Original Article

# Short-Term Outcomes of Double Omentopexy in One Anastomosis Gastric Bypass Surgery: A Controlled Clinical Trial

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**Abstract**

**Purpose:** This study aims to assess the efficacy of implementing a novel technique of reinforcement of gastric pouch and remnant stomach staple line with Double Omentopexy (DO) in patients undergoing One-Anastomosis Gastric Bypass (OAGB) surgery and evaluate its impact in reducing the early postoperative complications. **Materials and Methods:** The 123 patients were allocated into two groups: 61 in the standard OAGB group and 62 in OAGB with DO group. The primary outcomes are postoperative complications (including early postoperative bleeding, leakage, gastric twist, reflux, etc.) and hospital stay. The secondary outcome is excess body weight loss. Follow-up visits were planned after discharge: at two weeks, two months, and three months postoperatively. **Results:** Postoperative complications were significantly lower, 3 (4.84%) in OAGB with DO compared with 10 (16.39%) in standard OAGB ($P$ =0.037). There was no statistically significant difference in the incidence of early postoperative bleeding, deep vein thrombosis, biliary reflux, and gall bladder stone ($P$ >.05). No patient had leakage in either group. The mean operative time was significantly longer (68.66 ± 6.68 min) in OAGB with the DO group when compared with the standard OAGB group (62.16 ± 7.54 min) ($P$ <.001). **Conclusion:** Applying the DO technique may be a good measure to be added during OAGB to decrease the incidence of potential postoperative complications, especially the rate and severity of bleeding.

**Keywords:** *Bariatric surgery, gastric bypass, omentopexy*

## Introduction

For people with morbid obesity (body mass index (BMI) >35 Kg/m$^2$), bariatric surgery is the most efficient way to promote weight loss and manage comorbidities associated with obesity.[1,2] In recent years, a surgical technique known as One-Anastomosis Gastric Bypass (OAGB) or mini-gastric bypass (MGB) has been developed; its frequency of performance has increased considerably in the current decade.[3] It is now widely acknowledged that MGB is at least as effective as Roux-en-Y gastric bypass, if not more effective,[4] regarding weight loss and comorbidity resolution. It takes less time to perform, has a shorter learning curve, and is associated with fewer major complications.[4]

Although Laparoscopic Sleeve Gastrectomy (LSG) is considered a safe procedure, it has potential complications. The most frequent and typical problems following LSG include bleeding from the staple line, gastric leakage, and gastroesophageal reflux.[5,6] Many methods have been tried to make the staple line safer, such as oversewing, omental wrap, fibrin glues, absorbable, or nonabsorbable suturing material; however, there is still no clear view.

Omentopexy is a technique performed during the LSG in the past few years). In general, the staple line of the sleeved stomach is fixed to the gastrosplenic and gastrocolic ligaments.[7] This procedure was added to

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classic LSG to decrease the incidence of bleeding and gastric leaks.[8]

According to Arslan *et al*.,[9] omentopexy can avoid the gastric twist, a functional cause of gastric stenosis, by stabilizing the posterior stomach wall.

Sabry and Qassem reported that routine omentopexy could reduce the incidence rates of post-LSG leakage and bleeding and minimize hospital stay, although it consumes a longer operative time.[10]

Despite the advantages of OAGB surgery, it also has its complications. The most frequent complication of this technique is still leaking (0.1 to 1.9%); robust management strategies must be done to prevent subsequent complications once a leak is found.[11,12] The second most frequent consequence is bleeding, usually in the early postoperative setting. It commonly originates from the staple lining along with the gastric pouch, gastric remnant, or Gastro-Jejunal anastomosis, with a rate of less than 3%.[11] Other complications may include small bowel obstruction and dumping syndrome, stomal stenosis, marginal ulcer, and malabsorptive complications.

The promising results of applying the omentopexy technique to the classic sleeve gastrectomy[13] have led us to its use as an added safety measure in patients undergoing OAGB surgery.

There is a lack of data regarding using omentopexy during performing OAGB. So, studies are needed to evaluate all aspects of the omentopexy procedure in OAGB surgery.

Our study aims to assess the efficacy of implementing a novel technique of reinforcement of gastric pouch and remnant stomach staple line with Double Omentopexy (DO) in patients undergoing OAGB surgery and evaluate its impact in reducing the early postoperative complications.

