

Omentopexy versus Non-Omentopexy after Sleeve Gastrectomy: A Randomized Controlled Trial

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ABSTRACT

Background: Laparoscopic sleeve gastrectomy has been a common method performed exclusively for morbidly obese cases as an achieving weight loss means.

Objective: We aimed to compare outcome of omentopexy versus non-omentopexy in reducing of bleeding after sleeve gastrectomy.

Patients and Methods: This prospective randomized controlled trial was conducted on 64 morbid obese patients aged from 30 to 55 years old, both sexes, with body mass index (BMI) above 40 and were fit for general anesthesia and accepting participation in the research. Participants were randomly allocated into two equal groups; group A were morbid obese participants underwent omentopexy after sleeve gastrectomy and group B were morbid obese participants underwent non-omentopexy after sleeve gastrectomy.

Results: Sex was significantly different between both groups with more prevalence of females in group A. The operative time was significantly prolonged in group A in contrast to group B. Regarding the postoperative weight, and BMI change, the cases body weight in both group A and B was significantly reduced during follow up ($P < 0.001$). When comparing between both groups, the weight, and BMI at 1, 3, 6 and 12 months was significantly decreased in group A in contrast to group B ($P < 0.05$).

Conclusions: The results detected that although the procedure in group A was more time-consuming, it may have yielded superior long-term control overweight and BMI while maintaining comparable safety profiles.

Keywords: Omentopexy; Non-Omentopexy; Sleeve Gastrectomy; Operative Time.

INTRODUCTION

Laparoscopic sleeve gastrectomy (LSG) has been a common method done exclusively for morbidly obese patients as an achieving weight loss means. In recent years, its ascendancy as the preeminent bariatric procedure has been attributed to its ability to preserve gastrointestinal continuity and its comparatively straightforward nature [1].

Leakage and hemorrhage are two significant complications that are specifically linked to LSG. Gastric leakage is the most dreaded complication following SG; it occurs most frequently at the upper staple line in close proximity to the gastroesophageal junction. Failure to promptly and aggressively identify and treat this complication may result in the development of severe abdominal sepsis, potentially escalating into chronic gastric fistula or multiorgan failure, ultimately culminating in the patient's demise [1].

Over the past decade, LSG has been refined to be safer and more effective than alternative bariatric surgeries; numerous procedures have been identified to reduce postoperative complications like leakage and bleeding [2].

Several complications are frequently observed following LSG, including leakage (with an incidence of ~2.2 %) and bleeding (with an incidence range of 0—4.4 %) [3]. Although surgical intervention may be required in certain severe cases—for instance, to avoid a severe hemorrhage or to block a persistent leakage site following stent insertion—these complications are typically manageable conservatively, without the need for revision surgery [4].

Several approaches have been proposed to mitigate the occurrence of leakage and bleeding during staple line reinforcement (SLR), including buttressing the staple line or oversewing it with biological and synthetic materials. Its potential benefit was demonstrated by studies that evaluated its efficacy [5].

SLR is the subject of considerable debate and is strongly advised by the majority of surgeons as a means to minimize postoperative complications [6]. Primarily, the greater curvature dissection of the staple line or stomach can induce bleeding. In an effort to reduce SLB, numerous techniques have been applied, such as suturing and buttressing material [7].

We aimed to assess outcome of omentopexy versus non-omentopexy in bleeding decreasing of after sleeve gastrectomy.

PATIENTS AND METHODS

This prospective randomized controlled trial was carried out on 64 morbid obese participants admitted to the General Surgery Department, Benha University Hospitals of both sexes, aged from 30 to 55 years old, with body mass index (BMI) above 40 and were fit for general anesthesia. The study lasted from November 2022 to November 2023.

Exclusion criteria were all patients < 30 or > 55 years old, with BMI < 40, and with previous gastric surgeries history, cases demanding concomitant method (hiatal repair, or cholecystectomy) or with severe gastroesophageal reflux disease (GERD) symptoms history.

