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The Added Value of Concomitant Laparoscopic Cholecystectomy and Sleeve Gastrectomy in Morbidly Obese Patients with Gall Stone Disease (A prospective Single Arm Study)

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ABSTRACT

Background: Nowadays obesity is one of the most important health problems. Morbid obesity is defined when the body mass index exceeds 40 kg/m². Obesity is an independent risk factor for gallstones. In obese patients, gallstone is more symptomatic than in non-obese people. Bariatric procedures have been accelerating with simultaneous cholecystectomy application nowadays. However, the routine application of prophylactic cholecystectomy in patients with obesity surgery with gallstone has been discussed in previous literatures. Prophylactic cholecystectomy has come onto the agenda due to adhesions that may occur after past surgery, but currently it is not routinely accepted. Cholecystectomy is recommended in symptomatic patients. Methods: A prospective single arm clinical trial including 48 obese patients presenting in

bariatric clinic in Cairo university hospitals. Proper history was taken and investigations including abdominal ultrasound (US) were done to include the patients with disease whether gall stone symptomatic or not. The presence of preoperative gastroesophageal reflux disease (GERD) symptoms is assessed using Reflux symptomIndex (RSI)^[1]. All patients underwent concomitant laparoscopic sleeve gastrectomy and cholecystectomy and the clinical outcome of the procedure was evaluated in terms of postoperative complications including leakage whether gastric

Within the last MONTH, how did the following problems affect you?	0 =	No Pro	blem !	5 = Sev	ere Pro	blem
Hoarseness or a problem with your voice	0	1	2	3	4	5
Clearing your throat	0	1	2	3	4	5
Excess throat mucous or postnasal drip	0	1	2	3	4	5
Difficulty swallowing food, liquids, or pills	0	1	2	3	4	5
Coughing after you ate or after lying down	0	1	2	3	4	5
Breathing difficulties or choking episodes	0	1	2	3	4	5
Troublesome or annoying cough	0	1	2	3	4	5
Sensations of something sticking in your throat or a lump in your throat	0	1	2	3	4	5
Heartburn, chest pain, indigestion, or stomach acid coming up	0	1	2	3	4	5
	Your RSI is					

or biliary, bleeding, jaundice, and surgical site infection (SSI), operative time and postoperative stay. A 1 month postoperative Reflux Symptom Index score is compared to that collected preoperatively.

Results: In this study, 48 obese patients were included (males 31.3%, females 68.8%) with a mean age of 37.8 years (range 19-59). Regarding GERD assessment using RSI, we found statistically significant deterioration in RSI score collected 1 month postoperatively in comparison to preoperative score (P-value <0.001) with 22% of the cases developing de novo postoperative GERD. On the other hand, incidence of postoperative complications in general was 6.25% including leakage (gastric 2.08%, biliary 2.08%), SSI (4.16%), bleeding and jaundice (0%) while the mean operative time was 112 minutes (range 160-85 mins) and the mean postoperative stay was 2 days (range 12-1 days). Conclusion: In this study, Concomitant laparoscopic sleeve gastrectomy and cholecystectomy caused significant postoperative increase in GERD symptoms as interpreted by the subjective RSI score while no significant increase in postoperative complications including leakage (whether biliary or gastric), bleeding, SSI or jaundice. Operative time and postoperative stay were not significantly prolonged.

Keywords: Obesity, sleeve gastrectomy, cholecystectomy, GERD

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INTRODUCTION

Obesity is the second leading cause of preventable death in the United States, currently outdone only by smoking. However, obesity as a separate disease entity is still underappreciated and certainly misunderstood^[2]. Bariatric surgery has become a cornerstone in treatment of morbid obesity^[3,4]. Laparoscopic Sleeve gastrectomy (LSG) is the most commonly performed bariatric surgical procedure worldwide. ^[5,6] Obese subjects have notably higher incidence of cholelithiasis, cholecystitis, pancreatitis, and cholecystectomies as compared with the non-obese population. ^[7]

