

OUTCOME OF REMODIFYING OMENTOPEXY TECHNIQUE WITH LAPAROSCOPIC SLEEVE GASTRECTOMY

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ABSTRACT

Background : Gastric obstructions (LSG) leaks and staple line bleeding are reported after laparoscopic sleeve gastrectomy. There is no ideal method or technique to avoid these mishaps. Modified omentopexy (OP) added to LSG to determine its effect on gastric leaks and other complications. The aim of this study was the assessment of safety & feasibility of omentopexy technique in Laparoscopic sleeve gastrectomy. The aim of this study was to assess the safety & feasibility of omentopexy technique in Laparoscopic sleeve gastrectomy. Methods: This Prospective Randomized controlled clinical trial study was conducted in zagazig university hospital including 32 patients with morbid obese who were admitted to General Surgery Department of Zagazig University hospitals, for intervention surgery with laparoscopic sleeve Gastrectomy during the period from July 2020 to August 2021 .Patients underwent a standardized preoperative assessment, including complete history, physical examination and psychological evaluation. Results: There was a highly statistically significant regarding decrease mean of Weight and BMI at six month postoperative compared to pre operative Laparoscopic sleeve gastrectomy with and without omental fixation group. Omentopexy may not change the outcome for laparoscopic sleeve gastrectomy in terms of gastrointestinal symptoms or weight loss results although it is associated with longer operative time. However, it may serve as an extra guard against leakage, bleeding, vomiting, and gastroesophageal reflux disease, manifested by the decreased incidence of these complications with that technique. Laparoscopic sleeve gastrectomy with omentopexy can be a feasible procedure for decreasing morbidity and gastric leak rate.

Keywords: Bariatric surgery; Laparoscopic sleeve gastrectomy; Omentopexy.

INTRODUCTION

LSG is the preferred and most commonly performed bariatric operation in the USA. The fear of staple line leaks associated with LSG still remains high. This is eluded to the fact that LSG creates an elevated intraluminal pressure secondary to partial or complete closed-loop condition within the functional pyloric and lower esophageal sphincters ⁽¹⁾.

Laparoscopic sleeve gastrectomy (LSG) has been increasingly performed as a primary and sole weightloss operation for morbidly obese patients. It has grown in popularity and become the dominant bariatric procedure during recent years by maintaining gastrointestinal continuity and being a relatively easy procedure ⁽²⁾.

Routine omentopexy in Laparoscopic sleeve gastrectomy proved to show remarkable efficacy in reducing postoperative leakage and bleeding rates in comparison with Laparoscopic sleeve gastrectomy with no omentopexy. This decreases patient's morbidity and mortality ⁽³⁾.

AIM OF WORK

The aim of this study was to assess the safety & feasibility of omentopexy technique in Laparoscopic sleeve gastrectomy

PATIENTS & METHODS

This Prospective Randomized controlled clinical trial study was conducted in zagazig university hospital including 32 patients with morbid obese who were admitted to General Surgery Department of Zagazig University hospitals, for intervention surgery with laparoscopic sleeve Gastrectomy during the period from July 2020 to August 2021.

Written informed consent was obtained from all participants and the study was approved by the research ethical committee of Faculty of Medicine, Zagazig University International review board IRB#:7512-

10-12-2020). The work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Inclusion criteria:

- Obese patient with body mass index $>40\text{kg/m}^2$, or $\text{BMI}>35\text{kg/m}^2$, with associated co-morbidity(hypertension, diabetes mellitus and hyperlipidemia)
- Failure of medical and conservative modality.
- Fit for surgery.

Exclusion criteria:

- Previous bariatric surgery.
- Patient unfit for general anesthesia.
- Lack of motivation.
- Mental incompetence and uncooperative patient .

Randomization was done by computer to allocate Patients in two groups according to the used technique

Group(A) , 16 cases operated with omentopexy technique.

Group(B), 16 cases operated without omentopexy technique.

Preoperative preparations

Patients underwent a standardized preoperative assessment, including complete history, physical examination and psychological evaluation. Upper gastrointestinal endoscopy, abdominal ultrasound examination, Doppler ultrasound of the veins of the lower extremities and spirometry were performed in all the subjects.