## Patients and Methods

### Type of study

Controlled (non-randomized) Clinical Trial.

### Sampling method

Convenient sampling method.

The research Ethics Committee at the Faculty of Medicine, Ain Shams University, and the General Surgery Department have approved the study. The study was prospectively registered in Cochrane Pan African Clinical Trial Registry (identification number is PACTR202203637285531).

The minimal sample size is calculated based on a previous study aimed at examining the various complications after different bariatric operations that are currently performed in India.[14] Goel *et al*. (2021)[14] reported out of 3187 patients, 6.05% had any complications after OAGB surgery. Based on their results, adopting a power of 80% to detect a standardized effect size (non-inferiority margin, d) of 5 in success rate (primary outcome), and level of significance 95% ($\alpha = 0.05$), the minimum required sample size was found to be 59 patients per group (number of groups = 2) (Total sample size = **158 patients**).[15–17] The sample size was calculated using online Power (sample size) calculators https://www.sealedenvelope.com /power/binary-noninferior

Two hundred patients were assessed for eligibility; 140 patients were recruited in OAGB with DO group and standard OAGB group (70 patients each). After three months of follow-up, only 123 patients were analyzed [Figure 1].

### Study group allocation

#### *Standard OAGB group*

Sixty-one patients with laparoscopic OAGB without DO.

#### *OAGB with DO group*

Sixty-two patients with laparoscopic one anastomosis gastric bypass with DO of the gastric pouch and remnant stomach staple lines.

### Eligibility criteria

Patients between 18 and 60 years old of both sexes were recruited.

#### *Inclusion criteria*

The study included patients in whom surgical management of obesity is indicated: BMI ≥40, BMI 35–40 with obesity-related comorbidities (e.g., hypertension, hyperlipidemia, type II diabetes mellitus, Obstructive Sleep Apnea (OSA), obesity hypoventilation syndrome, non-alcoholic fatty liver disease, gastroesophageal reflux disease (GERD), and severe arthritis), able to be committed to follow-up.

#### *Exclusion criteria*

Patients were excluded from the study if the patient had previous upper gastrointestinal tract surgery or liver cirrhosis, were on oral steroid therapy, had previous bariatric surgery, and were not fit for general anesthesia (e.g., patients with severe heart disease or untreatable coagulopathies), contraindications for insufflation as those with severe cardiovascular or sever restrictive respiratory diseases, significant abdominal ventral hernia, major psychiatric illness, and pregnant patients.

All patients were subjected to complete history taking with special emphasis on personal history: age, sex, marital status, dietary habits and if the patient likes

sweets much or not, duration of obesity, history of previous trials of weight loss, whether surgical or non-surgical, medical history for comorbidities: as diabetes mellitus, hypertension, cardiac problems, respiratory problems, and previous deep vein thrombosis, GERD, and past surgical history.

Complete clinical examination: weight and height and calculate BMI, type of obesity (android or peripheral), abdominal examination for (scar of previous surgery, hernial orifices, organomegaly), cardiac and pulmonary evaluation, endocrinological assessment, psychiatric assessment (If indicated).

### Surgical technique

The operation was done under general endotracheal anesthesia when the patient was in the French position. At the time of the skin incision, a single dose of broad-spectrum antibiotic was given (ceftriaxone 2 gm). The pneumoperitoneum is performed using a direct puncture with a Veress needle in the left upper quadrant, near the costal margin at the level of the midclavicular line (Palmer's point). The initial pressure is set at 15 mmHg and maintained till the expected pressure (about 15 mmHg) is reached. Five ports were placed in a "diamond-shaped" pattern in the upper abdomen, the 10 mm camera port in the supra-umbilical region, two 12 mm working ports, one in the right and the other in the left hypochondrial regions midclavicular line, in addition to two 5 mm ports, one in the subxiphoid region for liver retraction, and the other in the anterior axillary line below the costal margin for gastric traction [Figure 2].

The operation begins with the dissection of the gastro-oesophageal angle; then, the surgeon proceeds with the ligation of the distal lesser sac, next to the insertion of the Latarjet nerve, using a LigaSure hemostatic device until the exposure of the posterior gastric wall. The gastric pouch must be lengthy and narrow, measuring around 15–18 cm, with a 50–150 ml reservoir capacity.

