pressure in animal models [22, 23]. In summary, there is no level-one evidence that buttressing decreases clinical leak rate in bariatric surgery.

### Over sewing the staple line

Over sewing the staple line during bariatric surgery is an inexpensive but time consuming technique. Additionally, there are no data that establishes its superiority. One study suggests it might even increase the risk of staple line failure. [24] Studies on over sewing to maintain staple line integrity are mainly level-three evidence and the results are not uniform. Some have stated that over sewing significantly reduces the leak pressure and, therefore, should be avoided, [25] while others have concluded that over sewing successfully prevents staple line bleeding and diminishes the incidence of leak formation. [26] Meta-analysis of 11 studies showed that there is no reason to believe that reinforcement by buttress or over-sewing provides protection against leak and the decision whether or not to use it is at the surgeon's discretion and experience [27].

### c) Postoperative Measures

Maintaining continuous positive airway pressure (CPAP), avoiding anemia, and checking for oxygen saturation levels postoperatively are as important as pre- and intraoperative measures to make sure that microcirculation and oxygen and micronutrient delivery to anastomotic area are not impaired. Since anastomotic leak after bariatric surgery can lead to serious morbidities, devastating consequences, and even death, early detection and diagnosis is essential. Early suspicion and low threshold to perform diagnostic tests play a key role to early detection and management of possible leaks. Placing nasogastric tube (NGT) and topical decontamination of the GI tract during wound healing have been suggested previously as tools to prevent leaks from happening; other postoperative diagnostic tools, such as methylene blue swallow, upper GI series, drain amylase level, and CT scans are usually applied for early detection of leaks.

## 2. Materials and Methods

We included selected group of patients who underwent sleeve gastrectomy (SG) to treatment of morbid obesity between May 2014 and May 2016. All patients were seen in an office setting within 2 weeks of surgery, and all patients had at least 2 months' follow-up.

We considered some technical modifications to minimize the leak rate at Faculty of Medicine, Al-Azhar University hospitals, Assuit and Cairo, Egypt and Harm Hospital., approval was obtained before adapting the SG.

Data obtained included patient demographics, comorbidities, intraoperative characteristics including performance and results of intraoperative leak testing, as well as postoperative complications. The performance of intraoperative leak testing and the type of test (air or methylene blue) were based on surgeon preference.

The leak rate was the primary outcome of evaluation in both the initial (the control group; group 1) and the current series (the intervention group; group 2). The secondary outcomes compared were the occurrence of bleeding, the operative time, the frequencies of prolonged hospital stay (LOS), and overall 30-day complication rate, which included any postoperative complication, re-admission, and/or re-operation regardless of the setting in which they occurred. Informed consent was taken from all patients included in this study.

All leaks were radiographically confirmed. For each patient who developed enteric leak, we gathered information about the duration from operation to leak presentation, location of the leak, presence of contrast extravasation on either esophageal or CT scan, and the type of treatment. Occasionally, an intraoperative leak test was performed at the time of leak presentation, and the results of these tests were recorded as well.

The surgical technique varied slightly with regard to various parameters including stapler manufacturer choice, staple height, boogie size, use of buttressing materials and/or Invagination sutures of the staple line and choice of energy source. All surgeons performed SG 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.

### Operative technique and postoperative care

Patients were positioned in a steep anti-Trendelenburg position with the pneumoperitoneum established through a 12-mm trocar, inserted a hand breadth (13–14 cm) beneath the xiphoid process and minimally deviated to the left of the midline. A second 12-mm optical trocar is inserted two fingers breadth beneath the costal margin just at the left midclavicular line. Three 5-mm trocars are inserted: One subxiphoid for liver retraction and manipulation of the gastric fundus when needed, another one at the left midaxillary line for the assistant, and the third one in the right pararectal line, two fingers breadth below the costal margin [Figure 1]). The last one may transfix the falciform ligament if found broad and long.