Concomitant laparoscopic cholecystectomy with LSG in obese patients with gallstone disease has recently been taken into consideration to spare the patients another surgery lateron specially in the presence of adhesions. ^[8] On the other hand, prolongation of the operative time and potential postoperative complications were still in the way of standardizing the combined procedure. ^[9]

Several investigators commented on the anatomical and physiological effects of LSG and postulated their effect on GERD. Using manometry, it was demonstrated that the pressure in the lower esophageal sphincter (LES) was reduced after LSG which could cause reflux symptoms and esophagitis. [10] On the other hand, A strong causal link appears to exist between cholecystectomy and duodeno-gastric bile Reflux. [11] The constant presence in the duodenum of bile makes its overflow through the duodenum and pylorus of the stomach. [12]

PATIENTS AND METHODS

This is a prospective single arm clinical trial conducted in Cairo University Hospitals during the period from March 2020 till September 2020. Ethical approval for this study was granted upon evaluation by the Scientific Committee of Cairo University. Written consent was obtained from all patients. The study included 48 obese patients eligible for sleeve gastrectomy procedure with gallstone disease whether symptomatic or asymptomatic. Patientsunderwent concomitant cholecystectomy and LSG.

Patients' data including age, sex, BMI, comorbidities, Surgical HO, gallstone (biliary)symptoms, and Reflux Symptom Index (RSI) score were collected preoperatively.

Operative time, RSI score ONE month after surgery and postoperative complications including leakage whether gastric or biliary, postoperative bleeding, jaundice and surgical site infection and the total postoperative hospital stay in days were recorded. Preoperative and postoperative Reflux Symptoms Index score collected from all the patients in the study group were compared. A score equal to or higher than 13 was considered significant for GERD.

Operative procedure briefly follows:Pneumoperitoeum using Verrus needle in Palmer's point, Insertion of four 12 mm trocars (epigastric, Rt and Lt upper quadrants and supraumbilical just to the left of midline) and one 5 mm trocar (Lt anterior axillary line).Patient positioning in anti-Trendelenburg position with the operating surgeon between the patient's legs (French position). Devascularization of the greater curvature. Insertion of 36Fr bougie through the mouth and gastric transection using a linear stapler starting 3-6 cm proximal to the pylorus up to the angle of HIS. Methylene blue test is carried out.Right lumbar 5 mm trocar is inserted for gallbladder fundus retraction.Dissection triangle of Calot till the critical view of safety is obtained. Clipping of cystic duct and cystic artery. Dissection of gallbladder from its bed. Hemostasis, drain insertion and specimen retrieval.

RESULTS

The study included 48 obese patients, of which There were 15 males (31.3%) and 33 females (68.8%). The age of the study subjects was ranging from 19 to 59 years with a mean age of 37 years. The BMI of the study subjects was ranging from 40 to 55 Kg/m2 with a mean BMI of 47 Kg/m2. 23 cases (47.9%) did not have any comorbidity while 25 cases (52.1%) had comorbidities.

Of the total cases, 17 cases (35.4%) had Diabetes Mellitus and 31 cases (64.6%) did not have Diabetes Mellitus. Out of the 25 cases with co-morbidities, 17 cases (35.4%) had co-morbidities other than Diabetes Mellitus mainly hypertension (HTN) and knee osteoarthritis with overlap of co-morbidities in 10 cases (20.8%).

Regarding the surgical history, 22 cases (45.8%) were free without past surgical history and 26 cases gave past history of surgical

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operations, of which, 21 cases had abdominal operations mainly Cesarean Section, appendectomies and mesh hernioplasty.

All the study subjects underwent routine investigations for bariatric surgery including routine blood tests, CXR, ECG, pulmonary function tests, thyroid profile, and pelviabdominal US while 39 cases (81.3%) underwent upper GI endoscopy versus 9 cases (18.8%) did not.10 cases (20.8%) suffered from gall symptoms in the form of biliary colic or fat dyspepsia while 38 cases (79.2%) had no gall symptoms.

