

# Laparoscopic Sleeve Gastrectomy. Is There a Need to Reinforce the Staple-line?

*Omar Ayed Al-Shawabkeh MD\*, Talal Mustafa Al-Jalabneh MD\*, Ibrahim Mohammed Al-Gwairi MD\*, Omar Yahiya Abu Zaytoon MD\*, Wael Al-Na'ssan MD\*.*

## ABSTRACT

**Objectives:** To assess the effect of staple-line reinforcement on the rate of staple-line leak and bleeding post laparoscopic sleeve gastrectomy.

**Methods:** In this retrospective study we analyzed 326 patients who underwent laparoscopic sleeve gastrectomy at King Hussein Medical Center between January 2010 and April 2016. Staple-line reinforcement using continuous lembert suture method was used in 229 patients (reinforcement group) while it was not used in 97 patients (non-reinforcement group). Patient characteristics, comorbidities, duration of surgery, hospital stay, as well as complications including staple-line leak and bleeding after surgery were obtained, analyzed and compared between the reinforcement and non-reinforcement groups.

**Results:** Patients of the reinforcement group had baseline characteristics and comorbidities similar to those in the non-reinforcement group but had two cases of leak (0.87%) and two cases of bleeding (0.87%). While patients of the non-reinforcement group had one case of leak (1.03%) and five cases of bleeding (5.15%). Although there was no significant difference regarding leak rate between the two groups ( $P = 1.000$ ), bleeding rate was significantly decreased in the reinforcement group ( $P = 0.026$ ). One of the patients with leak died in the reinforcement group while there were no deaths in the non-reinforcement group.

**Conclusion:** According to our results; reinforcement of the staple-line by lembert suture in laparoscopic sleeve gastrectomy reduced the incidence of staple-line bleeding but was associated with prolongation in operation time compared with no staple-line reinforcement. While the difference in leak rate between the two groups was not significant.

**Key words:** gastric leak, Bleeding, Staple-line reinforcement.

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### Introduction

According to the data that was published by the World Health Organization in 2014, <sup>(1)</sup> 39% of the world population over 18 years of age is overweight and 14% of them are obese. This has contributed to a global increase in obesity related co-morbidities, such as type 2 diabetes, hypertension, and cardiovascular disease.

Laparoscopic sleeve gastrectomy (LSG) is one of the most common bariatric procedures performed worldwide, and its prevalence continues to rise. 'Early findings from prospective and retrospective studies have been encouraging, with the potential advantages, including excellent weight loss outcomes, resolutions of co-morbidities, relative ease of the technique, avoidance of a

From Department of:

\*Department of Surgery, division of upper GI, laparoscopy, and bariatric surgery.

King Husain Medical Center, Royal Medical Services, Amman, Jordan.

Royal Medical Services, 0772356644, shawabkeh\_omar@yahoo.com. Amman, Jordan.

foreign body or need for adjustment, short operative time, and immediate restriction of caloric intake.<sup>(2)</sup>

Post-operative bleeding and gastric leak are two of the most serious complications of sleeve gastrectomy. 'While the incidence of both complications is relatively low (1–6 % for bleeding, 1–6 % for leak), the results can be both clinically devastating for the patient and expensive for the facility.'<sup>(3)</sup>Bleeding can be from the divided short gastric vessels, the staple line on the gastric surface or from the detached omental surface. It can be managed in some conditions conservatively but usually reoperation is needed. On the other hand, management of gastric leak is more difficult as it includes long hospital stay and sometimes stent insertion. Fortunately the incidence of leaks after LSG is decreasing from a generally accepted rate of 2.5% to 1.1% leak rates nowadays due to the increased experience and the development of new techniques.<sup>(4,5)</sup>At present, there are variable options for reinforcing gastric staple lines aiming to decrease staple-line complications (leak & bleeding) rate, such as; suturing the staple lines, using buttressed staplers or having linear staplers with shorter staple height. However, some surgeons choose not to reinforce staple lines either because of the insufficient conclusive published benefit in current literature and/or concern over the cost. The aim of the present study is to determine whether staple line reinforcement (SLR) with lembert's suture is effective when comparing it with no reinforcement.