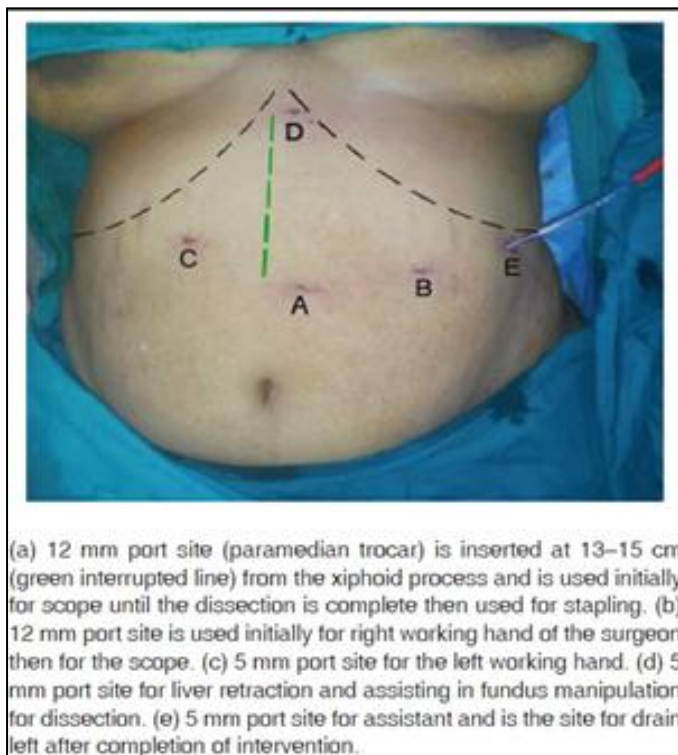


Fig 1

Dissection was pursued using ultrasonic dissector (Harmonic Ace; Ethicon Endo-Surgery, USA) through accessing the lesser sac, and then the whole greater curvature of the stomach is dissected. Afterwards, complete liberation of the posterior gastric attachments except for the unique left gastric vessel bundle is performed. All the remaining fat, peritoneal bands,

and posterior fundic vessels are freed from their gastric attachment [Figure 2] a and b. Complete exposure of the left crus is gained and mobilization of the angle of His is completed through dissection of the phrenogastric membrane from the left side until the gastroesophageal junction is mobilized [Figure 3].