Randomization and grouping:

A system generated by a computer performed the randomization. Following the acquisition of informed consent from the patients, the sealed envelopes containing the list were sequentially opened and numbered. Participants were randomly allocated using computer generated randomization tables at a ratio of 1:1. Opaque sealed envelopes containing sequential numbers were given to the trial participants, conferring to which each case was registered to one of the two equal groups: group A were morbid obese cases underwent omentopexy after sleeve gastrectomy and group B were morbid obese cases underwent non-omentopexy after sleeve gastrectomy.

Demographic data were collected from each patient (height sex, age, weight, and BMI = kg/m²), comorbidities of each patient were collected (hypertension (HTN), diabetes mellitus (DM), asthma and hyperlipidemia), complete clinical examination included (measurement of temperature, diastolic and systolic blood pressure (DBP and SBP), and heart rate (HR)), and routine laboratory investigations involving complete blood count [platelets (PLT) (*10⁹/L) WBCs (*10⁹/L), and hemoglobin (Hb) (g/dL)], kidney function test [Urea and serum creatinine (mg/dL)], and coagulation profile test [prothrombin time (PT), partial PT (PTT) and international normalized ratio].

Imaging:

Upper gastrointestinal endoscopy: The gastroenterologist performed upper endoscopies on patients who required them while under general anesthesia. On the basis of their endoscopic findings, the patients were subsequently categorized into four groups: those who exhibited complete normal endoscopy, those who had gastritis or esophagitis grades A or B, those who had small-sized hiatal hernias, and so forth [8]. US of the pelvic abdomen is used. For reflux patients, esophagogastroduodenoscopy was routinely performed. In order to determine the volume of the liver and pancreas using magnetic resonance imaging, the boundaries of the organs were delineated on each slice. The final volume was computed utilizing the reformat tool within the imaging software.

Workstation:

The analysis utilized the proton density fat fraction map derived from the IDEAL-IQ sequence to determine the pancreatic fat fraction (PFF) and liver fat fraction (LFF). The LFF was assessed by manually positioning nine circular regions of interest (ROIs), with a diameter of approximately 2.0 cm each, in each liver segment. Key bile ducts, ligaments, and vessels were deliberately omitted from the process. The averages of these ROIs were subsequently computed. The diagnosis of fatty liver required an LFF value exceeding 6.4%. One ROI per segment was positioned in the head, body, and the pancreas tail to evaluate the PFF; the averages of these ROIs were subsequently computed [9].

Intraoperative assessment:

While the case was in the French position, general endotracheal anesthesia was utilised to perform the operation. One broad-spectrum antibiotic dose was administered during the skin incision (ceftriaxone 2 gm). Following abdominal insufflation, the following ports were inserted: a camera port in the supra-umbilical region; two working ports, one in the right hypochondrial region and the other in the left; and two assisting ports, one for liver retraction in the subxiphoid region and the other for gastric traction in the anterior axillary line below the costal margin.

The greater curvature devascularization was executed using a harmonic scalpel or LigaSure haemostatic device, commencing 4–6 cm from the pyloric ring, subsequent to abdominal exploration. After dividing the short gastric vessels, the gastric fundus was entirely detached from the spleen until the left diaphragmatic crus was detected. Following the introduction of a 38-F bougie, gastric division commenced utilising a Covidien® endo-stapler (India). In the beginning, the gastric antrum was partitioned utilizing a green cartridge, while the remainder of the stomach was partitioned using four to five blue cartridges. Methylene blue was injected via the bougie to rule out any potential leakage from the staple line.

Following the extraction of the surgical specimen via the 15-mm port, an intraabdominal drain was introduced, and interrupted non-absorbable sutures were used to close the skin. In the omentopexy group, omental fixation to the staple line was performed using full-thickness PDS 2/0 sutures from the angle of His to the incisura, in addition to the aforementioned procedure. Suture bites were performed with caution while the bougie was present to prevent constriction of the gastric tube. Group A: Omental fixation was achieved using simple continuous sutures to secure the antrum using PDS 2-0 or Vicryl 2-0 covering the entire gastric thickness. Group B: No omental fixation was performed; however, titanium clips were applied to the site of bleeding in the event that it occurs. Blood loss, operating time, intraoperative and hospital stays constituted the entirety of the data (days).

