The Omentopexy Role in The Prevention of Post-Operative Gastric Sleeve Surgery Complications
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ABSTRACT
Background: Currently, there is still a debate about the omentopexy preventive mechanism of sleeve gastrectomy complications. The current study was conducted to evaluate the omentopexy role on the early outcomes after laparoscopic gastric sleeve surgery.

Patients and methods: This prospective randomized study included a total number 172 cases, divided equally into two groups (86 cases for each); the omentopexy (sleeve gastrectomy with omentopexy) and control groups (sleeve gastrectomy only). All cases were subjected for complete pre-operative assessment. Post-operative complications including leakage, bleeding, vomiting, and reflux symptoms, and gastric volvulus were recorded.

Results: patient characteristics including age, sex or comorbidities did not significantly differ between both groups. However, the duration of operation showed significant prolongation in the omentopexy group (78.33 vs. 62.47 minutes in controls). No difference was significantly noted between both groups regarding post-operative complications, apart from gastric twist that was not encountered in our study. Despite that, these complications showed a slight increase in controls. The duration of hospitalization did not differ significantly between the study groups (median = 1 day).

Conclusion: Omentopexy did not have a significant different impact on the prevention of post-sleeve gastrectomy complications although it is associated with longer operative time. However, it may serve as an extra guard against leakage, bleeding, vomiting, and GERD, manifested by the decreased incidence of these complications with that technique.

Keywords: Sleeve gastrectomy; Omentopexy; Leakage; Bleeding.

INTRODUCTION
Morbid obesity represents a growing health problem for both developed and developing countries, as it has serious social, financial, and health consequences. That makes obesity one of the major priorities of the World Health Organization (WHO). In Egypt, the prevalence of obesity has been increased significantly, as more than one third of the whole Egyptian population are obese. Nowadays, obesity surgery is the proven and effective long-term method for achieving weight loss in such cases. Laparoscopic gastric sleeve surgery has gained a great popularity as a safe and efficacious bariatric procedure that could achieve satisfactory post-operative outcomes. Moreover, sleeve gastrectomy has a relatively easier learning curve compared to other obesity surgeries like gastric bypass and biliopancreatic diversion. Nevertheless, gastric sleeve surgery has its own dreadful complications including staple line leakage, bleeding, and stenosis.

Multiple options are existing for staple line enforcement including oversewing, buttressing, and glue-type hemostatic agents. Although some surgeons believe that reinforcement does not add any significant advantages to the procedure, previous meta-analyses reported that reinforcement decrease efficiently the incidence of post-perative complications like bleeding and others.

Omentopexy is still a controversial technique, that involves fixation of the greater omentum to the stable line after creating the gastric tube. Multiple studies have reported the positive impact of omentopexy in decreasing post-operative volvulus, bleeding, and reflux symptoms. However, it was associated with minimal prolongation of the operative time.

In the current literature, there is a paucity of prospective trials evaluating the role of omentopexy in sleeve gastrectomy procedure. Therefore, this current study was conducted aiming to evaluate the omentopexy role on the early outcomes after laparoscopic sleeve gastrectomy.

PATIENTS AND METHODS
This is a prospective randomized study that was completed between June 2018 and June 2020 for patients diagnosed with obesity and prepared for laparoscopic gastric sleeve surgery. The current study included cases who presented to the outpatient clinic of Al-Hussein University Hospital, Bedaiat and Al Gabry private hospitals.

The required sample size was calculated using the IBM SPSS Sample Power version 3.0.1 (IBM Corp., Armonk, NY, USA). Based on literature review, the incidence of postoperative leakage in the group of cases with no omentopexy in the study conducted by Sabry and Qassem was 0.9% versus 0% of cases in the omentopexy group. A total number of 172 patients (86 in each group) was required with 95% level of significance and power of 80%.

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We included cases whose ages between 18 and 55 years, from both gender, with BMI of ≥ 40 kg/m², and BMI ≥ 35 kg/m² in with associated obesity related co-morbidity. On the other hand, cases with previous upper GIT surgery, liver cirrhosis, or psychological troubles were excluded from the current study. A total of 172 cases were divided randomly using the closed envelope method into two equal groups; the omentopexy group which included 86 cases subjected to laparoscopic sleeve gastrectomy with omentopexy, and the control group which included the remaining 86 cases who underwent the classic sleeve gastrectomy procedure.

All cases were subjected to detailed history taking, thorough physical examination, and routine preoperative laboratory and radiological investigations. Esophagogastroduodenoscopy was ordered in some cases with intractable gastroesophageal reflux disease (GERD) or when an intragastric pathology was suspected.

Ethical approval:
Informed written consent was gathered from the included cases after complete explanation of the details, advantages, and disadvantages of each approach. Furthermore, Ethical approval of the study was obtained by the local ethical committee of the Faculty of medicine, Al-Azhar University.

