Impact of the Staple Line Invagination on the Complications Of Laparoscopic Sleeve Gastrectomy

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ABSTRACT

Background : *Laparoscopic sleeve gastrectomy is one of the most commonly performed procedures for treatment of morbid obesity. Staple line reinforcement was recommended by many bariatric surgeons in order to reduce early post operative complications related to the staple line as bleeding and leakage.* ***Aim of work :*** *Studying the impact of staple line invagination during laparoscopic sleeve gastrectomy on the incidence of bleeding and leakage and on gastric pouch volume in the early post operative period.* ***Patients and Methods :*** *Laparoscopic sleeve gastrectomy was performed in 145 morbidly obese patients who were classified randomly into 2 groups; group A : includes 58 patients with invagination of the staple line by continuous absorbable sutures (3-0 vicryl) and group B : 87 patients without invagination of the staple line.* ***Results :*** *There is no effect of stable line invagination on the incidence of bleeding or leakage or on the gastric pouch volume measured by CT volumetry 1 month post operatively. Higher BMI ≥49.7 kg/m^2 is associated with increased probability of bleeding incidence in patients with invagination of the staple line. Also, male gender were associated with increased incidence of bleeding, while the patients' ages or the presence of co-morbidities were not affecting the incidence of bleeding.* ***Conclusion:*** *There is no significant difference between the two techniques on the incidence of bleeding and leakage and on gastric pouch volume. Incidence of staple line bleeding was higher in male patients and in cases with BMI ≥49.7 kg/m^2 in patients underwent invagination of the staple line.*

Keywords: *Morbid obesity, bariatric surgery, laparoscopic sleeve gastrectomy, staple line invagination, staple line, reinforcement, gastric pouch volume*

INTRODUCTION

Laparoscopic sleeve gastrectomy is increasingly performed as a safe method for weight reduction in morbid obese patients. [1] It involves removal of most of the gastric mass leaving a small volume gastric tube thus reducing food intake. [2]

It was performed as a first step in a staged procedure for high risk patients before the definite bypass surgery but now, it became a primary procedure for morbid obesity. [1,3]

Early post operative complications as leakage and bleeding were the major drawbacks of this procedure with increasing incidence due to the resulting long staple line. [4]

In a trial to reduce these complications, many modifications were advised. Staple line reinforcement has been applied whether by oversewing the stable line with a suture or by buttressing the staple line with some materials, natural or synthetic. [3,5] However, no satisfactory data in the literature regarding the necessity of performing staple line reinforcement over leaving it without reinforcement. [5]

Aim of Work:

Studying the impact of staple line invagination during laparoscopic sleeve gastrectomy on the incidence of bleeding and leakage and on gastric pouch volume in the early post operative period. Also, finding the effect of the patients' age, sex, BMI or the presence of co-morbid factors on the incidence of bleeding.

PATIENTS AND METHODS

Study design:

This was a randomized prospective study conducted in Cairo University hospitals in the period between Jan 2014 and Jan 2015 after approval from the institutional review board and

obtaining informed consent from all patients including approval of protocol of treatment.

Patients:

One hundred and forty five morbidly obese patients were included and divided into 2 groups randomly: *Group A*: includes 58 morbid obese patients (40% of cases) with invagination of the staple line by continuous absorbable sutures (3-0 vicryl) during LSG. *Group B*: includes 87 morbid obese patients (60% of cases) without invagination of the staple line during LSG.

Inclusion criteria:

- Patients with BMI > 40 kg/m^2 without comorbidities or patients with BMI > 35 kg/m^2 with one or more co-morbidities.
- Ages of patients between 17 and 60 years old.
- Acceptance of surgical risks.

Exclusion criteria:

- Patients with BMI <35 kg/m^2 and patients with BMI 35-40 kg/m^2 without co-morbidities.
- Patients suffering any severe psychiatric illness.
- Patients with endocrinological causes of obesity.
- Morbid obese patients underwent any previous bariatric procedures.