Postoperative data and follow up:

Prokinetics, proton pump inhibitors (40 mg vial pantoprazole), and intravenous fluids were administered to the patients (alizapride 50 mg ampoule). On the initial postoperative day, oral gastro-glycan was assessed, and prompt mobilisation was maintained. In the absence of clinical or radiological indications of leakage, oral fluid intake commenced on the same day. A dilaudid patient-controlled analgesia pump and 4 mg IV ondansetron at the conclusion of the procedure were administered immediately afterward. After the surgical procedure, nausea symptoms were managed with ondansetron or ondansetron, depending on the surgical team's assessment and the patient's response to medication, after the immediate postoperative duration.

Discharge of the majority of patients occurred on day two after the procedure. In addition to weight and nutritional monitoring, clinic visits might also include dietary counselling and, if necessary, psychological referral. Extensive emphasis was placed on the significance of long-term follow-up with a surgeon. Early complications included bleeding, infection, and leakage, while late complications included stenosis, bowel obstruction, and dumping. Weight and BMI measurements were taken at each of the following time points following the procedure: one week, one month, three months, six months, and twelve months. The primary outcome was postoperative complications after sleeve gastrectomy. The secondary outcomes were reducing operative time, and hospital stay.

Sample Size Calculation:

Assuming; mean \pm SD of duration of postoperative complications as bleeding in sleeve gastrectomy (7.3 ± 4.3 hours) and mean \pm SD of duration of omentopexy in sleeve gastrectomy was (12.9 ± 7 hours) level of confidence is 95% with power study 80%, sample size measured using open Epi, was 64 patients who were divided to 32 patients for each group.

Ethical consideration:

Following approval from the Ethical Committee of the Faculty of Medicine at Benha University Hospital (Approval code: Ms 2-11-2022). All participants provided informed consent to participate in the study. The Helsinki Declaration was followed throughout the study's conduct.

Statistical analysis: Using SPSS v28 (IBM Inc., Armonk, NY, USA), statistical analysis was performed. The quantitative variables were presented as the mean and standard deviation (SD), and unpaired Student's t-test was utilized to evaluate the difference between the two groups. The frequency and percentage (%) of qualitative variables were provided for analysis, and when applicable, the Fisher's exact test or Chi-square test was employed. A two-tailed P value < 0.05 was utilized to indicate statistical significance.

RESULTS

In this study, 97 patients were evaluated for eligibility, 24 participants failed to meet the criteria and 9 cases rejected to participate in the study. The remaining 64 participants were categorized into two groups (32 participants in each group). All allocated patients were followed-up and analyzed (**Figure 1**).