Preoperative laboratory evaluation should include the following: Complete blood count (CBC), Liver function tests, Renal function tests, Thyroid function tests, Lipid profile, Coagulation tests, Serum iron and total iron binding capacity (TIBC), Blood typing, Urinalysis

- **Radiological evaluation with abdominal ultrasound.**

- **Oesophago-gastro-duodenoscopy (OGD)** is routinely performed for reflux patient .

Study procedures

The procedure was performed under general anesthesia in a supine position). Creation of pneumoperitoneum was done using a small stab at the umbilical scar allowing the introduction of the veress needle; insufflation was done to establish carbon dioxide pneumoperitoneum up to 15 mmHg and then insertion of four ports was done. Devascularization of the greater curvature from the greater omentum from 2 cm proximal to pylorus to angle of His was done using ultrasonic harmonic scalpel or ligasure. Insertion of 36-Fr Bougie inside stomach through mouth was done. Johnson Stapler was introduced using at first green reload 60–4.8 mm, and then we used another green reload if needed, and stapling was continued using gold and blue reloads 60–3.8mm and 3.5, respectively, till the end. Methylene blue test is done to ensure sealed staple line and no intraoperative leakage.

Group I: No omental fixation was done, but if bleeding occurs, we apply titanium clips to the site of bleeding

Group II: Omental fixation by full gastric thickness stitches using PDS 2–0 or vicryl 2–0 by simple continuous sutures till the antrum only was done

Finally, insertion of an intraabdominal drain was done

Postoperative

Consistent and reliable postoperative care with support staff familiar with bariatric patients is essential.

- 1- All patients were given intravenous fluids 35 ml/kg body weight during the first postoperative day then according to their fluid chart in the subsequent days.
2. Ryle tube was removed after the intestinal movement was regained as evidenced by hearing the intestinal sound by the stethoscope.
- 3- Early ambulation was advised on first postoperative day.
- 4- H_2 blockers were given intravenously early postoperative and continued for one week after discharge. While proton pump inhibitors were given, only if there were postoperative bleeding from the Ryle tube
- 5- 3rd generation cephalosporin intravenously injection was continued postoperatively for additional 2 days.
- 6- Postoperative pain was controlled by diclofenac sodium 15 mg intramuscular injection whenever it was needed.
- 7- Drinking clear fluids was begun on the third postoperative day.
- 8- Drains were removed after making sure that there was no leak, in the 6th postoperative day.
- 9- The patients were discharged 4-8 days postoperative according to Postoperative course.

Follow-up.

Patients require regular and frequent follow-up in clinic. They are seen at 1 week, 1 month, 3 months, 6 months, 12 months, 24 months, and then annually after the first year. Clinic visits consist of weight and nutritional monitoring as well as dietary counseling and psychology referral as needed. The importance of long-term follow-up with a surgeon is highly stressed. Early complications as (bleeding, Leakage, Infection) and late complications as (Dumping, stenosis, Bowel obstruction).

STATISTICAL ANALYSIS

The collected data was entered to and analyzed by computer using Statistical Package of Social Services, version 25 (SPSS). Results were presented by tables and graphs. Quantitative data was presented as mean and standard deviation. Qualitative data was presented as frequencies and proportions. Pearson Chi square test (χ^2) and fisher’s exact were used to analyze qualitative independent data. P value of ≤ 0.05 was taken as significant.

RESULTS

Table (1): Demographic data of the studied patients.

Variables	Laparoscopic sleeve gastrectomy				t-test	P-value
	with omental fixation, n.16		without omental fixation, n.16			
Age per years						
• Mean \pm SD	32.4 \pm 8.4		33.2 \pm 7.8		0.27	0.79
• Range	(22-50)		(23-49)			
Sex	N	%	N	%	0.14	0.71
• Females	10	66.7	9	60.0		
• Males	6	33.3	7	40.0		

χ^2 Chi square test t= t test of sig p>0.05 non significant

This table shows that the mean age of Laparoscopic sleeve gastrectomy with omental fixation patients was 32.4 \pm 8.4years and ranged from (22—50) and mean age of Laparoscopic sleeve gastrectomy without omental fixation patients was 33.2 \pm 7.8 years and ranged from (23—49), the difference statistically nonsignificant .Females dominant in both groups were 66.7% with omental fixation patients and 60.0% without omental fixation the difference statistically nonsignificant.

