The effect of different types of laparoscopic bariatric procedures on type 2 diabetic obese patients

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Background: The rising global incidence and prevalence of type II diabetes (T2DM) has paralleled the rise in obesity. Bariatric surgery is currently the most effective treatment for obesity compared to maximal medical and lifestyle management.
Objectives: This work aimed to compare the efficacy and safety of LSG (group 1), (LRYGB) (group 2) and (MGB) (group 3) for T2DM obese patients.
Patients and Methods: A randomized prospective clinical study for 225 patients with morbid obesity (BMI 35 kg/m^2 or more with T2DM) treated by laparoscopic sleeve gastrectomy (LSG),laparoscopic Roux-en-Y gastric bypass(LRYGB) and mini gastric bypass (MGB),(75 patients in each group) conducted in Qena and Alexandria university hospitals from March 2019 to September 2020.The primary outcome was complete remission of type 2 diabetes with hyperglycemia control, (HbA1c <6 %). The secondary outcome was weight loss is by calculating the percentage of excess weight loss (% EWL)
Results: There was statistically significant difference between the three studied groups regarding time of surgery (96.5 ± 17.6, 107.3 ± 19.4, and 106.6 ± 15.8 among group 1, 2, and 3respectively; P-value < 0.05). There was no statistically significant difference between the three studied groups regarding hospital staying duration and postoperative complication. There was no statistically significant difference between the three studied groups regarding HbA1C post-operative.
Conclusion: Metabolic surgery has emerged as the single most effective treatment option for T2DM and obesity. There is a potential superiority of the LRYGB and MGB over the LSG in obtaining diabetes remission.

Keywords: Bariatric surgery, diabetes, gastric bypass, sleeve gastrectomy.

Introduction

T2DM has significant impacts on morbidity, mortality, quality of life, and healthcare costs. It is the second leading cause of obesity related death, and the leading cause of obesity related disability **(Akpinar et al., 2021)**.

Approximately 90% of T2DM is attributable to excess weight, and multiple trials have now demonstrated a reduction in all-cause mortality following bariatric surgery, with a 92% decrease in diabetes related deaths**(Shenoy et al., 2020)**.

The management of patients with obesity and T2DM is both complex and challenging. It is clearly evident from several experimental and observational studies and more recently from randomized controlled trials that diabetes surgery offers superior results both in terms of efficacy and durability of glycaemic control when compared to lifestyle modifications and pharmacotherapy **(Sha et al., 2020)**.

There is now also a significant body of evidence indicating that patients with BMI less than 35 kg/m^2 can also respond favorably to diabetes surgery in the short-term **(Shenoy et al., 2020)**.

Diabetes remission results from improvements in both insulin resistance and β-cell dysfunction, but the degree of their improvement also depends on the type of surgery performed **(Hanet al., 2020)**. The sleeve gastrectomy was initially thought to be a restrictive procedure. More recent studies have proposed that removal of the fundus may have a hormonal mechanism as it contains ghrelin-producing **cells (Mullallyet al., 2019)**.

Generally, immediately after bypass surgery, acute calorie restriction leads to improved glucose tolerance due to improved hepatic insulin sensitivity and reduced hepatic glycogen stores. Later, the incretin effect due to hormonal changes is responsible for further improvements in insulin secretion and sensitivity in conjunction with GLP-1 (Glucagon-Like Peptide 1), GIP (Glucose-Dependent Insulinotropic Polypeptide) and PYY (Peptide Tyrosine Tyrosine)**(Sha et al., 2020)**.

Patients and methods

This study was a randomized clinical study for 225 patients with morbid obesity (BMI 35 kg/m^2 or more with T2DM) treated by LSG,LRYGB and MGB. This study conducted in Qena and Alexandria university hospitals from March 2019 to September 2020.

Inclusion criteria: age from 20 to 60 years, both sexes with history of failed weight loss attempts in the past and good motivation for surgery and patients with a BMI 35 kg/m^2 or more with T2DM, with or without coexisting other medical problems. Exclusion criteria: Previous bariatric surgery, previous gastric surgery and females during pregnancy.

All patients were subjected for detailed history and clinical examination (general, local), obesity-related morbidities, causes of obesity, weight/BMI, weight loss history, and exclusions related to surgical risk. Intraoperative data including blood loss, mean operative time, and hospital stay were recorded. Follow-up occurred at approximate intervals of 4 weeks, 12 weeks, 24 weeks, 36 weeks, and then 48 weeks. The follow up parameters was submitted for weight, BMI, excess weight loss % (%EWL), HbA1c.