After the insertion of 36-F bougie, the gastric division was started using the Covidien® endo-stapler. The pouch is created using 60 mm green cartridges to perform the horizontal section and 3–5 units to perform the vertical section. After the gastric pouch's creation, the excluded stomach's staple line is reinforced along its whole length with omentopexy to the greater omentum using 2-0 polydioxanone full-thickness continuous sutures. The ileocecal junction is identified, and the small bowel is retrogradely counted until 300 cm from the ileocecal valve.

A side-to-side 45-mm gastrojejunostomy is performed using a 45 mm blue cartridge; the orifice for the cartridge insertion is closed using a continuous suture with 2-0 polydioxanone reinforced with separate stitches of 2-0 polydioxanone. Multiple anti-reflux stitches are taken between the efferent limb and the lower part of the gastric pouch to zero Polydioxanone suture (PDS). The gastric pouch staple line is then reinforced with omentopexy to the free part of the greater omentum from the level of the gastro-oesophageal angle down to the level of the anastomosis using 2-0 polydioxanone full-thickness continuous sutures. Care is taken to take the suture bites in the presence of the bougie to avoid narrowing of the gastric tube. Intra-abdominal drain is placed. Postoperatively close observation for vital signs (Intensive Care Unit admission if indicated) was done.

### Outcomes

The primary outcomes are postoperative complications (including early postoperative bleeding, leakage, gastric twist, reflux, etc.,) and hospital stay. The secondary outcome is excess body weight loss.

Patients were followed up all through the first three months postoperatively. Follow-up visits were planned after discharge: at two weeks, two months, and three months postoperatively.

### Statistical methodology

Data were collected and entered into the computer using Statistical Package for Social Science (SPSS) program for statistical analysis (ver 25).[18] Data were entered as numerical or categorical, as appropriate. Kolmogorov–Smirnov test of normality revealed no significance in the distribution of the variables, so parametric statistics was adopted.[19] Data were described using minimum, maximum, mean, standard deviation, and 95% Confidence interval (CI) of the mean.[20] Comparisons were made between two studied independent normally distributed variables using an independent sample *t*-test.[21] When Levene's test for equality of variances is significant, Welch's *t*-test is used.[22] *Chi*-square test was used to test the association between qualitative variables.[23] Monte Carlo correction[24] was carried out when indicated (n x m table and >25% of expected cells were less than 5). *Z*-test for comparing different independent proportions was used.[25] During sample size calculation, beta error accepted up to 20% with a power of study of 80%. An alpha level was set to 5% with a significance level of 95%. Statistical significance was tested at a *P* value <.05.[26]

## Results

The demographic data and perioperative findings of the patients included in the study are summarized

in Table 1. There were no statistically significant differences in age ($P$ =0.935), sex ($P$ =0.596), history of any abdominal surgery, or any associated comorbidities (hypertension, diabetes mellitus, cardiac problems, deep vein thrombosis, psychiatric disorder, cigarette smoking, anticoagulant therapy) ($P$ >.05). Also, there were no statistically significant differences in OSA and preoperative GERD ($P$ >.05). The mean operative time in the OAGB with DO group (68.66 ± 6.68 min) was significantly longer when compared with the standard OAGB group (62.16 ± 7.54 min) ($P$ <.001). There was no statistically significant difference in the duration of hospital stay (days) between both groups ($P$ =.797) [Table 1].

There was no statistically significant difference preoperatively in weight ($P$ =0.429) [Figure 3], BMI ($P$ =0.450), World Health Organization classification of BMI ($P$ =.810), and preoperative excess weight ($P$ =.517).

**Table 1: Demographic data, history of abdominal surgery, chronic diseases and present history of obstructive sleep apnea, gastroesophageal reflux, operative time, and hospital stay in the two studied groups**