Table (2): Postoperative complications of the studied patients.

Postoperative complications			Laparoscopic sleeve gastrectomy		f P-value
			with omental fixation, n.16	without omental fixation, n.16	
bleeding	yes	n	1	1	-
		%	6.25%	6.25%	
	No	n	15	15	
		%	83.75%	83.75%	
Leakage	yes	n	0	1	0.99 (NS)
		%	0.0	6.25%	
	No	n	16	15	
		%	100.0%	83.75%	
Twisting	yes	n	0	1	0.99 (NS)
		%	0.0	6.25%	
	No	n	16	15	
		%	100.0%	83.75%	

f=Fisher exact test p>0.05 non significant

This table shows statistically insignificant difference between Laparoscopic sleeve gastrectomy with omental fixation patients and with- out omental fixation patients regard their Intraoperative complications p>0.05.

Table (3): Anthropometric measures Six months post- operative of the studied patients.

Anthropometric measures	Laparoscopic sleeve gastrectomy		t-test	P-value
	with omental fixation, n.16	without omental fixation, n.16		
Weight 6 months post operative Mean ± SD range	84.733±6.3 76-95	85.6±5.43 76-94	0.403	0.690
BMI 6 months post operative Mean ± SD range	31.14±1.926 27.78-34.16	32.646±2.32 27.58-36.79	1.937	0.063
% of Weight loss 6 months post operative Mean ± SD range	40.513±3.52 35.81-47.47	39.677±3.86 31.88-48.99	0.62	0.54

t= t test of sig (HS) p<0.001 significant

Table indicates that patients Weight, BMI, 6 months post-operative of Laparoscopic sleeve gastrectomy with omental fixation lesser than patients Weight , BMI, 6 months post-operative of Laparoscopic sleeve gastrectomy with- out omental fixation but the difference statistically insignificant p>0.05.

Table (4): Anthropometric measures 1 year post -operative of the studied patients.

Anthropometric	Laparoscopic sleeve gastrectomy		t-test	P-value
	with omental fixation, n.16	without omental fixation, n.16		
Weight 1 year post -operative Mean ± SD range	64 ±4.88 56-72	63.6±3.2 59-71	.265	0.79
BMI 1 year post- operative Mean ± SD range	23.52±1.5 20.15-26.13	24.241±1.13 21.77-26.17	1.485	0.15

% of Weight loss 1 year post - operative Mean ± SD range	55.042±3.23 48.94-60	55.19±2.09 51.45-59.73	0.14	0.88
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t= t test of sig (HS) p<0.001 significant

Table indicates that there was statistically insignificant difference of patients Weight, BMI, percent of Weight loss one year post-operative of Laparoscopic sleeve gastrectomy with omental fixation and Laparoscopic sleeve gastrectomy with- out omental fixation p>0.05.

DISCUSSION

Laparoscopic sleeve gastrectomy is the preferred and most commonly performed bariatric operation in the United States. The fear of staple line leaks associated with Laparoscopic sleeve gastrectomy still remains high. This is contributed to the fact that Laparoscopic sleeve gastrectomy creates an elevated intraluminal pressure secondary to partial or complete closed-loop condition within the functional pyloric and lower esophageal sphincters. Laparoscopic sleeve gastrectomy is performed in a fundamentally similar fashion across the United States ⁽¹⁾.

Omentopexy during Laparoscopic sleeve gastrectomy, is one method amongst others that has been hypothesized to reduce the various complications Laparoscopic sleeve gastrectomy has been associated with, for example, gastric leaks, gastric obstruction due to strictures or rotation, and gastrointestinal complaints. A consensus has not been reached currently regarding this hypothesis, as current studies show mixed results, some favorable, while others no significant outcome ⁽⁴⁾.