Preoperative patient data were collected and recorded. History taking and full clinical examination were done. Routine investigations prior to bariatric procedures were done. All patients received intravenous antibiotics in form of 3rd generation cephalosporin ceftriaxone, subcutaneous unfractionated heparin and elastic bandage compression preoperatively.

- **Staple line reinforcement :**

After laparoscopic sleeve gastrectomy procedure, staple line reinforcement was done to Group (A) patients using running absorbable sutures (3-0 vicryl) taken in the Lembert fashion, inverting the entire staple line **(Figure 1)**.

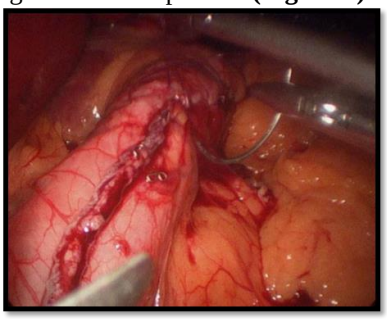

Fig. (1): Invagination using continuous sutures

After completion of the gastric transection the integrity of the staple line was tested by Methylene blue with the pylorus compressed by a surgical grasper. Methylene blue was injected (via the bougie) into the stomach and the staple line is inspected carefully to exclude macroscopic leak. A 18 Fr nelaton drain is inserted along the suture line. All trocar sites are closed with 0 Vicryl (Ethicon) using a suture passer (endoclose needle) to prevent abdominal wall hernias.

Postoperative follow-up :

Patients are cared for on the ward unless significant pre-existing cardiopulmonary disease, BMI >60 kg/m², diabetes, obstructive sleep apnea (OSA) or intraoperative complications indicate ICU care. Careful attention is needed for any general (i.e., pulmonary embolism or myocardial infarction) or procedure-related complication after surgery. Special attention must be taken to staple line hemorrhage, leaks, wound infection and stricture mainly at the gastroesophageal junction. In the postoperative period, all patients were given 3rd generation cephalosporins, anticoagulants, opioids, proton pump inhibitors and antiemetics.

Gastrographin meal was done to all patients in the 1st post operative day. All patients started oral fluids (if tolerated) after confirming that there is no leakage in the study. The drain was removed before discharging the patients. The patients are on a liquid diet only for two weeks that is then advanced to semi-solid diet and mashed food for another two weeks followed by poached food for two weeks. They are then advanced to a regular healthy diet.

Proton pump inhibitors are useful for several weeks in patients with dysphagia or reflux symptoms. Antihypertensive and oral hypoglycemic agents were continued and adjusted by primary care physician. Patients also received follow-up nutritional counseling for a protein-enriched diet and were given twice daily multivitamins, oral iron and calcium supplements. Patients were examined 4 weeks, 3 and 6 months postoperatively and then annually.

CT volumetry were done at the end of the first postoperative month to measure the volume of the gastric pouch.

Then, all data were statistically analyzed.

RESULTS

Mean age of the studied patients in group A was 35.05 ±10.17 years (ranged between 17-57 years), while in group B it was 35.06 ±11.06 (ranged 18-59 years). Females comprised 39 of cases of group A and 57 cases of group B. BMI in group (A) ranged between 36.6 and 62.5 Kg/m^2, while in group (B) ranged between 37.8 and 65.1 Kg /m^2. Co-morbidities were found in 17 patients of group A and in 29 patients of group B.

Table (1) shows the characteristics of the studied cases and its distribution between the two groups

Table 1: The basic characteristics of the studied cases

	Group A	***Group B***
Number of cases (%)	58 (40)	87 (60)
Mean ± SD age (range), years	35.05 ±10.17 (17-57)	35.06 ±11.06 (18-59)
Mean ± SD preoperative BMI (range), kg/m2	46.99±5.47 (36.6-62.5)	47.19±6.68 (37.8-65.1)
Female/male, n (%)	39(67.2)/19(32.8)	57(65.5)/30(34.5)
Co-morbidities, n (%)	17(29.3)	29(33.3)

All procedures were performed laparoscopically without conversions into open surgery and no intra-operative complications were encountered. Also, there was no mortalities.