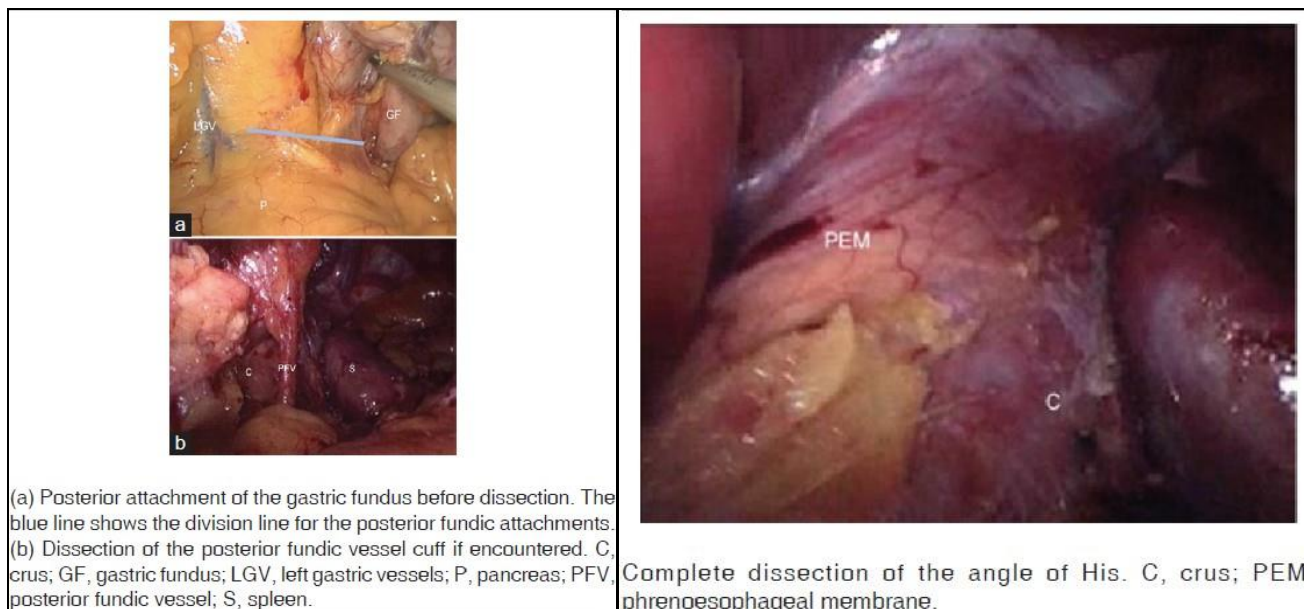


Fig 2

The resection is started 2-3 cm from the pylorus through the paramedian trocar with gold loads (closed staples height is 1.8 mm) mounted on a 60-mm stapler and is performed with a 38-Fr calibrating tube inside the pouch. The resection is continued until the angle of His through the same port. During resection, traction is applied at the greater gastric curvature that is slightly pulled toward the anterior abdominal wall to remove the relatively larger surface of the posterior wall of the gastric fundus. Care was always taken during the stapling not to crumble the stomach inside the stapler by avoiding caudal traction of the stomach. This was particularly important at the region of the fundus of the stomach.

It is also of importance to avoid the crossing over of the staples, which could cause the stapler's knife disturbing the junction between the consecutive firings. This could be achieved by applying the stapler to the middle of preceding end of the staple line.

Invagination sutures were taken into the superficial neuromuscular layer, 2-3 mm lateral to the staple line, in a continuous manner. The sutures covered the staple line from the gastro esophageal junction until approximately the level of the gastric incisura, using polypropylene 3/0, 26-30-mm round needle in a continuous manner.

A leak test with diluted methylene blue is performed and a tube drain is left with respect to the gastric pouch. We routinely keep the nasogastric tube (NGT) until the first postoperative night, and the tube drain is removed before discharge at 48 h unless otherwise indicated.

Leaks were assessed for by the presence of blue dye in the operative field, and the methylene blue solution was suctioned out of the stomach. One surgeon routinely performed intraoperative leak testing with an air leak test. The test consisted of instilling saline into the central upper abdomen. The stomach was insufflated with air through an endoscope with distal occlusion of the pylorus. Leaks in the staple line were evaluated for by the presence of air bubbles. The irrigation fluid was then suctioned out and the stomach decompressed.

Postoperative care followed a standardized guideline. An esophagram was performed on postoperative day (POD) 1. A liquid diet was started if no leak was observed on the esophagram study and if the clinical course was uneventful. Hospital discharge generally occurred between POD 1 and 3 depending on the patient's ability to maintain hydration, ambulate, and manage pain with oral analgesics. After discharge, patients were followed up at the bariatric surgery outpatient offices by a multidisciplinary team within 2 weeks of discharge, at 30 days, and at 3, 6, and 12 months, and yearly thereafter.

### 3. Results

We included selected group of patients who underwent sleeve gastrectomy (SG) to treatment of morbid obesity between May 2014 and May 2016. We considered some technical modifications to minimize the leak rate at Faculty of Medicine, Al-Azhar University hospitals, and Harm Hospital. Cairo, Egypt, approval was obtained before adapting the SG. All patients were seen in an office setting within 2 weeks of surgery, and all patients had at least 2 months' follow-up. Intraoperative leak testing (IOLT) was performed in all patients. The group who had invaginating sutures (group 2) had a significantly lower frequency of leak (0%) than those without invaginating sutures (group 1). There was no significant difference in the occurrence of postoperative bleeding, hospital stay or mortality between the groups.

All patients of this group remained in hospital for 48hs after surgery with a standard postoperative care, and all contrast studies were negative for leakage. The NGT was removed on the first postoperative day in all patients. The tube drain was removed before discharge in all patients except one in whom there was a continuous blood efflux of 500 ml/day during the first and the second day. Laparoscopic exploration was performed on the second postoperative day, but no active source of bleeding could be found. Nonetheless, a large intraperitoneal hematoma was irrigated and a large caliber drain was reinserted. Despite that, the patient continued to

have a bloody effluent of about 150 to 500 ml per day for 7 consecutive days without manifestations of systemic decompensation. After discharge, all patients were attended at 1 week and at 4 weeks' follow-up visits, where no clinical signs of leakage were demonstrated.

