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Gastric Staple Line Leaks After Laparoscopic Sleeve Gastrectomy, Endoscopic Stent Insertion Versus Surgical Intervention Treatment

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ABSTRACT

Background: Endoscopic stenting (ES) provides comfortable management of Gastric staple line leaks (GSLL); it is less invasive than conventional surgery. **Objective:** The aim of the current study is to assess the efficacy of endoscopic stenting versus surgical intervention in treating gastric stable line leakage following laparoscopic sleeve gastrectomy (LSG). **Patients and methods:** In Helwan University Hospitals, 40 patients had GSLL post LSG between January 2018 and August 2022. We proceeded our management to either: ES placement (*Group A*) or surgical management (SM) (*Group B*), 2o in each group.

Results: Regarding postoperative complications, there is a significant statistical difference regarding wound infection, but no significant difference regarding chest infection, DVT, subphrenic abscess, severe vomiting, GERD, failure of Roux-en-Y, stent migration, or stricture. There is a non-significant association between the type of participant management and the outcomes of the intervention. However, there was a statistically significant association between the type of participant management and the interval period between GSLL closure and its control (P value <0.001) and patients' hospital stay (P= 0.001), as participants who underwent ES spent less time in the hospital. **Conclusion:** Management of post-LSG leakage with ES is advocated as it is a minimally invasive technique that effectively manages GSLL and has a comparable control success rate to definitive surgical treatment with a shorter hospital stay, early return of function, fewer complications, and a well-tolerable safety profile. In stable patients, ES should be recommended as first-line therapy.

Keywords: Gastric staple line leaks, Endoscopic stent insertion, Laparoscopic sleeve gastrectomy.

INTRODUCTION

Obesity is a growing cause of death and has been linked to at least sixty chronic noncommunicable diseases, including heart disease, hypertension, cerebrovascular stroke, type 2 diabetes mellitus, sleep apnea, cancer, and chronic renal disease [(1,2)].

Since its initial description in 1988, laparoscopic sleeve gastrectomy (LSG) has gained popularity and is now the most commonly performed bariatric surgery in the world because it is faster, easier, and more effective at addressing comorbidities and promoting weight loss [(3-11)]. However, the operation is not without complications. In reality, the most common and dangerous complication after LSG, gastric staple line leak (GSLL), occurs in up to 5% of patients, causing significant morbidity, mortality, and additional hospitalization, outpatient therapy, and follow-up costs [(4, 8, 11)].

The following treatment challenges for GSLL that are influenced by the patient's clinical condition include; Initial conservative management followed by conventional surgical treatment of GSLL entails prompt reintervention to patch or close the site of the defect, but these procedures are accompanied by high patient mortality and morbidity [(5,6)].

Endoscopic stenting (ES) provides comfortable management of GSLL; it is less invasive than conventional surgery, aiming to cover or exclude the leak site to divert gastric contents, allowing patients early enteral nutrition, and allowing a temporary return to home if the patient's clinical condition is appropriate. However, the outcome reports of ES are incomplete, and the procedural aspects are not clearly defined [(6)].

Successful GSLL management requires rapid leakage identification and effective source control. Nevertheless, several treatment strategies have been proposed but no definitive management regimen has been recognized, a stepwise management escalation approach is essential to improve patients outcomes [(12-14)]. The lack of well-designed studies that included heterogeneous patient cohorts and lacked standardization is a noteworthy obstacle to determining the best treatment for GSLL. Because of this, there is no solid data basis that can be relied upon to definitively determine the optimal course of treatment to take in order to achieve the best management results [(8,15)].

The study's objective was to assess the efficacy of endoscopic stenting versus surgical intervention in treating gastric stable line leakage following LSG.

PATIENTS AND METHODS

In Helwan University Hospitals, 40 patients had GSLL post LSG between January 2018 and August 2022. We proceeded our management to either: ES placement (Group A) or surgical management (SM) (Group B), 20 in each group.

Inclusion criteria: The study involved patients operated with LSG and had a radiologically proven GSLL.

Exclusion criteria: Patient's not fit for general anesthesia or unwilling to participate in the study.

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Methods:

Pre-operative evaluation of a GSLL patients included taking a complete history of the participant (age, gender, BMI, past history medical diseases, date of LSG, and onset of leak symptoms). The participant is subjected to a general and local clinical examination, including vital signs and a local examination of the abdomen, as well as laboratory routine preoperative investigations (complete blood count, liver function tests, renal function evaluation tests, and electrolytes). All participants received preoperative upper gastrointestinal tract (GIT) endoscopy, nutritional and anesthesiologic assessment, and imaging investigations (gastrograffin swallow, pelvi-abdominal ultrasound, and computed tomography (CT) scanning).