Bleeding from the staple line was observed in 5 cases; 2 cases (3.4%) from group A and 3 cases (3.4%) from group B. There was no statistically significant relation between the occurrence of bleeding and invagination of the staple line (P=1.0).

There were no cases complicated with leakage in both groups.

Gastric pouch volume was measured 1 month post operative by CT volumetry (Fig. 2,3). In group A, the mean volume ± SD was 119.86 ± 44.43 cm^3 with a range (57.939-227.76)cm^3. In group B, the mean volume ± SD was 115.41 ± 36.914 cm^3 which were ranged between (60.294-209.508) cm^3. There was no effect of stable line invagination on the residual gastric pouch volume (P=0.872)

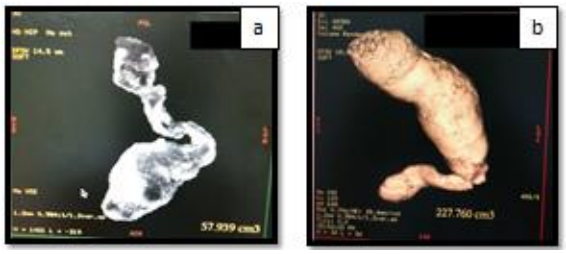

Fig. (2a,b): The least (a) and largest (b) gastric volumes in group A

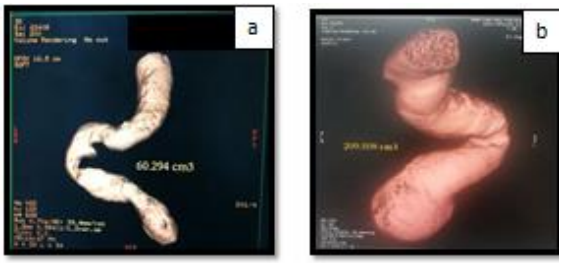

Fig. (3a,b): The least (a) and largest (b) gastric volumes in group B

Table (2) shows the differences between both groups regarding post operative outcomes (bleeding, leakage and gastric pouch volume)

Table (2) : differences between the 2 groups in operative outcomes

	Group A	*Group B*	*P value*
Bleeding, n (%)	2 (3.4%)	3 (3,4%)	1.0 (non-significant)
Leakage, n (%)	0	0	0
Gastric pouch volume, mean± SD (range), cm^3	119.86±44.43 (57.939-227.76)	115.41±36.914 (60.294-209.508)	0.872 (non-significant)

p< 0.05= significant

Bleeding occurred in 2 cases in group A with a mean age 33 years and in 3 cases in group B with mean age 36 years. Non-signifcant P values were found indicating that, there is no effect of age on the bleeding incidence. (Table 3)

Regarding the effect of BMI on the incidence of bleeding, it was found that, increase in BMI is associated with increase in bleeding incidence in patients with invagination of the staple line (P=0.023). (Table 3)

Table (3) : The relation between bleeding incidence and age & BMI of the patients

No. of cases / total		*Group A*	*Group B*
		2/58	3/87
AGE	**Mean age (years)**	33	36
	P-value	0.865 (non-significant)	0.650 (non-significant)
BMI	**Mean BMI (kg/m^2)**	58.6000	50.6000
	P-value	0.023 (significant)	0.240 (non-significant)

p< 0.05= significant

Bleeding was encountered more in male patients as noted in 4 cases (8.2%) while occurred only in 1 female patient (1%). It was found that male gender was significantly more liable to bleeding than females (P=0.045). (Table 4)

Table (4) : The relation between bleeding and the patients' gender

Gender	*Count and Percentage*	*Bleeding*		*Total*	*P value*
		No	**Yes**		
Male	**Count**	45	4	49	
	Percentage within gender	91.8%	8.2%	100%	0.045
Female	**Count**	95	1	96	significant
	Percentage within gender	99%	1%	100%	

p< 0.05= significant

Bleeding occurred in 5 patients; in group A, 2 patients were not diabetic or hypertensive, while in group B, 3 patients (2 patients of them were hypertensive), But more patients are needed to achieve a definite conclusion about the effect of DM and HTN on the bleeding incidence.