## Methods

This retrospective study analyzed 326 patients who underwent LSG between January 2010 and April 2016 at King Hussein Medical Center. LSG was performed in patients with a body mass index (BMI) of more than 40 kg/m<sup>2</sup>, and those with a BMI between 35 and 40 kg/m<sup>2</sup> in the presence of comorbid diseases. Patient characteristics, including age, gender, BMI, and comorbid conditions, operative time, hospital stay (from the operative day till the discharge day), and post-operative complications (any reported staple-line bleed or leak from the operative day till day 30 post operatively) were all; obtained

from the medical records of the patients, analyzed and compared between the two groups (Tables I,II and III).

After obtaining the approval from the Royal medical services ethical and research committee, data was obtained from the medical records of patients who underwent LSG in our center, and patients were included into two groups according to reinforcement of staple line with continuous lembert suture or not during surgery; the reinforcement group (RG) comprised of 229 patients who underwent LSG with continuous lembert suture as a form of staple-line reinforcement, and the non-reinforcement group (NRG) comprised of 97 patients who underwent LSG without any form of staple-line reinforcement. LSG procedures were performed by the same surgical team. The choice of (reinforcement or not) in the patients was according to the surgeon preference.

In this single-center, retrospective study we compared reinforcing the staple line (RG) and not reinforcing it at all (NRG). The trend in our center was to reinforce the staple line since we started doing LSG in 2006, but in the last two years we started to choose not to reinforce the staple line as multiple meta-analysis studies<sup>(3)</sup> showed no significant difference between the two choices regarding leak and bleeding rate. So that we end up with 229 patents in the RG, and 97 patients in the NRG.

All patients had pre-operative investigations and underwent a multidisciplinary evaluation by the surgeon, dietitian, endocrinologist and psychologist.

Under general anesthesia, the patient was carefully placed and secured to the operation table in reverse Trendelenburg lithotomic position and the surgeon performed the surgery whilst standing in between the legs of the patient. The procedure was performed through 4 trocars: (one 15 mm trocar and one 12 mm trocar) for stapler handle and instruments and one 12 mm trocar for the camera, and one 5 mm trocar for liver retractor. The omentum was liberated from the greater curvature with a vessel-sealing device (LigaSure Atlas) starting 5 cm proximal to the pylorus. (Covidien) staplers were used to divide the stomach approximately 5 cm proximal to the pylorus,

targeting 1 cm lateral to the esophagogastric junction after a 40 Fr orogastric tube (bougie) was passed trans orally by the anesthesiologist and oriented along the lesser curve. In RG, the line of staples was reinforced with a manual, lembert absorbable, PDS 2–0 suture (by inverting the staple line to the inside of the stomach). In NRG, no reinforcement method was used. The resected specimen then removed through the 15-mm port. A 16-Fr Redivac drain was placed under and along the remaining stomach.

30 min prior to the surgical incision antibiotic prophylaxis was given in addition to 3 doses postoperatively. Patients were kept on thromboprophylaxis along the duration of hospitalization post operatively. Furthermore, on the first day post operatively, all patients had water soluble gastrografen study.

postoperative complications such as; staple-line bleeding and leak with the management

of each complication were all obtained, analyzed and compared between the two groups. Regarding staple-line bleeding the decision to transfuse and/or do laparoscopic re-exploration was based on a combination of clinical evaluation, changes in hemoglobin levels, and hemodynamic monitoring. Data regarding complications were summarized according to patient risk factors, time of occurrence after surgery, presenting signs and symptoms, type and duration of management. (Tables IV, V)

Continuous variables were expressed as mean  $\pm$  standard deviation; categorical variables were expressed as percentages. Statistical analysis for the categorical variables was performed using the Fisher's exact test. While for continuous variables, comparisons were performed using unpaired t-test. Level of statistical significance was defined as  $P < 0.05$ .

**Table I:** Baseline characteristics of 326 patients that had laparoscopic sleeve gastrectomy

	RG (n=229)	NRG (n=97)	P value
Age (yr.) {range (mean $\pm$ -SD)}	16-60(32.79 +/- 9.72)	15-62(33.44 +/- 10.68)	0.593 <sup>a</sup>
Male, n (%)	59(25.8)	27(27.8)	0.683 <sup>b</sup>
Female, n (%)	170(74.2)	70(72.2)	0.683 <sup>b</sup>
BMI(kg/m <sup>2</sup> ) {range(mean $\pm$ -SD)}	35-62 (44.4 +/- 4.2)	36-61 (44.7 +/- 4.6)	0.566 <sup>a</sup>
Hospital stay (d) {mean $\pm$ -SD}	3.08 +/- 0.86	3.15 +/- 0.93	0.476 <sup>a</sup>
Duration of surgery (min) {mean $\pm$ -SD}	90.87 +/- 19.37	82.91 +/- 18.55	0.0007 <sup>a</sup>

RG: Reinforcement group; NRG: Non-reinforcement group; BMI: Body Mass Index. <sup>a</sup> Unpaired t-test used to compare continuous measures between groups; <sup>b</sup> Fisher's exact test used to compare categorical measures between groups.