The mean operative time was 112.9 minutes (range 85-160 minutes) with a median value of 110 minutes.Postoperative follow up of the study subjects showed that 45 cases (93.75%) did not experience postoperative complications in general while 3 cases (6.25%) suffered postoperative complications with overlapping of some complications.Regarding distribution postoperative complications, 1 case had gastric leak (2.08%), 1 case had biliary leak (2.08%), and 2 cases had SSI (4.16%) while no cases had bleeding or jaundice. The mean postoperative stay was 2 days range (1-12 days) with a median value of 1 day.

By interpreting the preoperative RSI score, 7 cases (14.6%) had GERD while 41 cases (85.4%) had no GERD and by interpreting the postoperative RSI score, 16 cases (33.3%) had GERD while 32 cases (66.7%) had no GERD. Through analysis of the pre and postoperative RSI score of the study subjects it was found that 32 cases (78%) had no pre or postoperative GERD, 9 cases (22%) had no preoperative but developed postoperative GERD, 7 cases had pre and postoperative GERD. All patients with preoperative GERD remained with postoperative GERD and 22% of patient with no preoperative GERD developed postoperative GERD according to RSI score after operation.

Regarding the RSI score there was statistically significant deterioration in the mean and median of RSI score before and after operation (median 7 in pre to be 8.5 in postoperative, mean 7.19 in pre to be 9.58 in postoperative, P-value <0.001). In the group of patients with preoperative RSI score more than 13 (the cut off score significant for GERD); the score worsened in patients with statistically significant increase in the mean and median of postoperative score when compared to

their preoperative score (mean 17.57 in pre to be 21.43 in postoperative and median 18 in pre to be 19 in postoperative, P-value 0.042).

4 cases (8.3%) were admitted in ICU with 3 cases due to anesthetic complications and 1 case due to sepsis from gastric leak. No mortality cases were recorded.

DISCUSSION

The prevalence of cholelithiasis in morbidly obese patients varies between 19% and 45%. In addition to obesity as a well-known factor for development of symptomatic cholelithiasis, rapid weight loss and altered GB function after bariatric surgery is associated with an even greater risk. [13] Therefore, cholecystectomy is often required in obese people, but timing remains controversial. Since most patients remain asymptomatic, there is no basis for routine cholecystectomy. [14]

The mean operative time in our study was 112.9±18.3 minutes (range 85-160 minutes) while the mean postoperative stay was 2.13 ± 2 days range (1-12 days). In a study by Coskun H et al, a retrospective case control study conducted over 48 patients allocated into 16 morbidly obese patients treated with concomitant LSG and cholecystectomy (Group A) whether symptomatic or not and 32 randomly selected patients who underwent laparoscopic sleeve gastrectomy alone. The mean operative time for concomitant laparoscopic cholecystectomy and gastrectomy was with 157.2 minutes while for LSG alone was 95 minutes which means an additional mean operative time of 49.1± 27.9 minutes without any specific complication is needed to perform cholecystectomy. The mean postoperative stay was 3.5 days.[15]

In a study by *Dincer M et al*, A total of 97 patients were divided into two groups according to the applied surgical technique: laparoscopic sleeve gastrectomy + concomitant cholecystectomy (LSG + CC) (n = 27) and laparoscopic sleeve gastrectomy (LSG) (n = 70). The surgery duration of the LSG + CC group was longer (65.7 \pm 8.5 min vs. 57.1 \pm 8.7 min), while the mean postoperative stay was 4 days for concomitant cholecystectomy + LSG versus 3 days in LSG alone. [16]

In a study by *Hanaa et al*, LSG was performed in 21137 patients. Of these, 422 (2%) underwent laparoscopic cholecystectomy at the

time of their operation (LSG+CC). The average operative time was significantly higher in LSG+CC (128.2 \pm 53.9 minutes) versus LSG alone (95.3 \pm 47.3 minutes) by around 33 minutes (p<0.001). Length of hospital stay was similar in both groups (2.3 vs 2.1 days, p=0.57)^[17]