| | Group | | Test of significance |
|---|---|---|---|
| | Standard OAGB ($n$=61) | OAGB with Double Omentopexy ($n$=62) | $P$ |
| Age (years) | | | |
| - Min.–Max. | 15.00-60.00 | 26.00-65.00 | $t_{(df=121)}$=0.082 |
| - Mean±SD | 43.44±10.40 | 43.29±10.14 | $P$=0.935 NS |
| - 95% CI of the mean | 40.78-46.11 | 40.72-45.87 | |
| Sex | | | |
| - Male | 17 (27.87%) | 20 (32.26%) | $\chi^2_{(df=1)}$=0.282 |
| - Female | 44 (72.13%) | 42 (67.74%) | $P$=0.596 NS |
| History of Any Abdominal Surgery | 30 (49.18%) | 34 (54.84%) | $Z$=0.628 |
| | | | $P$=0.528 NS |
| Hypertension | 33 (54.10%) | 29 (46.77%) | $Z$=0.812 |
| | | | $P$=0.418 NS |
| Diabetes mellitus | 21 (34.43%) | 24 (38.71%) | $Z$=0.493 |
| | | | $P$=0.624 NS |
| Cardiac problems | 4 (6.56%) | 1 (1.61%) | $Z$=1.388 |
| | | | $P$=0.165 NS |
| Deep Vein thrombosis | 0 (0.00%) | 2 (3.23%) | $Z$=1.414 |
| | | | $P$=0.159 NS |
| Psychiatric disorder | 2 (3.28%) | 0 (0.00%) | $Z$=1.438 |
| | | | $P$=0.150 NS |
| Cigarette smoking (current or ex) | 6 (9.84%) | 9 (14.52%) | $Z$=0.793 |
| | | | $P$=0.430 NS |
| Current anticoagulant drug therapy | 21 (34.43%) | 16 (2625.81%) | $Z$=1.042 |
| | | | $P$=0.300 NS |
| Obstructive Sleep Apnea (OSA) | 42 (38.85%) | 37 (59.68%) | $Z$=1.061 |
| | | | $P$=0.289 NS |
| Gastro-Esophageal Reflux Disease (GERD) | 31 (50.82%) | 37 (59.68%) | $Z$=0.988 |
| | | | $P$=0.322 NS |
| Operative time (minutes) | | | |
| - Min.–Max. | 50.00-82.00 | 55.00-85.00 | $t_{(df=121)}$=5.058 |
| - Mean±SD | 62.16±7.54 | 68.66±6.68 | $P$= <0.001* |
| - 95% CI of the mean | 60.23-64.10 | 66.96-70.36 | |
| Hospital stay (days) | | | |
| - Min.–Max. | 1.00-3.00 | 1.00-4.00 | $t_{(df=121)}$=0.257 |
| - Mean±SD | 1.07±0.36 | 1.05±0.38 | $P$=0.797 NS |
| - 95% CI of the mean | 0.97-1.16 | 0.95-1.15 | |

OAGB: One Anastomosis Gastric Bypass, DO: Double Omentopexy, $n$: number of patients Min-Max: Minimum to Maximum SD: Standard deviation, CI: Confidence interval, t = Independent samples t-test, c2=Pearson Chi-Square Z = Z score for two proportions df= degree of freedom, *Statistically significant ($p$<.05), NS: Statistically not significant ($p$>.05)