Definition and classification of GSLL:

a) Extravasation of contrast dye or GIT discharges through the intraperitoneal drain (The drain amylase levels after LSG is a significant predictive factor of GSLL with high specificity and sensitivity) [(16)].
b) Confirmatory laboratory and clinical evidence of sepsis.
c) Imaging confirmation of dye contrast extravasation.

According to the time of GSLL detection:

i) Early leaks (GSLL discovered 1–2 days following LSG).
ii) Intermediate (GSLL discovered 3-14 days following LSG).
iii) Late leaks (GSLL discovered ≥ 14 days following LSG)**(20)**.

Management:

After the confirmation of GSLL diagnosis placement of drain near the site of leakage was done. Initial conservative management include: intravenous antibiotics, nutritional support, and close follow up monitoring. Afterwards, once the participant was considered clinically stable, we preceded our management to either ES placement (Group A) or SM (Group B).

ES technique (Group A): ES placement was achieved by 2 qualified skilled endoscopists, Insertion for 6-8 week and reinsertion of another stent when indicated.

SM (Group B): Participants SM include GSLL direct suturing of the defect for closure, defect patching or conversation to Roux-en-Y.

Definition of success management: Complete resolution of sepsis manifestations with imaging confirmation of sealed, absent, or localized contrast dye extravasation outside the GIT.

Postoperative follow up:

Assessment after management of GSLL: Participant vital signs (pulse and temperature), output of the drain, early detection of any postoperative problems, period of hospital stay, CBC, and abdominal CT scan for degree of GSLL resolution.

Follow up of GSLL discharge: follow up weekly until control of GSLL is achieved by: Assessment of GSLL amount of output and control rate (drains output, abdominal CT scan) and complications development.

Follow-up after GSLL control: once a month for six months. Afterwards, patients were instructed to reconnect with us if they had any problems.

Ethical consent:

An approval of the study was obtained from Helwan University Academic and Ethical Committee. After explaining our research objectives, written informed consent was obtained from all study participants. This study was conducted in compliance with the code of ethics of the world medical association (Declaration of Helsinki) for human subjects.

Statistical analysis

Data entry was set up using an Excel spread sheet. The programme Statistical Package for the Social Sciences (SPSS), version 23, was used to analyse the collected data from participants. A p-value of 0.05 is considered statistically significant.

RESULTS:

Our study included 21 (52.5%) males and 19 (47.5%) females, with a participant mean age of 34.1 years (range: 22–51 years) and a mean preoperative BMI of 46.18 kg/m2 (range: 32–59 kg/m2). According to Table 1, there was a non-significant statistical association between the type of patient management and the patient's age, gender, BMI, comorbidities, time from LSG to the occurrence of a leak, or the location of GSLL.

There was a non-significant association between type of patient management and initial conservative management. Regarding postoperative complications, there is a significant statistical difference regarding wound infection, but no significant difference regarding chest infection, DVT, subphrenic abscess, severe vomiting, GERD, failure of Roux-en-Y, stent migration, or stricture.

There was a non-significant association between the type of participant management and the outcomes of the intervention. However, there was a statistically significant association between the type of participant management and the interval period between GSLL closure and its control (P value <0.001) and patient hospital stay (P= 0.001), as participants who underwent ES spent less time in the hospital.

Table 1: The association between type of patient management and patients' characteristics.