Research outcome measures**:** Primary (main):Complete remission of type 2 diabetes with hyperglycemia control, (HbA1c <6 %). Partial remission was defined as sub-diabetic hyperglycemia (HbA1c 6–6.4 %) of at least 1year duration**.** Secondary (subsidiary): Weight loss is by calculating the percentage of excess weight loss (% EWL).Co morbidity changes were assessed either resolution or improvement. Complications (leakage, bleeding, and mortality) were recorded. The operative technique was standardized for all patients.

All patients were subjected for general anesthesia. We used Optical trocars that allow visual control of the access to the peritoneum and the creation of the pneumoperitoneum using CO_2 up to pressure of 14 to 15 mmHg.

In our technique we used five trocars. The first trocar (camera port), 10 – 12 mm, was placed at the supra umbilical region slightly to the left, two more 5- mm ports were placed in the supra umbilical region, one sub xiphoid and another in the right upper quadrant. One 12 or 15-mm trocar, (12-15 cm caudal to the xiphisternum at the Rt paramedian plain passing through the rectus sheath), was placed in the mid-abdomen just medial to the mid clavicular lines in the right. Finally, a 5-mm trocar used by an assistant for retraction was placed in the left upper quadrant, high enough to reach the top of the gastric fundus(**Fig.1**).

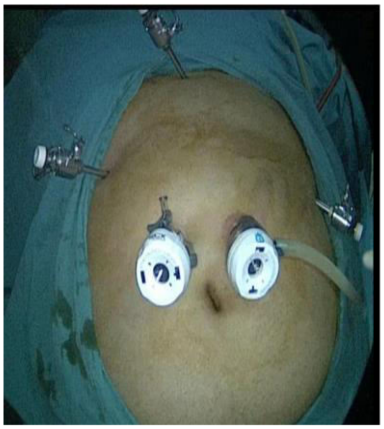

Fig.1. Port distribution

All procedures were performed laparoscopically, described in the literature previously (Borgeraas, Hofsø et al. 2020). LSG was performed by dissection of the greater curvature free from the omentum at site between the antrum and the corpus upward toward the angle of His with creation of a tubular sleeve using a 34-Fr bougie(**Fig.2**).

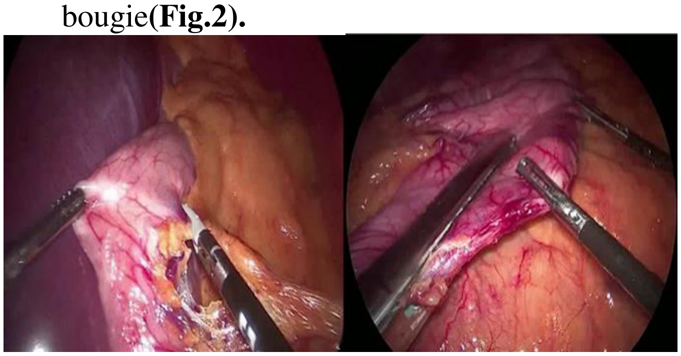

Fig.2. Detachment of the greater omentum from the stomach and cutting the short gastric vessels

LRYGB was performed by creating a gastric pouch using a 34-Fr bougie, an alimentary limb of 150 cm, and a biliopancreatic limb of 50 cm (**Fig.3**).

MGB was performed by preparing a gastric pouch and tailoring a mechanical linear wide gastrojejunal anastomosis at 150 cm from the ligament of Treitz(**Fig. 4).**

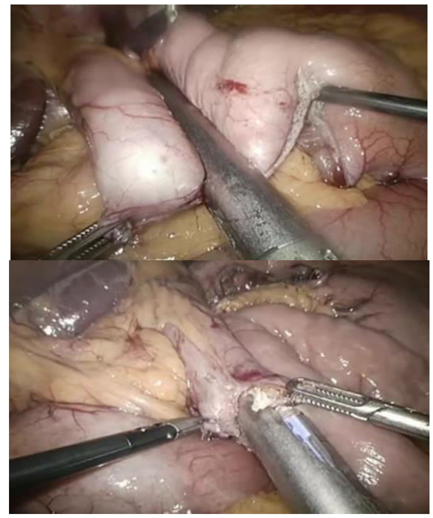

Fig.3. Performance of the gastric section and End-to-side gastro-jejunostomy

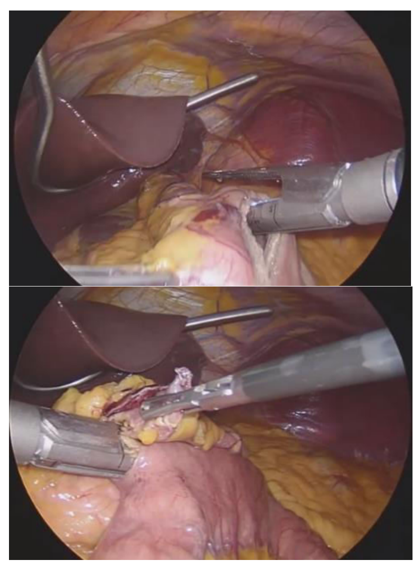

Fig.4. Performance of the gastric section and side-to-side gastro-jejunostomy

Ethical Approval: The study protocol was approved by the Ethical Committee of Faculty of Medicine, South Valley

University and written informed consent was taken from each patient.