**Table II:** Comorbidities of the patient's n (%)

	RG (n=229)	NRG (n=97)	P value <sup>a</sup>
Hypertension, n (%)	35(15.2)	14(14.4)	1.000
Type 2 diabetes mellitus, n (%)	38(16.5)	15(15.4)	0.870
Sleep disorders, n (%)	26(11.3)	10(10.3)	0.849
Hyperlipidemia, n (%)	32(13.9)	12(12.3)	0.859
Bronchial Asthma, n (%)	15(6.5)	7(7.2)	0.812

<sup>a</sup> Fisher's exact test used to compare categorical measures between groups.

**Table III:** Comparison of postoperative complications

	RG (n=229)	NRG (n=97)	P value <sup>a</sup>
Staple-line leaks, n (%)	2(0.87)	1(1.03)	1.000
Staple-line bleeding, n (%)	2(0.87)	5(5.15)	0.026

<sup>a</sup> Fisher's exact test used to compare categorical measures between groups.

**Table IV:** Patients with acute staple-line le

Age	Sex	BMI (kg/m <sup>2</sup> )	Prior surgery	Time of occurrence after surgery (weeks)	Symptoms	Treatment	Group	Total treatment duration
32	F	44	Yes	1 <sup>st</sup> day	Fever, Tachycardia	Re-laparoscopy, drainage, suture repair.	NRG	7 days
47	F	61	Yes	25 <sup>th</sup> day	Fever, abdominal Pain, tachycardia	Percutaneous drainage, stent insertion, TPN	RG	45 days
23	F	58	No	1 <sup>st</sup> day	Fever, tachycardia	Re-laparoscopy, drainage, suture repair.	RG	8days

\*M male, F female, BMI body mass index, TPN total parenteral nutrition,

**Table V:** Patients with acute staple-line bleeding

Age (yr.)	Sex (M/F)	BMI (Kg/m <sup>2</sup> )	Prior surgery	Time of occurrence after surgery	Treatment	Group	Total treatment duration (day)
45	F	49	Yes	1 <sup>st</sup> day	Blood transfusion	RG	4
26	M	48.9	-	Day of surgery	Laparoscopic re-exploration, identification of bleeding site (stapler-line), hemostasis secured using endoclip.	RG	4
42	F	43.2	Yes	1 <sup>ST</sup> day	IV fluid	NRG	4
35	F	50	-	1 <sup>ST</sup> day	Blood transfusion	NRG	6
36	M	48.7	-	1 <sup>st</sup> day	Laparoscopic re-exploration, identification of bleeding site (stapler-line), hemostasis secured using endoclip.	NRG	4
23	F	45.8	-	1 <sup>ST</sup> day	IV fluid	NRG	4
20	F	44.29	-	1 <sup>ST</sup> day	Laparoscopic re-exploration, identification of bleeding site (stapler-line), hemostasis secured using endoclip.	NRG	5

\*M male, F female, BMI body mass index

## Results

Generally there were no significant differences between the RG and NRG regarding patient's characteristics ( $P > 0.05$ ) including: age, gender, BMI and hospital stay while the mean of operation time in RG was higher than in NRG (90.87 minute in RG and 82.91 minute in NRG), the difference was statistically significant ( $P=0.0007$ ) (Table I). Of the 326 patients who were included in the study, 86 were male and 240 were female (male/female ratio was nearly the same in the two groups) ( $P>0.05$ ). There were 5 different comorbidities in each of the two groups and the most common comorbidities were

hypertension (14.8%) and diabetes mellitus (15.9%) in both groups, and there were no differences between the two groups regarding rates of comorbidities ( $P > 0.05$ )

Staple line leak developed in two patient (0.87%) in the RG and one patient (1.03%) in the NRG ( $P=1.000$ ). All of the three patients with leak were females and presented with fever and tachycardia. Two leaks were at the proximal part of the stomach; the other was near the antrum. Two of the leaks were observed on the 1<sup>st</sup> day post-op and was treated by performing a Re-laparoscopy and suture repair, those patients were discharged 7-8 days later with no leak. while the third case presented on 25<sup>th</sup> day post-operatively

and the gastrografen study showed a leak at the proximal stomach, a double-contrast abdominal computed tomography scan showed an intra-abdominal 4\*5 cm collection, radiographic percutaneous drainage was performed for the patient, stent insertion, and total parenteral nutrition. Having prolonged hospitalization period (45days) the patient was on thromboprophylaxis, despite that, she developed pulmonary embolism and died.