The operation was done under general endotracheal anesthesia when the patient was in the French position. At the time of skin incision, a single dose of broad-spectrum antibiotic was given (ceftiraxone 2 gm). After abdominal insufflation, ports were inserted as follows; the camera port in the supra-umbilical region, two working ports, one in the right and the other in the left hypochondrial regions, in addition to two assisting ports, one in the subxiphoid region for liver retraction, and the other in the anterior axillary line below the costal margin for gastric traction.

After abdominal exploration, devascularization of the greater curvature was performed via harmonic scalpel or LigaSure hemostatic device, starting 4 – 6 cm from the pyloric ring. The gastric fundus was completely freed from the spleen after division of the short gastric vessels, till the left diaphragmatic crus was identified.

After insertion of 38-F bougie, gastric division was started using Covidien® endo-stapler. The gastric antrum was initially divided by a green cartridge, whereas the remaining stomach was divided using 4 – 5 blue cartridges. Injection of methylene blue was done through the bougie to exclude staple line leakage. After removal of the surgical specimen through the 15-mm port, an intraabdominal drain was inserted, and skin was closed by interrupted non-absorbable sutures.

In the omentopexy group, the same procedure was done in addition to omental fixation to the staple line by a full-thickness PDS 2/0 sutures starting from the angle of His till incisura (Figure 1). Care was taken to take the suture bites in the presence of the bougie to avoid narrowing of the gastric tube.

The patients were commenced on intravenous fluids, proton pump inhibitors (pantoprazole 40 mg vial), and prokinetics (alizapride 50 mg ampoule). Early mobilization was ensured, and on the first post-operative day, an oral gastrograffin test was performed, and if there were no clinical or radiological signs of leakage, oral fluid intake was started. Discharge of most patients was done on day 2 post-operatively. Post-operative complications including bleeding, leakage, GERD, and twist were observed and recorded in both groups. The follow up period ranged between 5 and 27 months.

Our primary outcome was the leakage rate between the two groups, while secondary outcomes included operative time, post-operative bleeding, vomiting, GERD, and gastric tube twist.

Statistical analysis
Data were entered, tabulated and analyzed using SPSS software version 25 for Windows. Patient characteristics were tabulated as mean and standard deviations (SD), median and range, or frequencies and percentages (%). Additionally, Fisher’s exact test (or Chi-Square test) was used to compare qualitative data of the two study groups, whereas quantitative data were compared via Mann-Whitney U and independent-Samples t tests (for non-parametric and parametric and data respectively). For all tests P value <0.05 was significantly considered.

RESULTS
The included cases mean age were 41.3 years and 39.91 years (in the omentopexy and control groups respectively). Females represented 66.28 and 68.6% of cases in both groups respectively. The mean BMI of the included cases was 45.58 and 43.74 kg/m² in both groups respectively. GERD was the commonest co-morbidity as it was present in 6.98 and 8.14% of cases, while diabetes was present in 5.81 and 6.98% of cases in both groups respectively. Other co-morbidities included dyslipidemia, hypertension, and obstructive sleep apnea. Neither of the previous parameters had significant statistics between the study groups (p > 0.05), illustrated below in table (1).
Table (1): Preoperative data.

<table>
<thead>
<tr>
<th></th>
<th>Omentopexy group (n = 86)</th>
<th>Control group (n = 86)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>41.30 ± 5.09</td>
<td>39.91 ± 4.62</td>
<td>0.184 ¶</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Male</td>
<td>29 (33.72%)</td>
<td>27 (31.40%)</td>
<td>0.226 *</td>
</tr>
<tr>
<td>- Female</td>
<td>57 (66.28%)</td>
<td>59 (68.60%)</td>
<td></td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>45.58 ± 3.44</td>
<td>43.74 ± 3.22</td>
<td>0.178 ¶</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Diabetes mellitus</td>
<td>5 (5.81%)</td>
<td>6 (6.98%)</td>
<td></td>
</tr>
<tr>
<td>- Hypertension</td>
<td>5 (5.81%)</td>
<td>5 (5.81%)</td>
<td>0.360 *</td>
</tr>
<tr>
<td>- GERD</td>
<td>6 (6.98%)</td>
<td>7 (8.14%)</td>
<td></td>
</tr>
<tr>
<td>- Dyslipidemia</td>
<td>4 (4.65%)</td>
<td>5 (5.81%)</td>
<td></td>
</tr>
<tr>
<td>- Obstructive sleep apnea</td>
<td>2 (2.33%)</td>
<td>2 (2.33%)</td>
<td></td>
</tr>
</tbody>
</table>

¶: Independent samples t-test
*: Chi square/Fischer’s exact test
GERD: Gastroesophageal reflux disease

Operation duration time was significantly prolonged in omentopexy group (78.33 vs. 62.47 minutes in controls – p = 0.002). Bleeding from the short gastric vessels was encountered only in one case (1.16%) in the control group due to hemostatic device failure, and it was controlled by gauze pressure and replacement of a LigaSure device. Table (2) illustrates these data.