Forty patients, 10 (25%) men and 30 (75%) women, were operated before these adaptations (group 1). Their mean preoperative BMI was  $47.2 \pm 8.1 \text{ kg/m}^2$  and their mean age was  $38.2 \pm 9.7$  years. The mean operative time of this group was  $130 \pm 24$  min. The estimated mean operative blood loss was  $150 \pm 45$  ml. Five patients (12 %) remained in hospital for more than 48 h; this included two readmissions. Two patients remained in hospital under conservative management of a drain effluent of 250 and 300 ml of fresh blood per 24 h. The effluent amount decreased to less than 50 ml before discharge on the fourth and fifth postoperative day. The drain was removed on the seventh postoperative day in one patient and on the 10th postoperative day in the other. None of them required blood transfusion.

The other three patients with prolonged hospital stay had staple line leaks. Leak was diagnosed clinically in one patient on the first postoperative day, which was brought back to the operating theater for laparoscopic exploration. The leak site was located by a diluted methylene blue administration through the NGT. It was at the most proximal part of the pouch for which a single figure-of-eight stitch was taken.

Peritoneal lavage was performed and a drain was left nearby the pouch. The patient's drain continued to have leakage efflux for 45 days during which the patient was on regular enteral feeding, with nearly normal daily activity. In a second patient with a BMI  $64 \text{ kg/m}^2$ , leak was diagnosed on the third postoperative day. Computed tomography (CT)-guided drainage of intraperitoneal collection was attempted and an endoscopic stent was placed, which failed to contain the leak. The patient developed pulmonary embolism during the course of treatment, despite the antithrombotic measures, on the 16th postoperative day, which led to consumption of the patient reserve, and the patient died on the 34th postoperative day. The leak in the third patient was diagnosed on the seventh postoperative day. The patient had CT-guided drainage and was successfully managed conservatively for 3 weeks. The diagnosis of leak in the last two patients was achieved by CT scan, which was requested upon clinical suspicion.

Statistical analysis showed that group 2 had a significantly lower incidence of leaks, lower intra-operative and post-operative bleed loss than group 1. [Figure 1]. There were no significant differences in the occurrence of mortality between the groups. The frequencies of a hospital stay longer than 48 hours were significantly higher in group 1.

There were no significant differences between groups in the preoperative BMI or the age. The operative time was longer in group 1. [Table 1] summarizes the main findings of this study.

**Table 1:** Summary of the outcome data and the comparison of both groups

Complication	Group 1 (no suture) 40	Group 2 (invagination suture) 40	Significance
Leakage	3	0	
Post-operative bleeding	2	1	
Mortality	1	0	
Hospital stay	5	3	
Age	38.2 years old	39 years old	
Operative time	130 minute	116 minute	
BMI	47.2kg	48.4 kg	
Intra operative bleeding	150 ml	50 ml	

A leak was clinically suspected in 4 patients (5%) and later confirmed by imaging or operative findings. Leaks were diagnosed at a median of 7 days (range, 1–120 days) postoperatively:

In this study: recommend that staple-line reinforcement reduces leak rate and bleeding along the staple line, and that either buttressing or invaginating sutures of the staple line is valid options with should be routinely performed, and the performance of routine use of an IOLT did not reduce the incidence of postop leak.

**4. Discussion**

Leak after LSG is reported in the literature and its incidence varies from 0 to 5% [28, 29]. Devascularization and increased intraluminal pressure were widely accepted predisposing factors for leaks [30]. We believe that preservation of the left gastric bundle adequately supplies the pouch by its branches along the lesser curvature. That is, the extensive posterior dissection and the dissection of the whole greater curve are less likely to jeopardize the pouch vascularity.

Leak is most common at the proximal part of the stomach [5]. This could be attributed to the difficulty to manipulate the proximal gastric area from the earlier trocar sites, and the

temptation to reduce the pouch volume lead to stapling over the relatively more vulnerable bare area of the stomach or even the stretched lower esophageal end, if excessive traction is posed during stapling. We had one patient in the first group with stapling over a small part of the lower esophagus, which passed without complications. The stapling in this patient was conducted through the left midclavicular trocar.

Over sewing and buttressing of the staple line have received great attention as prophylactic measures against leaks. Buttressing of the staple line was found to be effective in reducing the incidence of leak in some studies [31], which, nevertheless, has a higher cost than sutures [28].