DISCUSSION

Laparoscopic sleeve gastrectomy has become a first choice procedure for morbid obesity among large number of surgeons and patients due to its relative technical simplicity and fewer complications rate in comparison with other bariatric procedures [6].

In spite of providing good results in the short-term and long-term periods with gaining popularity worldwide [6,7], there is still a reported incidence of serious complications as leakage or bleeding from the staple line [8].

The rate of complications is variable between different surgeons [9]. Gumbs et al. reported the

incidence of complications to 646 patients post laparoscopic sleeve gastrectomy including leakage (0.9%), strictures (0.7%), postoperative bleeding (0.3%) and mortality (0.6%) [10].

The main early and life threatening complications are bleeding from the staple line and gastric leakage [11]. The sleeve gastrectomy, having the longest gastric staple line of any procedure and is the closest to the lesser curvature blood supply, may therefore be more prone to bleeding intraoperatively and postoperatively [12].

Leakage, being a serious complication that is usually proximal and result in significant difficulties, may necessitates multiple reoperations. Post sleeve gastrectomy leak seems more difficult to resolve than other bariatric surgeries because of the resulting high gastric pressure and acid and bile content in the gastric sleeve remnant [13].

Staple line reinforcement has been suggested to reduce these postoperative complications [14].

In this study we compared bleeding and leakage incidence and gastric pouch volume measured by CT volumetry 1 month after operation between (58 patients with staple line invagination by continuous suturing) and (87 patients without invagination) during laparoscopic sleeve gastrectomy. (both groups are matched regarding age, gender, BMI and co-morbidity).

Results showed that there were no cases of leakage in both groups. Bleeding occurred to 2 patients (3.4%) in group A and 3 patients (3.4%) in group B. Cases of bleeding are 4 males and 1 female. Mean gastric pouch volume 1 month after operation is 119.86 (± 44.43) cm^3 in group A and 115.41 (± 36.914) cm^3 in group B. The results showed no significant difference between two techniques on the incidence of bleeding, leakage and on gastric pouch volume.

In a systematic review done by Knapps et al. on 2013, it was found that there is no effect of stable line reinforcement on the incidence of bleeding and leakage [3].

On the contrary, other studies were done by Karakoyun et al., Durmush et al. and Choi et al. on 2015, 2014 and 2012, respectively, and concluded that, staple line reinforcement decreases post operative bleeding and leaks [2,15,16].

By a study done by Aggarwal et al. on 2013, it was reported that, staple line oversewing resulted in reduction of leakage but did not affect the incidence of bleeding [17].

Another study was done by Albanopoulos et al. on 2015 revealed that, the incidence of intraoperative complications as hematoma formation is more frequent with staple line oversewing while no effect on post operative complications [18].

The results also showed that male gender was significantly liable to bleed more than female gender as documented in 4 male patients (8.2%) and in 1 female patient (1%) with a P value (0.045). This is may be explained by the thicker gastric tissues in males more than females.

Albanopoulos et al. on 2015, Aggarwal et al. on 2013 and Al Hajj and Haddad on 2013 reported that, there was no relation between bleeding incidence and the patient gender [17,18,19].

In our study, we found that there was no effect of age of patient on the incidence of bleeding from the staple line. This was consistent with studies done by Aggarwal et al. on 2013 and Al Hajj and Haddad on 2013[17,19].

In this study, BMI ≥49.7 kg/m^2 of patients was found to be significantly related to the bleeding incidence as observed in group A (staple line invagination) with (P=0.023), while it was not affecting the patients of group B (P=0.240).

Other studies did not reveal strong relation between the BMI of the patients and the incidence of bleeding from staple line post laparoscopic sleeve gastrectomy[17,19].

CONCLUSION :

There is no significant difference between staple line reinforcement by continuous suturing with vicryl 3-0 or not, on the incidence of bleeding, leakage or on gastric pouch volume that was measured 1 month post operatively. Male gender was significantly liable to bleed more than female gender and increased BMI ≥49.7 kg/m^2 is associated with increased probability of bleeding incidence in patients with invagination of the staple line. Also, no effect of patients age on the bleeding incidence.

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