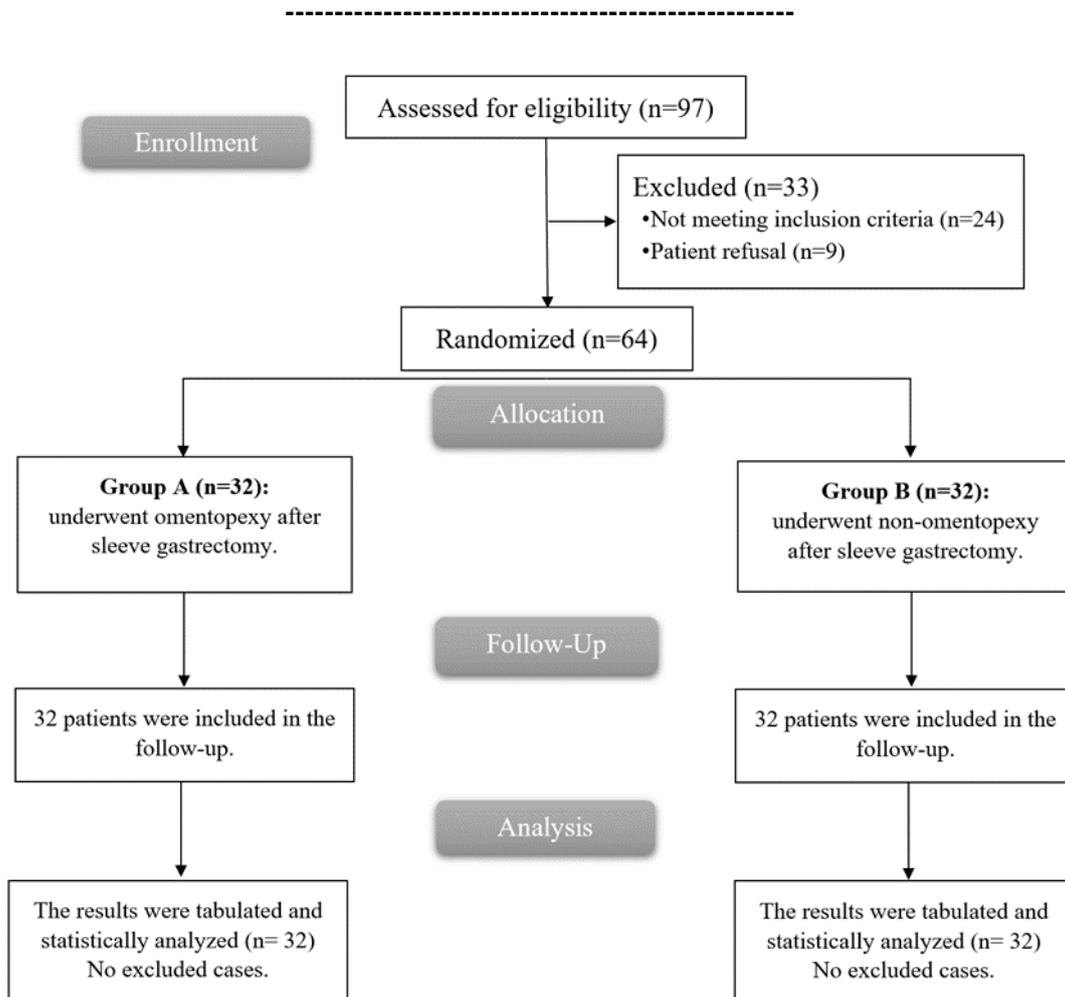


Figure 1: CONSORT flowchart of the enrolled patients

Regarding the baseline characteristics, sex was significantly different between both groups with more female's prevalence in group A. Other baseline characteristics (Age, BMI, weight, and height), comorbidities (Hypertension,

DM, asthma, and hyperlipidemia), clinically examined vital signs (DBP, SBP, and HR,), and laboratory investigations (WBCs, serum creatinine, Hb, platelet, and urea) were insignificantly different between studied groups (**Table 1**).

Table 1: Baseline characteristics, comorbidities, clinical examination, and laboratory investigations of the studied groups

		Group A (n=32)	Group B (n=32)	P value
Baseline characteristics				
Age (years)		41.3 ± 8.36	41.4 ± 8.05	0.964
Sex	Male	7 (21.88%)	17 (53.13%)	0.020*
	Female	25 (78.13%)	15 (46.88%)	
Weight (Kg)		128.9 ± 17.83	134.9 ± 17.04	0.178
Height (m)		1.7 ± 0.08	1.7 ± 0.1	1
BMI (Kg/m²)		46.96 ± 7.32	49.07 ± 8.71	0.299
Comorbidities				
Hypertension		7 (21.88%)	5 (15.63%)	0.748
DM		6 (18.75%)	4 (12.5%)	0.732
Asthma		2 (6.25%)	3 (9.38%)	1.000
Hyperlipidemia		9 (28.13%)	5 (15.63%)	0.364
Clinical examination				
HR (beats/min)		80.3 ± 6.17	80.7 ± 6.07	0.776
SBP (mmHg)		127.8 ± 13.13	131.3 ± 13.14	0.299
DBP (mmHg)		73.1 ± 9.31	75.6 ± 9.48	0.291
Laboratory investigations				
Hb (g/dL)		12.04 ± 1.13	11.9 ± 1.21	0.611
PLT (*10⁹/L)		266.6 ± 52.67	254 ± 61.38	0.381
WBCs (*10⁹/L)		7.8 ± 1.14	7.7 ± 1.42	0.823
Serum creatinine (mg/dL)		0.92 ± 0.06	0.91 ± 0.06	0.435
Urea (mg/dL)		40.0 ± 2.88	42.0 ± 3.83	0.552

Data are presented as mean ± SD or as frequency (%). BMI: Body mass index, DM: Diabetes mellitus, HR: heart rate, SBP: systolic blood pressure, DBP: Diastolic blood pressure, Hb: hemoglobin, PLT: Platelets, WBCs: White blood cells, *: statistically significant.