Staple-line bleeding developed in two patients (0.87%) in RG and five patients (5.15%) in NRG ( $P=0.026$ ) (Table III), four patients with bleeding had been managed conservatively (two of them with IV fluid, the other two with blood transfusion), while the other three patients received blood transfusion preoperatively and had laparoscopic re-exploration where the site of bleeding was identified and hemostasis was secured using endoclip.

There was statistically significant decrease in the staple-line bleeding rate post operatively in patients of the RG in comparison with the patients of the NRG ( $P=0.026$ ), however the rate of staple-line leak didn't show significant difference between the two groups ( $P=1.000$ ) (Table III).

## Discussion

Staple line leak is the most common cause of major morbidity and mortality after LSG,<sup>(6)</sup> with a mean incidence in the literature around 2.3%.<sup>(7,8)</sup> so that variable efforts has been advocated by many surgeons in order to minimize this devastating complication.

Causes of leak are usually due to mechanical and/or ischemic factors. Cutting in irregular zigzags and stapler misfiring, are two of the mechanical factors, and usually appear within 2 days of surgery (early). Ischemic factors including aggressive dissection resulting in improper vascularization, and thermal injuries to the gastric tube by energy devices (Harmonic, Ligasure), those usually appear on day 5-6 post operatively (intermediate).<sup>(6)</sup> So that, surgeons must handle the tissues gently when using ultrasonic devices and staplers to avoid distal stenosis and leak<sup>(9,10)</sup> Some surgeons sustain steady compression on the staple device before firing as they think that the tissue fluid will be washed out and the

vessels collapse in this way.<sup>(11)</sup> Our team too perform these precautions. Regarding the three cases of leak in our study, two of them appeared on the 1<sup>st</sup> day post operatively while the third case presented to us on the 25<sup>th</sup> day post operatively.

'The incidence of staple line bleeding has been reported to be (0-8.7%).'<sup>(12)</sup> 'Bleeding may originate from different sites; hemorrhage can be intraluminal, from the staple lines; or intraperitoneal, either from the staple lines, vessels sectioned during dissection, or from the abdominal wall incisions.'<sup>(8)</sup> 'One should not perform blunt dissection and, instead, should make a small hole first with laparoscopic dissector and then cut the vessel with energy device under direct vision. Escaping from much tension between the stomach and spleen is important to avoid tearing the spleen.'<sup>(12)</sup> Our team also takes these precautions while performing dissection.

Multiple techniques have been proposed to reinforce the staple line in order to decrease the risk of stable line complications. 'Whether these techniques have any impact for reducing the risk is still controversial and the randomized trial to definitely estimate the effectiveness of each technique might be impossible.'<sup>(12)</sup> These techniques comprise oversewing the staple line, seroserosal suture invagination of staple line, the application of fibrin glue or sealants, and more recently the use of buttressing materials (buttress stapler) such as biologic materials and synthetic absorbable polymers.<sup>(8,12)</sup> According to the 5th international consensus summit on sleeve gastrectomy 2014,<sup>(13)</sup> 73% of the surgeons experienced in LSG surveyed reinforced the staple line; In fact, 45% of expert use buttress materials and 28% oversew the staple line. In our study we used the lembert (invagination) suture in the RG which includes the collagenous submucosal layer with serosal apposition.

Of all leaks, 75%-100% were seen in the proximal 1/3 of the stomach, particularly at the level of the esophagogastric junction while 6.8%-14.3% of them occurred in the distal 1/3 of the stomach.<sup>(14)</sup> In our study; two cases of the leaks occurred in the proximal third of the stomach, while the third one occurred in the lower portion of the stomach.

A meta-analysis including 112 studies and a total of 9991 patients by Parikh and authors<sup>(15)</sup> reported the incidence of leak to be around 2.2% and bougie size had been identified as the only significant prognostic factor. It also reported that Utilizing of bougie size  $\geq 40$  Fr decreased leak rate without impacting weight loss up to 3 years.<sup>(15)</sup> 'Although it is inconclusive, the optimal bougie size should be more than 40 Fr for decreasing risk of leak and less than 50 Fr for effective and sustained restrictive function based on the available evidence so far.'<sup>(12)</sup> In our series we used 40 Fr sized bougie in all patients.