Table (2): Operative data.

<table>
<thead>
<tr>
<th></th>
<th>Omentopexy group (n = 86)</th>
<th>Control group (n = 86)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative time (minutes)</td>
<td>78.33 ± 10.78</td>
<td>62.47 ± 7.03</td>
<td>0.002 ¶</td>
</tr>
<tr>
<td>Operative complications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Bleeding from short gastric vessels</td>
<td>0 (0%)</td>
<td>1 (1.16%)</td>
<td>0.692 *</td>
</tr>
</tbody>
</table>

¶: Independent samples t-test
*: Chi square/Fischer’s exact test

Generally, No significant difference was noted between the study groups as regard either of the studied complications (p > 0.05). However, the incidence of complications was often increased in controls versus the other group. 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. Post-operative transient vomiting was reported by 2.33 and 6.98% of cases in the omentopexy and control groups respectively. The cases reporting GERD symptoms before operation decreased down to 3 cases in each group. Nevertheless, 4 cases developed denovo post-operative GERD symptoms, three controls (3.49%) in addition to one case with omentopexy (1.16%). No cases with gastric twist was diagnosed throughout the follow up period. As regard the hospitalization period, no difference was significantly noted between both groups (p = 0.238). The previous data are summarized in table (3).

Table (3): Post-operative data.

<table>
<thead>
<tr>
<th></th>
<th>Omentopexy group (n = 86)</th>
<th>Control group (n = 86)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leakage</td>
<td>0 (0%)</td>
<td>1 (1.16%)</td>
<td>0.692 *</td>
</tr>
<tr>
<td>Bleeding</td>
<td>0 (0%)</td>
<td>2 (2.33%)</td>
<td>0.326 *</td>
</tr>
<tr>
<td>Vomiting</td>
<td>2 (2.33%)</td>
<td>6 (6.98%)</td>
<td>0.158 *</td>
</tr>
<tr>
<td>GERD</td>
<td>3 (3.49%)</td>
<td>3 (3.49%)</td>
<td>1 *</td>
</tr>
<tr>
<td>Denovo GERD</td>
<td>1 (1.16%)</td>
<td>3 (3.49%)</td>
<td>0.284 *</td>
</tr>
<tr>
<td>Twist</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 *</td>
</tr>
<tr>
<td>Hospital stay (days)</td>
<td>1 (1 – 2)</td>
<td>1 (1 – 3)</td>
<td>0.238 ¶¶</td>
</tr>
</tbody>
</table>

¶¶: Mann-Whitney u-test
*: Chi square/Fischer’s exact test
GERD: Gastroesophageal reflux disease
DISCUSSION

The current study was completed for evaluation of the omentopexy role in the prevention of post-sleeve gastrectomy complications. We included a total of 172 cases who were divided randomly into equal groups; the omentopexy group and controls. The age did not differ significantly between the study groups (p = 0.184), which had mean values of 41.30 and 39.91 years in both groups respectively.

Afenah et al. also reported age range similar to ours as the mean age was 37 years and 43 years in the same groups, with no significant difference between the groups (p = 0.07) 17.

In the current study, females represented 66.28 and 68.60% of cases on the omentopexy and control groups respectively (p = 0.226). In line with our findings, Sharma and Chau reported that the female gender formed 54.86 and 57.76% of cases in the same groups respectively, while the remaining cases were males, without significant difference between the groups (p < 0.05) 18. Another recent study also confirmed the higher prevalence of females (72%) 19. On the other hand, another study reported higher prevalence for males, as they represented 55.9 and 63.3% of cases in the omentopexy and control groups respectively 16.

In our study, operation duration time was significantly prolonged in the omentopexy group (78.33 vs. 62.47 minutes in controls – p = 0.002). Of course, that significant difference in duration should fade away with the increased learning curve. In accordance with our findings, other authors also reported a significant prolongation in operative time in omentopexy group (85 vs. 55 minutes in controls – p = 0.001) 16. Nosrati et al. also confirmed the previous findings as operative time had mean values of 65 and 54 minutes in the same groups respectively 20.

When it comes to the incidence of leakage in the current study, it was detected in 1 case in controls (1.16%) versus no cases in the omentopexy group, without significant difference between the groups (p = 0.692). According to the present literature, the incidence of post-sleeve gastrectomy leakage ranges between 0.5 and 7% 21, and that agrees with our results as out leakage incidence lies within the previous range.