Operative time was significantly longer in group A compared to group B. The intraoperative blood loss, and hospital stay were insignificantly different between studied groups (**Table 2**).

Table 2: Intraoperative data and hospital stay of the studied groups

	Group A (n=32)	Group B (n=32)	P value
Operative time (min)	66.6 ± 4.7	45.5 ± 2.88	<0.001*
Intraoperative blood loss (ml)	123.5 ± 15	129.7 ± 17.02	0.128
Hospital stay (days)	2.1 ± 0.83	2.2 ± 0.86	0.769

Data are presented as mean ± SD. *: statistically significant.

Regarding the postoperative weight, and BMI change, the patient's body weight in both group A and B was significantly reduced during follow up. When comparing between both groups, the weight, and BMI at 1, 3, 6 and 12 months was significantly reduced in group A in contrast to group B with insignificant difference between both groups at 1 week postoperatively. Complication (Bleeding, leakage, nausea, vomiting, wound infection, abdominal wall hematoma, and seroma) were insignificantly different between studied groups. There was no reported mortality related to laparoscopic sleeve gastrectomy (Table 3).

Table 3: Postoperative weight, BMI change, and complications of the studied groups

	Group A (n=32)	Group B (n=32)	P value
Weight change			
At 1 week	126.4 ± 17.87	133.2 ± 17.02	0.122
At 1 month	119.8 ± 17.87	130.3 ± 16.92	0.019*
At 3 months	108.4 ± 18.54	125.5 ± 17.24	<0.001*
At 6 months	97.5 ± 18.29	117.03 ± 18.19	<0.001*
At 12 months	86.9 ± 17.51	108.3 ± 18.65	<0.001*
P value within group	<0.001*	<0.001*	
BMI change			
At 1 week	46.02 ± 7.26	48.6 ± 7.88	0.175
At 1 month	43.6 ± 7.1	47.6 ± 7.77	0.038*
At 3 months	39.4 ± 7.11	45.8 ± 7.75	0.001*
At 6 months	35.5 ± 6.87	42.7 ± 7.83	<0.001*
At 12 months	31.6 ± 6.46	39.5 ± 7.71	<0.001*
P value within group	<0.001*	<0.001*	
Complications			
Bleeding	0 (0%)	2 (6.25%)	0.492
Leakage	1 (3.13%)	2 (6.25%)	1.00
Nausea	4 (12.5%)	8 (25%)	0.337
Vomiting	2 (6.25%)	5 (15.63%)	0.426
Wound infection	1 (3.13%)	1 (3.13%)	1.00
Abdominal wall hematoma	0 (0%)	1 (3.13%)	1.00
Seroma	0 (0%)	0 (0%)	---

Data are presented as mean ± SD or frequency (%). BMI: Body mass index, *: statistically significant.