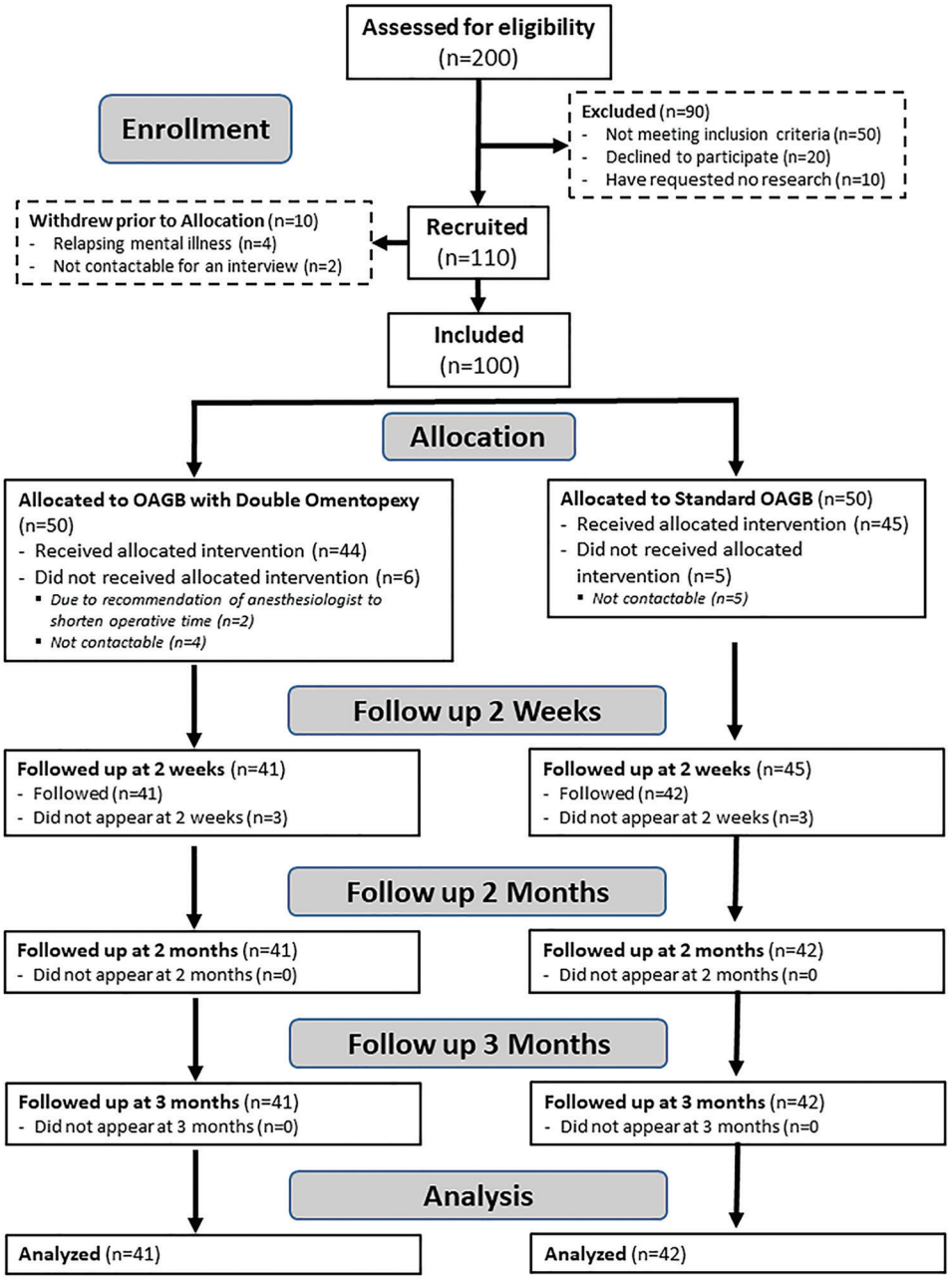


**Figure 1:** Consort Flow chart

At two weeks of follow-up, there was no statistically significant difference in weight ($P$ =0.413) [Figure 3], and the percentage of total weight loss (5.72 ± 1.41%) has no statistically significant difference in the OAGB with DO group compared with 5.60 ± 1.96% in the standard OAGB group ($P$ =0.706) [Figure 4]. Also, the percent of excess weight loss (13.85 ± 6.77%) has no statistically significant difference in the OAGB with DO group compared with 11.13 ± 4.17% in the standard OAGB group ($P$ =.354) [Figure 5]. At two months of follow-up, there was no statistically significant difference in weight ($P$ =.219) [Figure 3], and the percentage of total weight loss (14.47 ± 3.53%) has no significant difference in the OAGB with DO group compared with 13.39 ± 3.41% in the standard OAGB group ($P$ =.087) [Figure 4]. Also, the percent of excess weight loss (29.60 ± 10.07%) has no statistically significant difference in the OAGB with DO group compared with 26.46 ± 7.97% in the standard OAGB group ($P$ =.058) [Figure 5]. At three months of follow-up, the weight (112.77 ± 20.86 kg) has no statistically significant difference in the OAGB with DO group compared with 116.20 ± 15.00 kg in the standard OAGB group ($P$ =.299) [Figure 3]. Also,