Statistical analysis

Data collected throughout history, basic clinical examination, laboratory investigations and outcome measures coded, entered and analyzed using Microsoft Excel software. The collected data was computerized and statistically analyzed using SPSS program (Statistical Package for Social Science) version 26. Data was tested for normal distribution using the Shapiro Walk test. Qualitative data was represented as frequencies and relative percentages. Chi square test ($\chi 2$) was used to calculate difference between qualitative variables as indicated. Quantitative data was expressed as mean and standard deviation. Paired t test to compare between pre and post operative quantitative data of the same group. One way ANOVA and Kruskal-Wallis test was used to calculate difference between quantitative variables in the three groups for parametric and non-parametric variables. Level of P-value < 0.05 indicates significant while, P≥ 0.05 indicates non-significant difference.

Results

Sociodemographic data of the participants are shown in (**Table.1).** There was no statistically significant difference between the three studied groups regarding age, sex and marital status.

Table 1: Sociodemographic data of the participants.

Variables		Group 1 Sleeve (n=75)	Group 2 Roux-en-Y bypass (n=75)	Group 3 Mini gastric bypass (n=75)	P value
Age/year	Mean ± SD	37.7± 8.8	39.3± 11.1	38.3± 10.5	0.723
Gender	Female, n (%)	56 (75)	57 (76)	53 (70)	0.847
	Male, n (%)	19 (25)	18 (24)	22 (30)	
Marital status	Married, n (%)	22 (42)	42 (56)	36 (48)	0.399
	Single, n (%)	53 (58)	33 (44)	39 (52)	

Preoperative anthropometric measures among the three studied groups were shown in (**Table.2).** There was no statistically significant difference between the three studied groups regarding weight, height and BMI.

The mean HbA1C preoperatively was 7.9± 0.7, 8.0± 0.7, and 8.2± 0.7 among group 1, 2, and 3 respectively. There was no statistically significant difference between the three studied groups regarding mean HbA1C.

Table 2. Preoperative anthropometric measures among the three studied groups.

Variables	Group 1 Sleeve (n=75)	Group 2 Roux-en-Y bypass (n=75)	Group 3 Mini gastric bypass (n=75)	P value
Weight/kg Mean ± SD	119.0± 12.5	124.9± 24.8	127.3± 19.5	0.101
Height /cm Mean ± SD	161.8± 5.9	160.4± 9.2	161.9± 8.3	0.566
BMI Mean ± SD	45.8± 4.3	48.6± 9.7	48.7± 6.4	0.082

Operative data among the three studied groups were shown in (**Table.3).** There was statistically significant difference between the three studied groups regarding time of surgery.

Table 3. Operative data among the three studied groups.

Variables	Group 1 Sleeve (n=75)	Group 2 Roux-en-Y bypass (n=75)	Group 3 Mini gastric bypass (n=75)	P value
Time of surgery Mean ± SD	96.5 ± 17.6	107.3 ± 19.4	106.6 ± 15.8	P1=**0.021*** P2=>0.999 P3= **0.007***
Drain				
No	0	0	0	--
Yes	75 (100)	75 (100)	75 (100)	
Hospital stay				
One day	31 (42)	40 (54)	21 (28)	
Two days	36 (48)	30 (40)	40 (54)	0.220
Three days	8 (10)	5 (6)	14 (18)	
Complications				0.490
No	60(81)	61(82)	68(91)	
Bleeding	8 (10)	8 (10)	3 (4)	
Leakage	7 (9)	6 (8)	4 (5)	
Mortality	0 (0)	0 (0)	0 (0)	

Comparison between pre and postoperative weight of the participants were shown in (**Table.4).** There was statistically significant difference between pre and postoperative weight in the three studied groups.

Table 4. Comparison between pre and postoperative weight of the participants.

Variables	Group 1 Sleeve (n=75)	Group 2 Roux-en-Y bypass (n=75)	Group 3 Mini gastric bypass (n=75)
Weight/kg preoperative Mean ± SD	119.0± 12.5	124.9± 24.8	127.3± 19.5
Weight after 48 weeks Mean ± SD	69.5± 7.9	63.6± 6.2	70.1± 7.6
P value	**<0.001***	**<0.001***	**<0.001***

Comparison between pre and postoperative BMI of the participants were shown in (**Table.5).** There was statistically significant difference between pre and postoperative BMI in the three studied groups.

Table 5: Comparison between pre and postoperative BMI of the participants.