CASE PRESENTATION

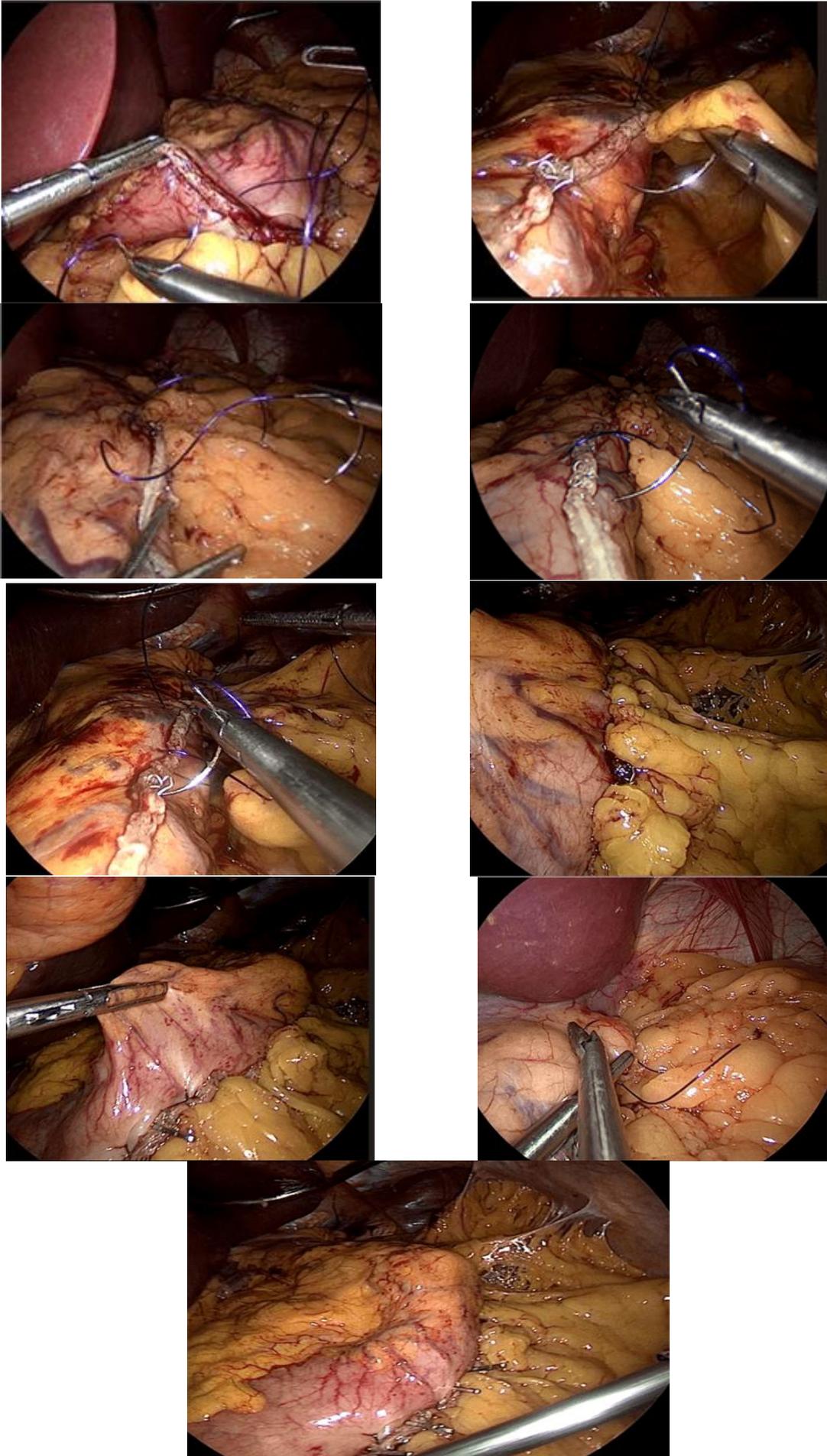


Figure 2: Operative technique of sleeve gastrectomy

DISCUSSION

Morbid obesity is regarded as a worldwide concern. According to the World Health Organization (2016), 39% of adults are overweight and 13% are morbidly obese. While numerous approaches were developed to address this issue, bariatric surgeries have demonstrated themselves to be the best effective and efficacious method to date [13]. In addition to influencing one's physical appearance, weight loss has a substantial impact on the comorbidities management like hypertension and type II diabetes mellitus [10].

There were insignificant differences between the studied groups as regard the associated comorbidities (Hypertension, DM, asthma, and hyperlipidemia).