Characteristics	Total	Endoscopic stenting group (N= 20)	Surgical management group (N= 20)	P-value
Age mean (years) (range)	34.1 (22-51)	34.2 (22-51)	34 (24-46)	NS
Gender male/female n (%)	19/21 (47.5%/52.5%)	8/12 (40%/60%)	11/9 (55%/45%)	NS
BMI mean (kg/m^2) (range)	46.18 (32-59)	47.5 (40-59)	44.85 (32-58)	NS
Comorbidities				
HTN n (%)	17 (42.5%)	10 (50%)	7 (35%)	NS
DM n (%)	17 (42.5%)	10 (50%)	7 (35%)	NS
HTN + DM n (%)	11 (64.7%)	7 (35%)	4 (20%)	
Osteoarthritis n (%)	3 (7.5%)	0	3 (15%)	NS
Interval between surgery and leak in days	5.48 (1-13)	6 (1-13)	4.95 (1-8)	NS
Leak site				
GE Junction n (%)	32 (80%)	16 (80%)	16 (80%)	NS
Mid-Sleeve n (%)	7 (17.5%)	4 (20%)	3 (15%)	NS
Distal n (%)	1 (2.5%)	0	1 (5%)	NS
Initial conservative management (NPO, IV Fluids, TPN, ABT, PPI) +				
No drainage	22 (55%)	10 (50%)	12 (60%)	NS
Percutaneous drainage	17 (42.5%)	9 (45%)	8 (40%)	NS
Hospital stay in days mean (range)	11.23 (4-26)	8.95 (4-18)	13.5 (7-26)	< 0.01
Interval period between intervention and leak control in days mean (range)	19.8 (2-42)	34.15 (28-42)	5.45 (2-17)	<0.01
Early complications n (%)				
Chest infection	2 (5%)	0	2 (10%)	NS
Wound infection	5 (12.5%)	0	5 (25%)	< 0.05
DVT	1 (2.5%)	0	1 (5%)	NS
Subphrenic abscess	4 (10%)	2 (10%)	2 (10%)	NS
Sever Vomiting & GERD	1 (2.5%)	0	1 (5%)	NS
Failure of Roux-en-Y	4 (10%)	2 (10%)	2 (10%)	NS
Stent migration	5 (12.5%)	5 (25%)	-	NA
Stent related ulcer	2 (5%)	2 (10%)	-	NA
Stricture	4 (10%)	2 (10%)	2 (10%)	NS
Outcome n (%)				
leak control	34 (85%)	17 (85%)	17 (85%)	NS
Conversation to Roux-en-Y	5 (12.5%)	3 (15%)	2 (10%)	NS
Mortality	1 (2.5%)	0	1 (5%)	NS

NS, not statistically significant; NA, not applicable.

DISCUSSION

As a standalone primary bariatric surgery, LSG is becoming more and more practiced operation. However, GSLL remains a major feared complication. Surgeons need dependable methods to deal with GSLL as its management is challenging and selecting the best treatment is a complex process. Recent years have seen a rapid advancement in the ES which aids with the healing of the leak by simultaneously draining perivisceral collections and reducing local inflammation and tissue damage [9,17-22].

According to our data, there was no significant association between the age, gender, BMI, and comorbidities in the current study and the type of management of GSLL (either SM or ES). in line with these findings **Billman *et al.*[8]** published that age, gender, BMI, hypertension, diabetes mellitus type 2, dyslipidemia, NAFLD/ NASH and ASA had no significant association with type of management of the participant (P-value 0.475, 0.684, 0.591, 0.667, 0.089, 0.999, 0.414 and 0.565 respectively); in agreement with our findings. In their work, **Maaty *et al.*** [6] found that the majority of the participants were of female gender and that the included patients had a mean age of about 35 years, in excess of two thirds of the participants had

one or more comorbidities. **Juza *et al.*** [4] intended to review the different methods in treating GSLL and the majority of participants (165 patients underwent LSG with GSLL) were women (60%) with a mean age of thirty-seven years old.

Our results emphasize the interval mean between the primary surgery and post LSG leakage was intermediate leak of 4.95 (1-8) days which had no statistical significant association with type of management of the participant, in agree with findings of **Billman *et al.*** [8] published that and interval of time from LSG to leak had no significant association with type of management (P-value= 0.112), **Sakran and colleagues** [20] found that GSLL were detected at 7 days median post LSG: early in 20 %, intermediately in 73%, and late in 7 %. **Maaty *et al.*** [6] reported in their work that the mean time interval between LSG and GSLL was 5.6 ±2.8 days in the endoscopy patient group and 4.5 (SD 2.1) days in the surgery group. Most of the GSLL was of the intermediate type in both study groups, with non-significant differences. Additionally, the most common site of GSLL in both groups was the GE junction.

The results of our work had shed light on the site of GSLL as it was most commonly at GEJ (80%) or beyond it (17.5%) while, 1 (2.5%) case developed leak at incisura angularis. Similarly, **Hughes *et al.*** [23] reported the GEJ as the most common location of GSLL in their series, in line with **Sakran *et al.*** [20] informed GSLL near GEJ in 75% of patients. This preferential site of GSLL was explained by decreased blood supply of that part of stomach due to damage of blood vessels during LSG or because of increased intragastric pressure due to conservations of pyloric [19]**. Southwell and collaborators** [10] published that the majority of GSLL occurred at GEJ junction (71%) with less in mid-gastric (21%) and distal (8%).