This study demonstrates that invaginating the staple line could help in reducing the leak rate after LSG. This finding is supported by a recent meta-analysis [32] that has, nevertheless, included only two randomized studies with over 1000 patients. We previously reported our leak rates after various bariatric procedures [33]. In that series, there were three cases of leak (7.3%) after LSG. Our initial experience involved only reinforcement of the crossing points of the consecutive firings of the staple line in some patients or hemostatic sutures for bleeding points, but it neither involved the adapted higher trocar positioning nor the invagination of the upper two-third

of the staple line. Besides, in our earlier experience, we used to perform only the first firing through the paramedian port and the rest of the firings were performed through the left midclavicular port. The recently adapted firing direction facilitated easier gastric manipulation and more consistent pouch calibration.

The extensive gastric mobilization is not only valuable for reducing the gastric pouch volume, but also necessary for safe stapling. This was assisted with the adapted more ergonomic positions of the ports, which facilitated the manipulation at the proximal gastric area, particularly when only regular length staplers are available.

Recent recommendations support the use of a relatively large calibrating tube ( $\geq 40$  Fr), as it is thought to be associated with a lower incidence of leak [5]. The use of a calibrating tube of 38 Fr seems to be safe in our experience as long as there is no much traction applied to the stomach during stapling. Excessive traction would lead to overstretch of the pouch wall, which could lead to stricture or narrowing of the gastric pouch.

Caudal traction is equally unfavorable as this would crumple the stomach inside the stapler, leading to higher tension on the fired staples. Besides, the struggle with the abdominal wall to overcome the shortage in instrument length would also render the stapling process difficult, subsequently contributing to its failure. Indeed, one of our known bariatric surgeons had gastric slippage from the stapler during firing as a consequence of this struggle; this led to staple misfire that he had to sew.

Noteworthy, the current evidence has controversial statements regarding the value of staple line enforcement in reducing either leak or bleeding from staple line [9, 28, 32]. We emphasize that bleeding detected during the postoperative period could be from sources other than the staple line. Therefore, unless a definitive source of bleeding is identified during laparoscopic exploration, no bleeding in the postoperative stage could be linked to the staple line. Perhaps, this is one reason why it is difficult to link staple line enforcement to postoperative bleeding [10]. One other value of staple line invagination, in our opinion, is to decrease the postoperative adhesions between the pouch and the liver, thus reducing the difficulty of a second intervention if needed.

The mean operative time was shorter in the second group,

despite the additional time incurred because of sutures. This could be ascribed to the learning curve of the procedure. Besides, in the first group, we had to take multiple figure-of-eight sutures for the purpose of hemostasis or at the crossings of consecutive firings, which could have consumed a significant time. We could not estimate the suturing time in group 1 as there was no dedicated step for sutures and many of them were taken before completion of stapling. The mean suturing time in group 2 was  $23 \pm 4$  min. It might not be possible, in this study, to demonstrate that sutures will not significantly increase the operative time. It is yet unimpeachable that, if the reduction in the leak rate is true, invagination of the staple line could save much more time than it would take.

The lower frequency of back pain in the second group could be due to the modification of the patient positioning. We used to support the arch of the lordosis early in our experience. This was modified to support also the thoracic region rather than the lumbar alone. The philosophy of this modification comes from the hypothesis that pain originates from the over stretch of the spinal ligaments as a result of the exaggerated lordosis, particularly in patients with full buttocks. This is also accentuated by the leg abduction that could lead to more strain on the ligaments as a result of the internal rotation of the hips that is reflected on the sacroiliac joints with more stretch. With thoracic support, the lordosis angle is reduced; hence, the tension over the ligaments could also be reduced.

The beforehand study results should be cautiously interpreted as the study was conducted retrospectively and without a priori power analysis. Moreover, the control group (first or historical) contained a relatively small number of patients, which could have inflated the type II error in this study; this was also the reason why the percentage of leaks in this group was 7%. It is, nonetheless, evident that the leak rate after LSG has been minimized to zero, in the subsequent consecutive patients, after the technical modifications described herein.