Previous two studies have also denied any significant positive impact of omentopexy on post-sleeve gastrectomy complications 15, 22, and that supports our findings. Conversely, Sabry and Qassem reported a significant reduction in leakage rates in the omentopexy group versus controls (p = 0.003). leakage was happened in 9 cases (0.9%) in controls versus no cases in the omentopexy group. They attributed their finding to the tremendous physiological ability of omentum to seal leakage sites 16. Also, another study suggested that omentopexy decreases the incidence of twisting or kinking that could cause sleeve tube obstruction and proximal leakage 12. Moreover, another study reported that gastric disruptions were encountered in 1.91% of controls versus no cases in the omentopexy groups, with a difference statistically significant between both groups (p = 0.01) 18. Perhaps, the difference in sample size and statistical tests could explain the difference between our results and the latter two studies.

In our study, bleeding was encountered in 2 cases in the control group (2.33%) with no reported cases in the omentopexy group. However, that difference was statistically insignificant (p = 0.326). Likewise, other authors reported no difference between the groups as regard the incidence of bleeding (p = 0.37), as it was encountered in 0.27 and 0.82% of cases in the omentopexy and control groups respectively 18. On the contrary, another Egyptian study reported a significant decrease in bleeding incidence with omentopexy (p = 0.003). Bleeding occurred in 0.8 and 2.6% of cases in the omentopexy and control groups respectively 16. Like leakage, the omentum with its characteristics could seal oozing surfaces and thus decrease the incidence of bleeding 16.

In the current study, transient post-operative vomiting was reported by 2.33 and 6.98% of cases in omentopexy and control groups respectively (p = 0.158). Sleeve gastrectomy procedure is associated with alternations in gastric emptying. Multiple reports reported that the incidence of gastric emptying and food intolerance may reach 30% 23-25, and that may explain the incidence of this symptom. The decreased incidence of vomiting in the omentopexy group could be explained by the proper gastric tube positioning which prevents its twist 19.

In the current study, cases reporting GERD symptoms before operation decreased down to 3 cases in each group (3.49%), without significant difference between the groups. Similarly, Sharma and Chau reported that significantly there was no difference between the groups regarding post-operative GERD symptoms. It was reported in 13.24 and 15.53% of cases in the omentopexy and control groups respectively (p = 0.4) 18. On the other hand, Silva et al. reported that omentopexy was associated with a significant decrease in post-operative GERD scores and reflux symptoms 15. Whether the orientation of gastric tube altered by omentopexy could affect gastric emptying still needs further investigations.

In our study, denovo GERD symptoms were reported by 1.16 and 3.49% of cases in the omentopexy and control groups respectively (p = 0.284). The relationship between sleeve gastrectomy and GERD has been a matter of debate. Although decreased gastric mass should lead to decreased gastric acid production 26, multiple studies have reported GERD promotion and/or aggravation after sleeve gastrectomy 27-29, with high incidence that may reach up to 22% 29. The proposed mechanisms are as follows; disruption of the normal anatomy of the angle of His that work as one barrier against reflux, hypotony of lower esophageal
sphincter, decreased gastric emptying, and formation of a high-pressure tube. All of the previous mechanisms could explain the development of new GERD symptoms in these cases.

In this study, no significant difference was detected between the two groups regarding the duration of hospital stay, as it had median value of 1 day in both groups \( (p = 0.238) \). In agreement with our results, Afaneh et al. reported no significant difference between the two groups regarding the duration of hospital stay, which had mean values of 71 and 71.1 hours in the omentopexy and control groups respectively \( (p = 0.72) \). In contrast with our findings, Sabry and Qassem reported a significant prolongation in hospital stay in controls \( (30 \text{ hours}) \) compared to omentopexy cases \( (24 \text{ hours}) \) \( (p = 0.001) \). That difference is clinically insignificant despite its statistical significance.

Although our study revealed no significant impact of omentopexy in post-sleeve gastrectomy complications which follow the previous report by Hanna et al. and Afaneh et al., the decreased incidence of complications in the omentopexy group could offer some hope to conduct more studies including more cases, to elucidate the impact of this technique on sleeve gastrectomy outcomes.

Our study has some limitations, the relatively small sample size. Also, the assessment of GERD should have been assessed based on endoscopic findings rather than subjective assessment. These drawbacks should be fulfilled in the upcoming studies.

CONCLUSION

Based on our findings, omentopexy did not have a significant positive impact on the prevention of post-sleeve gastrectomy complications although it is associated with longer operative time. However, it may serve as an extra guard against leakage, bleeding, vomiting, and GERD, manifested by the decreased incidence of these complications with that technique.

Conflict of interest

The author has no conflict of interest.

REFERENCES