Abdelrahman et al. [11] found that there was insignificant difference among both groups regarding DM and hypertension. **Nosrati et al.** [12] indicated that DM was insignificantly different among both groups. **Labib** [13] demonstrated that GERD was the most prevalent comorbidity, group A: occurring in 6.98 and 8.14 % of cases, respectively, while diabetes occurred in 5.81 and 6.98 % of cases in both groups. Additional concurrent medical conditions that were present were hypertension, obstructive sleep apnea, and dyslipidemia.

The current study found that the mean hospital stay for group A was 2.3 ± 0.82 days, while for group B it was 2.9 ± 0.79 days. These figures were lower than those previously found by **Pilone et al.** [14], who detected 4.5 versus 5.8 days, while **Hassan** reported 1.33 ± 0.38 versus 1.67 ± 0.33 days. This statistical difference is hypothesized to be attributable to differences in postoperative outpatient care and adherence to ERAS guidelines [15].

Regarding the postoperative weight change, the body weight of patients in both group A and B was significantly reduced during follow up ($P < 0.001$). In contrast to group B, group A exhibited a significantly lower weight at 1, 3, 6, and 12 months ($P < 0.05$) in contrast to the other group. However, no significant difference was detected between the two groups, one week postoperatively.

Same as the current study **Nosrati et al.** [12] exhibited that the mean preoperative weight of patients in Group A was 124.5 ± 19.7 kg, whereas in Group B it was 115.9 ± 21.4 kg, indicating a statistically significant difference ($P = 0.003$). One year following the procedure, the average weight of patients in Group A was 76.4 ± 15.7 kg, while in Group B it was 79.3 ± 16.1 kg ($P = 0.199$). Group A experienced a total weight loss of 45.2 ± 12.7 kg, whereas Group B observed a significantly greater reduction of 39.5 ± 12.6 kg.

Regarding the postoperative BMI change, the BMI of patients in both group A and B was significantly decreased during follow up ($P < 0.001$). When comparing both groups, the BMI at 1, 3, 6 and 12 months was significantly lower in group A compared to group B with insignificant difference between studied groups at 1 week postoperatively.

In the study of Nosrati et al. [12], the preoperative patients BMI mean was found to be 45.3 ± 5.8 kg/m² in Group A and 41.6 ± 6.4 kg/m² in Group B. This difference between the two groups was statistically significant ($P = 0.001$). After one year from the surgery, the average BMI of patients in Group A was 27.0 ± 4.2 kg/m² and in Group B it was 28.8 ± 5.2 kg/m² ($P = 0.009$). One year following the procedure, Group A exhibited a significantly greater excess BMI loss (EBMIL) than Group B (14.6 ± 4.3 kg/m² vs. 14.6 ± 5.3 kg/m², $P = 0.004$).

Regarding the postoperative complications, bleeding happened only in 2 (6.25%) patients in group B, leakage occurred in 1 (3.13%) participants in group A and 2 (6.25%) patients in group B, nausea occurred in 4 (12.5%) participants in group A and 8 (25%) patients in group B, vomiting occurred in 2 (6.25%) patients in group A and 5 (15.63%) patients in group B, wound infection occurred in 1 (3.13%) patient in group A and 1 (3.13%) patient in group B and abdominal wall hematoma occurred only in 1 (3.13%) participants in group B, whereas seroma was not reported in any patient in both groups.

Abdelrahman et al. discovered that postoperative bleeding transpired in two cases within group A, whereas only one case in group B reported it ($P = 0.073$). There was no statistically significant difference observed between the two groups in terms of postoperative complications, such as seroma, abdominal wall hematoma, leakage, or wound infection. Nevertheless, the complications incidence was frequently higher in the control group than in the other. One instance of leakage (1.16 %) was observed in the control group; in contrast, no leakage happened in the omentopexy group. Gastric stent insertion underwent endoscopic management in this instance. Only two cases of bleeding (2.33 %) occurred in the control group, whereas there were none in the omentopexy group; both instances were resolved through blood transfusion without the necessity for further investigation. A total of 6.98 and 2.33 % of cases in the control groups and omentopexy, respectively, reported transient vomiting following surgery [11].