In this study, postoperative follow up of the study subjects showed that 45 cases (93.75%) did not experience any postoperative complications in general while 3 cases (6.25%) suffered postoperative complications with overlapping of some complications. Gastric leak occurred in only one case who also developed SSI along with another case and biliary leak occurred in one case while none of the cases developed bleeding or jaundice. In the study by *Dincer M et al*, that was mentioned before. Bleeding developed in 1 (3.7%) patient while no postoperative leakage developed of in any the patients. Simultaneous cholecystectomy in this study was found to be more difficult to implement than standard cholecystectomy. [16]

In the study by *Hanaa et al* that was mentioned before, Bleeding occurrences were higher in LSG+CC group (1.9%) than LSG alone (0.9%), but the difference was not statistically significant (p=0.07) while no differences in wound complication rates was found between 2 groups.^[17]

Despite CC being reported as safe during LSG, *Raziel et al* reported in his study, which included 180 patients who underwent concomitant cholecystectomy with LSG, intraoperative bile duct injuries with a ratio of 1.1%. Other complications encountered were observed such as bleeding (2.2%) and gastric leakage (1.1%). [18]

A study by *Gibson SC et al*, reported improvement of GERD symptoms after LSG. The study was a retrospective review of prospectively collected data of 500 consecutive patients undergoing LSG, 225 (45%) patients reported GERD symptoms preoperatively, with 130 (26%) already on acid lowering medication. In contrast, post-sleeve reflux symptoms were present in just 30 patients (6%), manifesting as simple heartburn responding to acid lowering medication in 26 patients (5.2%), significant belching in two patients (0.4%) or volume reflux in two of the patients (0.4%). [19]

In contrast to a study by *DuPree CE et al*, that reported worsening and developing de novo GERD in post LSG patients. A total of 4832

patients underwent LSG of which 44.5% had preexisting GERD. Most patients (84.1%) continued to have GERD symptoms postoperatively, with only 15.9% demonstrating GERD resolution. Of patients who did not demonstrate preoperative GERD, 8.6% developed GERD postoperatively. The presence of preoperative GERD was associated with increased need for revisional surgery. [20]

A meta-analysis by **Yeung KT et al,** that included a total of 46 studies totaling 10,718 patients, found that the increase of postoperative GERD after sleeve (POGAS) was 19% and de novo reflux was 23% [21]

Regarding the effect of cholecystectomy on GERD, A prospective study by *Uyanıkoğlu et al*, included 14 patients with cholecystolithiasis and a control group including 10 healthy control subjects and reflux symptom score scale and 24-hour impedance pH values of the 14 cholecystolithiasis cases and the control group were evaluated. The impedance pH study was repeated 3 months after cholecystectomy. No statistically significant difference was found in the comparison of symptoms between the subjects in the control group and the patients with cholecystolithiasis, in preoperative, postoperative and postcholecystectomy status.^[22]

Another study by *Lin OS et al*, included 321 subjects, including 125 cholecystectomy patients (study group) and 196 hernia surgery (control group), they were assessed for GERD by Reflux Symptom Index (RSI) and Gastrointestinal Symptom Rating Scale (GSRS) questionnaires preoperative and 1 month postoperative. It showed that cholecystectomy does not lead to worsened reflux symptoms; in fact, there is a trend towards improvement.^[23]

CONCLUSION

Concomitant cholecystectomy and LSG is a safe procedure with no significant morbidities in our study.

Concomitant cholecystectomy and LSG does not significantly increase the postoperative stay and the increase in operative time is progressively shortened by the advance in laparoscopy and with experienced hands.

GERD symptoms increased significantly in this study subjects comparing pre to postoperative status; however, more studies are required to clearly define the relationship between GERD and the concomitant procedure.

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