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 peri sleeve abscesses and chronic fistula to an abdominal catastrophe with sepsis, hemodynamic instability, multisystem organ failure, and rarely, patient demise [34, 35],

**Table 2:** Studies of staple line leaks after sleeve gastrectomy

Author	No. of patients	Leaks n (%)	Years
Cottam <i>et al.</i> [36]	126	2 (0.9)	2006
Serra <i>et al.</i> [37]	993	6 (0.6)	2007
Burgos <i>et al.</i> [34]	214	7 (3.2)	2009
Casella <i>et al.</i> [26]	200	6 (3)	2009
Sanchez-Santos <i>et al.</i> [38]	540	11 (2)	2009
Csendes <i>et al.</i> [39]	343	16 (5)	2010
Dapri <i>et al.</i> [40]	75	4 (5.3)	2010
Daskalakis <i>et al.</i> [41]	230	10 (4.3)	2010
Lacy <i>et al.</i> [42]	294	11 (4)	2010
Tan <i>et al.</i> [43]	500–600	14 (2.5)	2010
Bellanger and Greenway [44]	529	0	2011
Current study	2,834	44 (1.5)	

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 over sewing of the staple line. Atkins *et al.* [45] 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 [5, 46].

To date, no study has unequivocally supported or obviated the use of buttressing material or suture reinforcement for leak prevention [47, 48, 38]. A recent systematic analysis showed that over sewing or buttressing of the staple line does not have a clinically significant effect on leakage [5]. However, Bellanger and Greenway [44] used a 34-Fr bougie without buttressing or over sewing 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].

Routine or selective use of intraoperative diagnostic methods is controversial. Intraoperative endoscopy, air leak testing, and trans gastric 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 [49, 50, 51, 52, 53]. 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 re-stapling or suturing. A negative methylene blue test does not eliminate the possibility of a leak [26].

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 claim that over testing is unnecessary and that good clinical judgment suffices [49, 50, 51, 54, 55]. 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.

Not surprisingly, the most sensitive method for leak detection is a high index of suspicion. This is consistent with similar observations in numerous reports [54, 56]. 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 [54, 56].

The procedure’s safety overall is good; developing proven surgical strategies to minimize the risk of potentially life-threatening staple-line leak after LSG is of critical importance. Systematic review of 88 included studies representing 8,920 patients found that the leak rate in LSG was significantly lower using APM staple-line reinforcement than over sewing, BPS reinforcement, or no reinforcement [57].

The most important reason why intraoperative leak testing does not reliably detect leaks after LSG is that most leaks develop after surgery. Intraoperative leak testing can only detect the rare leaks due to technical staple line failure, such as those occurring due to stapler misfire or other intraoperative complications [4, 58]. However, staple line failure tends to be infrequent in the hands of experienced surgeons at high-volume centers.

The pathogenesis of postoperative or delayed leaks that occur days to weeks after LSG is not fully understood. Some authors suggest that these postoperative leaks are caused by ischemia, thermal damage, or misplacement of the staple line to involve the distal esophagus in patients with hiatal hernias [59]. These scenarios all lead to intraluminal pressure that exceeds tissue and suture line resistance, thus causing leak. Additionally, narrowing the sleeve at the incisura angularis can lead to a physiologic stricture that may contribute to leaks at the gastroesophageal junction by creating a distal obstruction [60]. Classically, leaks due to ischemia present on POD 5 or 6. This is in line with data from Sakran *et al.* [4], which cites a median of 7 days to leak presentation. In our study, however, the number of days to leak presentation was longer than previously reported, with a mean of 17.3 days. Additionally, with leaks in our study presenting up to 67 days postoperatively, the pathophysiology of staple line leaks after LSG deserves further study.

Regardless of the type of test, intraoperative leak testing prolongs operative time and is associated with increased costs and resource utilization. The cost of routine intraoperative leak tests for sleeve gastrectomy has not, to our knowledge, been addressed in previous studies. When considering the prevalence of bariatric surgery, and LSG in particular, it becomes apparent that routinely using resources that are not necessary or tests that are not evidence based can be costly and wasteful [61].

## 5. Conclusions

The procedure’s safety overall is good; developing proven surgical strategies to minimize the risk of potentially life-threatening staple-line leak after LSG is of critical importance. In this study: recommend that staple-line reinforcement reduces leak rate and bleeding along the staple line, and that either buttressing or invaginating sutures of the staple line is valid options with should be routinely performed, and the performance of routine use of an IOLT did not reduce the incidence of postoperative leak.

## 6. References

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