In another study, there was a reduction in the number of cases reporting GERD symptoms prior to surgery, with each group now consisting of only three cases. However, de novo postoperative GERD symptoms developed in four cases, including three controls (3.49 %) and one case undergoing omentopexy (1.16 %). No gastric twist instances were identified during the duration of the follow-up duration. The hospital stay was insignificantly different between the two groups ($p = 0.238$) [13].

Sharma and Chau [16] emphasized that only seven out of 367 participants in the NP group had gastric disruptions (GD), whereas in the OP group, no GD was observed, with a significant p value. All other complications exhibited similarity between the two cohorts. The postoperative reflux incidence did not differ significantly in both groups.

In another research, using CT-guided drainage, parenteral nutrition, antibiotics, endoscopic management, and observation, four of the seven GD were managed conservatively. The Roux-en-Y procedure was utilized to convert the operative management of the three remaining patients. Mortality was not observed in either of the two cohorts; Total 737 patients underwent LSG from January 2012 to December 2017. Out of these, 370 that had OP and 367 that had NP were analyzed. NP group was subdivided into Lemberted Staple line (LS) and bioabsorbable staple line reinforcement (BSLR) groups. Gastric leaks and perforations were clubbed together as GD. No gastrointestinal obstructions were observed in any of the groups. Statistically insignificant was the difference between 13 and 15 % in the incidence of gastric reflux between the two groups. Based on clinical manifestations and the requirement for acid-reducing therapy in both groups for more than three months following LSG, reflux was diagnosed [16].

In previous study, it was detected that the occurrence rate of leakage following sleeve gastrectomy differs from 0.5 to 7 (21%). Our findings are consistent with this range, as our leakage incidence falls within the aforementioned range [17].

Sabry and Qassem. [18] found that during the follow-up duration, staple line leakage was detected in nine cases (0.9 %) of group A (NO), but in none of the cases (0.0 %) of group B (RO) (P=0.003). In cases of gastric leakage, patients were treated with an intragastric stent insertion and a feeding jejunostomy. Significant postoperative bleeding was identified in twenty-six cases of group A (NO), whereas it was observed in only eight patients (0.8 percent) of group B (RO) (P=0.003). Fifteen cases (1.5 %) necessitated a return to the operating room for relaparoscopy with full thickness sutures for omental fixation. Conversely, eleven patients (1.1%) were successfully treated conservatively with blood transfusion and hemostatic measures. A perigastric located collection was observed in a mere one case (0.625) of the two groups, compared to three cases (0.3 %). The evacuation of these patients was accomplished via pigtail catheter insertion in conjunction with the administration of antibiotics.

Previous studies have documented omentopexy by multiple groups for a variety of motives. In their study, **Greenbaum et al.** detailed the experiences of 41 patients who underwent revisional bariatric surgery, which involved the several procedures conversion into a BPD/DS with feeding jejunostomy and omentopexy [19].

In this investigation, the omentopexy was performed along the lateral gastric staple line and gastrogastrostomy was intended to reduce the rate of leakage. Despite the potential or suspected leak rate being 20%, [20] surgical or radiographic intervention was not needed in any of the cases. In brief, a randomized controlled trial was required to assess the omentopexy efficacy during the RYGB conversion to a duodenal switch, according to the authors. **De Godoy and Coelho**

[20]. detailed their method for gastric fixation of the stomach greater curvature subsequent to LSG in an additional study. The method described in the authors' article has the potential to reduce the GERD incidence and food intolerance. As a result, the authors merely speculated regarding the technique's effectiveness and provided no supporting evidence.

Limitations: Relatively small sample size, single-centre design, and absence of GERD assessment—should have been remedied through endoscopic findings as opposed to subjective evaluation; these shortcomings should be addressed in future research.

We recommend that multicentre collaboration be utilised to increase the sample size and validate our results regarding GERD assessment, which is predicated on endoscopic findings as opposed to subjective evaluation. Subsequent research must address these limitations, and additional extensive multicentric studies are required to validate our findings.

CONCLUSIONS

The results indicate that although the procedure in group A was more time-consuming, it may have yielded superior long-term control of overweight and BMI, while maintaining comparable safety profiles.

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Conflict of Interest: Nil.

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