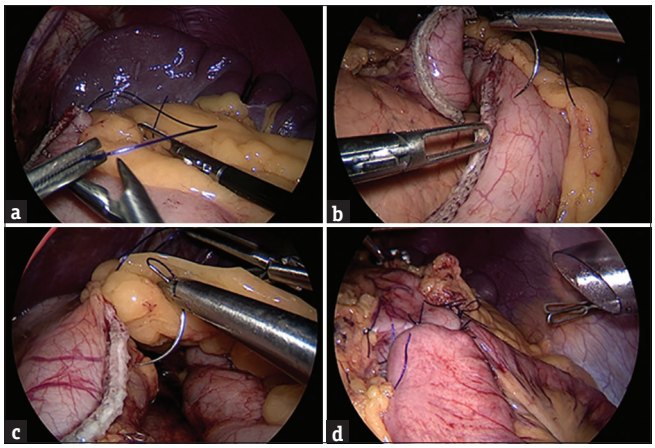


**Figure 2:** Steps of double omentopexy technique (a) Omentopexy of the uppermost part of the excluded stomach stapler line, (b) Continuous suturing of the remnant stomach stapler line using 2-0 polydioxanone sutures, (c) Omentopexy of the gastric pouch's stapler line, (d) The final configuration of the gastrojejunostomy after double omentopexy of the gastric pouch and remnant stomach stapler line

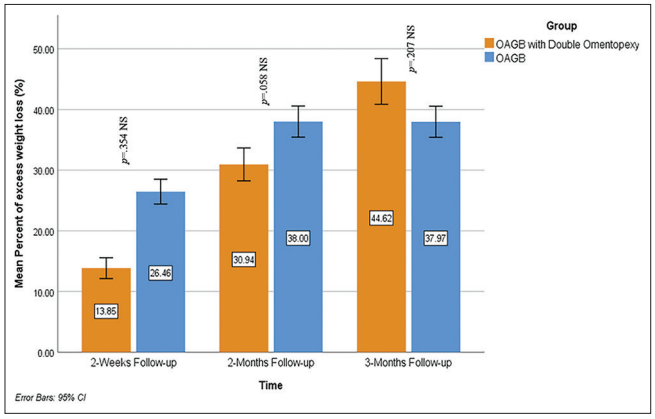


**Figure 4:** Bar chart of mean (Â± 95% CI) of percent of excess weight loss (%) in the two studied groups

the percent of total weight loss (116.20 ± 15.00%) has no statistically significant difference in the OAGB with DO group compared with 19.29 ± 4.44% in the standard OAGB group ($P$ =.479) [Figure 4]. Also, the percent of excess weight loss (40.42 ± 11.05%) has no significant difference in the OAGB with DO group compared with 38.00 ± 10.04% in the standard OAGB group ($P$ =.207) [Figure 5] [Table 2].

The incidence of any postoperative complication (s) was significantly higher in the standard OAGB group 10 (16.39%) patients compared with 3 (4.84%) in the OAGB with DO group ($P$ =0.037) [Table 3]. There was no statistically significant difference in the incidence of 1) early (first 24 hours) postoperative bleeding, 3 (4.92%) patients in the standard OAGB group, compared with 1 (1.61%) in the OAGB with DO group ($P$ =0.303), 2) postoperative deep vein thrombosis ($P$ =.992); 3) newly developed GERD ($P$ =.631); 4) biliary reflux ($P$ =.149);