The main findings of our study are that there was a statistical significant association between the method of management and the time between patient management and GSLL control (p0.001) and period of hospital stay (P= 0.001), accordance with **Olmi and collaborators** [17] in their study for management of 69 GSLL after 4294 consecutive LSG; ES results well tolerated by the majority of participants with less costs than the other methods with shortest hospital stay period : 10.4 ± 4.9 days with (P= 0.015). Similarly, **Southwell and collaborators** [10] concluded ES appears to shorten the time till GSLL closure in addition to the total period of participant hospital stay.

The complications incidence in ES group in our study, was as the following: Stent migration 5 (25%), sub-phrenic abscess 2 (10%) and a same number of cases developed ES related ulcer and similar number 2 (10%) patients developed stricture, while in SM group, the numbers of short-term complications was as the next: Deep venous thrombosis (DVT) (5%), chest infection (10%), wound surgical site infection 5 (25%), severe distressing vomiting (5%), and subphrenic abscess (10%), 2 (10%) patients developed stricture.

Even though the overall complication rates were equivalent between the ES and SM arms, there were noteworthy more severe postoperative complications in the SM group regarding DVT, surgical wound site infection (P <0.05), and severe distressing vomiting and GERD that can have disturbing consequences postoperatively; for example, the postmortem autopsy reports documented that 50% of all dying patients in the hospital had DVT. Such findings may shed light on the benefits of ES in terms of hospital stay and time to return to normal function. In agreement with our findings, **Campo *et al.*** [12] published, included 24 patients with GSLL treated with ES, migration stent occurred in 22% of all ES placements. **Southwell and collaborators** [10] concluded that migration of stents was main limiting factor in optimizing management success and the innovations in stent design offer hope for solving this issue.

Tan *et al.* [24] published, although LSG leaks are often disappointing consequence, it can be managed with attention to the fundamental principles of surgical care of enterocutaneous fistulae, early identification, and a high index of suspicion. **Nguyen *et al.*** [14] published the use of ES for management of GSLL after LSG should be in the mind of the bariatric surgeons as when indicated as an effective minimally invasive technique (MIT) for the treatment of GSLL**.** In accordance, **Casella *et al.*** [11] concluded; drainage only or drainage in combination with ES is a feasible management for GSLL post LSG. Additionally, it is a MIT with lower rate of complications and little embarrassment for the participants, escaping more invasive surgical procedures**.**

The results of our work are quite different to **Kiriakopoulos and collaborative** [7] as they published that non-stenting management of GSLL after LSG is possible with better outcomes than ES regarding the period of hospital say and leak control**.** However, **Diab *et al.*** [19] concluded that most cases of GSLL after LSG could be successfully managed by ES. Similarly, **Chung and collaborators** [22] published ES remains the mainstream management for GSLLs.

Hughes and collaborators [23] published treatment decisions for definitive control of the source are directed by the participant clinical condition, surgeon expertise and accessible resources. When patients stable, a conservative management can be accepted. Early control of the source of GSLL through a laparoscopy is expected to be better than open surgery management as the perioperative stress of the surgery is minimized for the patient. This is in contrast with the findings of **Botaitis *et al.*** [18] advocate for urgent SM for early GSLL because the nearby tissues are in an early phase of inflammation. This is consistent with the findings of **Juza and collaborators** [4] which supported ES management of GSLL based on their experience, because ES not only effectively control the leaks but also, early combined laparoendoscopic care of GSLL can result in successful management without the need for additional invasive operations.

Southwell and collaborators [10] reported similar clarifications in their work with a ninety five percent success rate with no participants deaths, the figures supported using ES can be practicable in the treatment of GSLL following LSG. Similarly, **Vix and collaborators** [13], Recommended drainage and ES with parenteral nutrition and antibiotics as an effective treatment for GSLL and should be recommended as first-line management in GSLL stable patients**.**

LIMITATION OF THE STUDY

The most obvious blemish in the work presented here is the requirement for a sequential therapy escalation approach from less invasive to invasive surgery. In order to determine the best algorithm-based multidisciplinary team approach (both intervention and timing) for patients who experience a staple line leak following sleeve gastrectomy, further study is necessary.

CONCLUSION

Management of post-LSG leakage with ES is advocated as it is a minimally invasive technique that effectively manages GSLL and has a comparable control success rate to definitive surgical treatment with a shorter hospital stay, early return of function, fewer complications, and a well-tolerable safety profile. In stable patients, it should be recommended as first-line therapy.

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