This Prospective Randomized controlled clinical trial study was conducted in zagazig university hospital including 30 patients with morbid obese who were admitted to General Surgery Department of Zagazig University hospitals, for intervention surgery with laparoscopic sleeve Gastrectomy during the period from July 2020 to August 2021 to assess the safety & feasibility of omentopexy technique in Laparoscopic sleeve gastrectomy

The current study showed that the mean age of Laparoscopic sleeve gastrectomy with omental fixation patients was 32.4 ± 8.4years and ranged from (22-50) and mean age of Laparoscopic sleeve gastrectomy without omental fixation patients was 33.2 ± 7.8 years and ranged from (23-49), the difference statistically nonsignificant. Females dominant in both groups were 66.7% with omental fixation patients and 60.0% without omental fixation the difference statistically nonsignificant. Which in agreement with the study of **AlHaddad et al., (5)** who reported that the mean age was 33.7 ± 10.4 for omental group and 37.4 ± 10.9 for non- omental group with no significant difference, while regarding gender there was a significant difference between both groups; Male sex represents 9 (12.9%) cases in omental group and 26 (37.1%) in non- omental group while the female sex was 61 (87.1%) patients 44 (62.9%) patients of group 1 and 2, respectively.

Sharma & Chau ⁽¹⁾ in their study of total 737 patients undergoing Laparoscopic sleeve gastrectomy from 2012 to 2017. Out of those, 370 underwent Laparoscopic sleeve gastrectomy with omentopexy and 367 underwent Laparoscopic sleeve gastrectomy without omentopexy, the mean age was 45.1 ± 12.58 and 45.5 ± 10.5 respectively with no significant difference (p= 0.75), males were 167 and 155 (P = 0.24), females were 203 and 212 respectively with no significant difference (P=0.45).

The current study showed that there was a statistically insignificant difference between Laparoscopic sleeve gastrectomy with omental fixation patients and with- out omental fixation patients regard their postoperative complications (such as bleeding, leakage, twisting) p>0.05.

Arslan et al. ⁽⁶⁾ suggest that omentopexy stabilizes the posterior stomach wall and can prevent the gastric twist, which is a functional cause of gastric stenosis.

Sharma and Chau, ⁽¹⁾ found that gastric disruptions was reported in 7 out of 367 non-omentopexy patients (1.9%), while no gastric disruptions was seen in 370 omentopexy patients (P = 0.01). Bleeding was seen in 1 omentopexy versus 2 non-omentopexy patients (P = 0.6). Venous thromboembolism was reported in 2 omentopexy versus 1 non-omentopexy patients (P = 1). Wound infection was seen in 1 omentopexy versus 2 non-omentopexy patients (P = 0.6).

Labib ⁽⁷⁾ reported that no significant difference was noted between the study groups as regard either of the studied complications (bleeding, leakage, gastroesophageal reflux disease, and twist) (p > 0.05). However, the incidence of complications was often increased in controls (Laparoscopic sleeve gastrectomy without omentopexy) versus the other group (Laparoscopic sleeve gastrectomy with omentopexy). Leakage was encountered only in one case in the control group (1.16%), while it did not occur in the omentopexy group. This case was managed by endoscopic insertion of gastric stent. Bleeding occurred only in two cases in controls (2.33%) versus no cases in the omentopexy group, the two cases were managed by blood transfusion with no need for exploration.

Fouly et al., ⁽⁸⁾ reported that no statistically significant difference was found between the two study groups as regard post-operative leakage, hemorrhage and twisting although overall complications were less in

omentopexy group and leaks detected in reinforcement group are mostly contained leaks but this was statistically insignificant.

The current study showed that patients Weight, body mass index, 6 months post-operative of Laparoscopic sleeve gastrectomy with omental fixation lesser than patients Weight, body mass index, 6 months post-operative of Laparoscopic sleeve gastrectomy without omental fixation but the difference statistically insignificant $p > 0.05$.

Haider⁽⁹⁾ found that Weight Loss At 3- and 6-month follow-up, both groups had lost significant weight relative to baseline. At 3 months, in omentopexy Group body mass index decreased 7.3 ± 2.3 (6.6, 8.0), from 42.5 ± 6.1 to 35.2 ± 5.4 ($p < 0.001$). body mass index in non omentopexy Group had decreased by 5.9 ± 10.3 kg/m² (95% CI, 3.9, 7.9), from 43.2 ± 8.1 to 37.3 ± 12.8 ($p < 0.001$).