According to The Cochrane Database of Systematic Reviews 2015,<sup>(8)</sup> five systematic reviews and a large meta-analysis have been published in literature to study the leak, bleeding rate and the effect of staple line reinforcement in LSG.<sup>(3,4,15-18)</sup> Two of these reviews,<sup>(4,16)</sup> and one large meta-analysis<sup>(3)</sup>, included studies from large series and from comparative trials, found a decrease in the leak rate and general complications with the use of reinforcement Methods (buttress staplers and oversewing).<sup>(3,4,16)</sup> While the other three reviews showed a lack of statistical difference in leak rate, overall morbidity, or mortality rate in LSG with or without staple-line reinforcement<sup>(15,17,18)</sup>

In our study, staple-line bleeding rate was significantly reduced in the RG in which lembert suture was the method of reinforcement, while the leak rate was not statistically different between the RG and NRG. Our results are similar with many studies that reported a reduced rate of staple-line bleeding and general complication when using reinforcement material in LSG.<sup>(19-22)</sup> For example: Stamou *et al*<sup>(19)</sup> demonstrated in a prospective comparative study that staple-line reinforcement with bovine pericardium strips (PSD) in LSG significantly reduced the occurrence of bleeding from the staple line and intra-abdominal collections while no significant difference was found between the RG (with PSD) and NRG in leak rate.

Moy *et al*<sup>(20)</sup> reported that buttressing the staple line with a reinforcement synthetic material (Gore Seamguard) reduced the risk of perioperative bleeding and may reduce the risk of staple line failures resulting in leak. Also Rogula *et al*<sup>(21)</sup> compared reinforcement

techniques using suture on staple-line in LSG with no reinforcement of staple line, the study concluded that Lembert's suture reinforcement technique was associated with less leak rate in comparison to non-reinforced staple-line. Furthermore full consensus (100%) was achieved on the reduction of bleeding rate with the use of staple line reinforcement by the expert panelist (surgeons with the most LSG experience), according to the International Sleeve Gastrectomy Expert Panel Consensus that represented the best practice guidelines based on experience of 12,000 cases of LSGs.<sup>(22)</sup> Nevertheless many studies demonstrated that LSG is safe without staple line reinforcement and avoids additional costs for reinforcement materials.<sup>(15,17,18,23)</sup>

Finally the first report from the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) 2016 studied the impact of different surgical techniques on outcomes in LSGs and demonstrated that staple-line reinforcement (SLR) cases were associated with higher leak rates and lower bleed rates compared to no SLR at patient level.<sup>(24)</sup>

Early diagnosis and treatment of staple line complications (leak and bleeding) are essential in order to reduce morbidity and mortality, since death may result if leak is not identified and treated rapidly. In our center, an upper GI series was performed for all patients, in which water-soluble gastragrafin was administered orally to the patient on postoperative day 1. In addition to that patients with suspected SLL also had repeated the gastrografen study along with double-contrast abdominal CT scan. Regarding the patients who developed complications among our study, one patient in whom a leak occurred died due to massive pulmonary embolism, and actually this patient presented to our unit on the 25<sup>th</sup> day post-operatively.

Certain patient risk factors may increase the possibility of staple-line complications. Most of the patients who developed complications in our study had a BMI $>44$  kg/m<sup>2</sup>. So that, high BMI is a possible risk factors for Staple line complications after LSG.

## Conclusion

The number of bariatric procedures is rising. Most dreadful complications after LSG include postoperative staple-line bleeding and leaks. Any technique that can decrease the staple line complications rate will reduce health-care costs and improve patient quality of life. In our study, both groups (RG and NRG) were comparable in terms of baseline characteristics and comorbidities. The difference in leak rate between the two groups was not statistically significant, while bleeding rate was significantly less in the RG. So that reinforcement of the stable line may be necessary during LSG, although staple line leaks may still occur, and these methods increase the cost of surgery and prolong the operation time, it still can significantly decrease the bleeding rate post operatively. Future larger prospective randomized trials are needed to determine the true effect of staple-line reinforcement on leak and bleeding rates and overall morbidity in LSG.

### Limitation

There are two limitations of this study as it was not a prospective randomized trial, instead of that it was retrospective comparison between two operative techniques, and the 229 patient whose staple lines were reinforced represented the larger part of the author's experience with LSG.

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