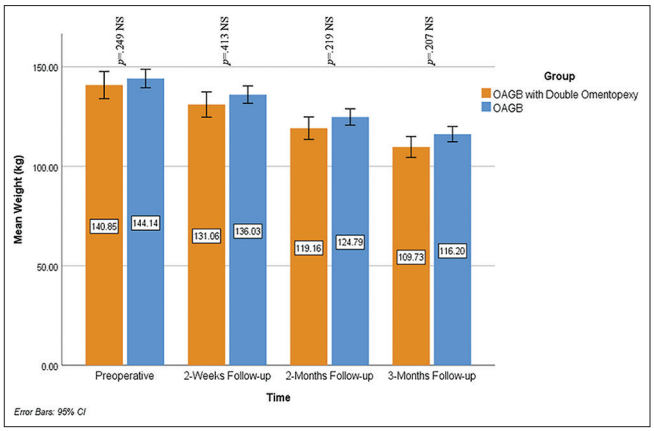


**Figure 3:** Bar chart of mean (± 95% CI) of weight (kg) in the two studied groups

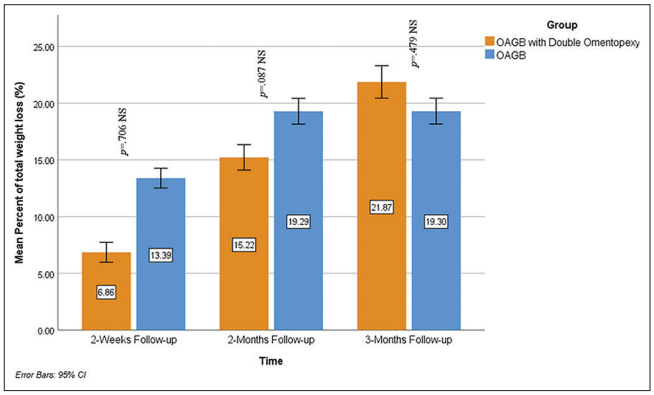


**Figure 5:** Bar chart of mean (Â± 95% CI) of percent of total weight loss (%) in the two studied groups

**Table 2: Postoperative complications during the first three months postoperatively in the two studied groups**

| | Group | | Test of significance *P* |
|---|---|---|---|
| | Standard OAGB (*n*=61) | OAGB with Double Omentopexy (*n*=62) | |
| Bleeding | 3 (4.92%) | 1 (1.61%) | *Z*=1.033 *P*=0.303 NS |
| Deep vein thrombosis | 1 (1.64%) | 1 (1.61%) | *Z*=0.011 *P*=0.992 NS |
| Gastro-Esophageal Reflux Disease (GERD) | 3 (4.92%) | 2 (3.23%) | *Z*=0.475 *P*=0.631 NS |
| Biliary reflux | 2 (3.28%) | 0 (0.00%) | *Z*=1.437 *P*=0.149 NS |
| Gall bladder stone | 1 (1.64%) | 0 (0.00%) | *Z*=1.012 *P*=0.312 NS |
| Any postoperative complication (s) | 10 (16.39%) | 3 (4.84%) | *Z*=2.084 *P*=0.037* |

*n*: number of patients, *Z*=*Z* score for two proportions, NS: Statistically not significant ($P \geq 0.05$), * Statistically significant ($P < 0.05$)

5) gall bladder stone ($P$ =.312). No patients had leakage in either group.

In the four patients with early postoperative bleeding, there was some amount of blood in the drain (200–500 ml), and all of them were managed conservatively.

## Discussion

The laparoscopic OAGB is one of the most effective procedures for weight reduction and improving comorbidities. In the last few years, it has been growing in popularity worldwide.[27,28] Weight loss after OAGB is excellently maintained.[29]

Although there was no statistically significant difference between both groups regarding early postoperative bleeding ($P$ =0.303), we think that DO may reduce the severity of postoperative bleeding by containing and tamponade of the bleeding site, hence minimizing the need for re-exploration. In the present study, three patients experienced postoperative bleeding in the standard OAGB group, which mandates exploration despite adequate resuscitation measures. Exploration revealed a widespread collection of intra-peritoneal blood with the identification of the bleeding point in one patient. On the other hand, the patient with postoperative bleeding in OAGB with DO group was managed conservatively. There is no data in the literature regarding DO in OAGB and its sequelae, so we can compare our results with published data.

In the present study, none of the patients have leakage. Liagre *et al*. (2019)[30] reported that 1.7% of patients experienced postoperative leakage in their retrospective review, including 2780 patients who underwent OAGB. Applying the proper surgical technique may add more safety against postoperative leakage in both groups.

Although the operative time in the OAGB with DO group was significantly longer than the standard OAGB group (mean difference = 6.5 minutes), this difference did not significantly impact the clinical outcome. In the standard OAGB technique, considerable time is spent during clipping or stitching the bleeder points in the gastric pouch and excluded stomach, part of this time will be preserved in OAGB with DO technique, which leads to a decrease in the mean time difference between the two techniques.

The statistically significant difference in weight loss in the OAGB with DO group may be attributed to the added restriction exerted by the re-enforcement stitches on the gastric pouch stapler line. However, a long-term assessment of weight is required.

### Limitations of the study

The study was not randomized, and the sample size is relatively small, so an error could have missed a difference although one was not detected.

## Conclusion

Applying the DO technique may be a good measure to be added during OAGB to decrease the incidence of potential postoperative complications, especially the rate and severity of bleeding. Further studies, hopefully with a larger number of patients, should be performed to evaluate this technique and assess outcomes.

### Informed consent

Informed consent was obtained from all individual participants included in the study.

### Ethical consideration

All procedures performed in this study were in accordance with the research Ethics Committee at the Faculty of Medicine, Ain Shams University, Egypt, approved the study, and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

The study was prospectively registered in Cochrane Pan African Clinical Trial Registry (identification number is PACTR202203637285531).

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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