The current study showed that there was decrease mean of Weight and body mass index at six month post operative compared to pre operative Laparoscopic sleeve gastrectomy with omental fixation group; difference highly statistically significant $p < 0.001$. Moreover decrease mean of Weight and body mass index one year post operative compared to six month post operative difference highly statistically significant $p < 0.001$. The current study showed that there was decrease mean of Weight and body mass index at six month post operative compared to pre operative Laparoscopic sleeve gastrectomy without omental fixation group; difference highly statistically significant $p < 0.001$. Moreover decrease mean of Weight and body mass index one year post operative compared to six month post operative difference highly statistically significant $p < 0.001$.

Lasheen & Mahfouz⁽¹⁰⁾, reported that Preoperative body mass index was 45 ± 7 in omentum group (A) which decreased to 40 ± 5 , 36 ± 6 , 33 ± 5 and 30 ± 6 kg/m² after 3, 6, 9 and 12 months respectively. While in non omentum group (B), preoperative body mass index was 46 ± 5 decreased to 39 ± 6 , 37 ± 5 , 34 ± 6 and 32 ± 1 kg/m², after 3, 6, 9 and 12 months respectively, with $P > 0.05$ = non significant.

The current study showed that there was a statistically insignificant difference between Laparoscopic sleeve gastrectomy with omental fixation patients and without omental fixation patients regard their post-operative associated comorbidity $p > 0.05$.

AlHaddad et al.,⁽⁵⁾ reported there with no significant difference between study groups regarding gastroesophageal reflux disease, that there are several theories that have been proposed as to reasons why Laparoscopic sleeve gastrectomy may promote gastroesophageal reflux disease. These include hypotensive lower esophageal sphincter, disruption of the angle of His, reduced gastric compliance with higher intra-gastric pressure, decreased gastric emptying, and the hiatal hernia. Taking this into consideration, omentopexy does not correct the previously mentioned and has been shown not to have any effect on the lower esophageal sphincter, this may explain the similar gastroesophageal reflux disease scores between patients in both group 1 and 2.

The current study showed that that, statistically insignificant difference between associated comorbidity gastroesophageal reflux disease pre and post-operative of both technique Laparoscopic sleeve gastrectomy with omental fixation patients and without omental fixation among studied patients $p > 0.05$.

Silva et al.⁽¹¹⁾ showed that Laparoscopic sleeve gastrectomy with omentopexy improved the clinical score of gastroesophageal reflux disease and that omentopexy was indeed associated with decreased clinical reflux symptoms and strictures.

Another study showed that omentopexy could reduce complications arising from improper positioning and gastric tube alterations in Laparoscopic sleeve gastrectomy, particularly symptoms related to food intolerance and gastroesophageal reflux disease in the immediate postoperative period⁽¹²⁾.

Limitations: Limitations of the research include the small sample size; therefore further larger multicentric studies are needed to be performed to confirm our results.

Conclusion: Omentopexy may not change the outcome for laparoscopic sleeve gastrectomy in terms of gastrointestinal symptoms or weight loss results although it is associated with longer operative time. However, it may serve as an extra guard against leakage, bleeding, vomiting, and gastroesophageal reflux disease, manifested by the decreased incidence of these complications with that technique. Laparoscopic sleeve gastrectomy with omentopexy can be a feasible procedure for decreasing morbidity and gastric leak rate

Recommendations: Currently, the role of omentopexy is controversial and further larger multicentric detailed studies need to be performed to confirm our results in validating the role of omentopexy. It can be suggested that surgical technique is one of the main factors in the promotion of gastrointestinal symptoms and gastroesophageal reflux disease, and hence correction of technical errors may be the best method in their prevention.

Abbreviations:

LSG: Gastric obstructions; OP: Modified omentopexy; OGD: Oesophago-gastro-duodenoscopy;; BMI: body mass index; HSS: Knee - rating Score; AP: anteroposterior.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request

Conflicting Interest (If present, give more details): No Conflict of Interest

No financial disclosure

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Not applicable

Declarations

-Ethics approval and consent to participate

Written informed consent was obtained from all patients and the study was approved by the research ethical committee of Faculty of Medicine, Zagazig University (International review board IRB #:7512-10-12-2020). The study was done according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

-Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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