Variables	Group 1 Sleeve (n=75)	Group 2 Roux-en-Y bypass (n=75)	Group 3 Mini gastric bypass (n=75)
BMI Mean ± SD	45.8± 4.3	48.6± 9.7	48.7± 6.4
BMI after 48 weeks Mean ± SD	27.5± 1	24.8± 3.6	26.9± 2.7
P value	**<0.001***	**<0.001***	**<0.001***

Comparison between pre and postoperative HbA1C of the participants were shown in (**Table.6**).There was statistically significant difference between pre and postoperative HbA1C in the three studied groups.

Discussion

In our study we found a significant lower operative time of LSG group versus LRYGB group and MGB group (96.5 ± 17.6 min. for LSG group, 107.3 ± 19.4 min. for LRYGB group, and 106.6 ± 15.8 min. for MGB group), *P* value = 0.007. In line with our results, Wehrtmann et al. reported an operative time significantly shorter in LSG than LRYGB, (mean 66 min., range 40-188 vs mean 94 min., range 52–195), respectively **(Wehrtmannet al., 2020**).

Table 6. Comparison between pre and postoperative HbA1C of the participants.

Variable	Group 1 Sleeve (n=75)	Group 2 Roux-en-Y bypass (n=75)	Group 3 Mini gastric bypass (n=75)
HbA1C Mean ± SD	7.9± 0.7	8.0± 0.7	8.2± 0.7
HBA1c after 48 weeks Mean ± SD	4.9±0.3	4.6±0.3	4.8±0.2
P value	**<0.001***	**<0.001***	**<0.001***

In this study, bleeding occurred in 19 cases (8 in LSG group,8 in LRYGB group and 3 in MGB group). In 11 cases, the bleeding was discovered intraoperatively and managed immediately by application of metal clips and absorbable suture and postoperatively these cases were followed and improved. In 8 cases, there was bleeding postoperative in the drain in the first 48 hours. As the patients were stable, all these cases were managed conservatively by giving haemostatic measures and blood and plasma transfusion.

In this study, leakage occurs in 17 cases. Leak test was done intraoperative, and 10 patients were positive (4 in LSG, 3 in LRYGB and 3 in MGB). This leakage which discovered intraoperatively, undergone repair using vicryl 3/0 stitches. Methylene blue test was repeated and was negative.

In this study,7 cases of leakage were detected postoperatively, from the third to the fifth day, (3 cases in LSG, 2 cases in LRYGB and 3 cases in MGB).

Patients presented postoperatively with sudden abdominal pain, accompanied with fever and tachycardia. Computed tomography (CT) of the abdomen with IV and oral contrast was done and showed the presence of small abdominal collection, extravasation of contrast into the abdominal cavity through minute perforation.

In cases of LSG, as the patient was stable, we managed these cases non-surgically with percutaneous drainage for intraabdominal collection and Mega stent insertion endoscopically and left for 6 weeks then removed. In cases of LRYGB and MGB, 3 cases were managed conservatively with percutaneous drainage and 2 cases need diagnostic laparoscopy and repair of the identified leakage site.

This protocol of management is involved in treatment algorithm by **Bashah et al., 2020** for management of leak after sleeve gastrectomy, in contrast to Nimeri et al.,2016 who reported that 21% of patients required conversion to an extensive laparoscopic procedure(**Nimeri et al., 2016;Bashahet al., 2020**).

The degree of decrease of BMI was greater in LRYGB cases than LSG and MGB cases during follow up visit except after 24 weeks. Mean ± SD degree of BMI decrease in LSG, LRYGB and MGB cases after 48 weeks 27.5±1, 24.8± 3.6 and 26.9± 2.7 respectively.

Our findings extend and support some secondary and exploratory outcomes from the STAMPEDE trial, which showed that the proportion of patients with diabetes remission was non-significantly higher 1 year after gastric bypass than after sleeve gastrectomy (42% vs 27%), and that the proportion of patients not using any antidiabetic medication at 1 year was 78% after gastric bypass and 51% after sleeve gastrectomy(**Castro et al., 2020**).

Our finding seems to confirm those hypotheses that diabetes remission may be independent from weight loss and reinforces the concept that the type of surgery may play a more relevant role (**Carlsson et al., 2021**). If we consider, for both MGB and LSG, the changes of HbA1c in relation to BMI decrease, we did not find any significant correlation between BMI decrease and diabetes remission

Conclusion

From this study we can conclude: Metabolic surgery has emerged as the single most effective treatment option for Type II diabetes and obesity. According to our results at 1 year, both LSG, MGB and LRYGB in patients presenting a BMI >35 kg/ m^2, provide significant weight loss and Type II DM remission. All procedures result in amelioration of hyperglycaemia and reduction of HbA1c levels, and this effect starts immediately after surgery and continues for the first year of follow up. Overall, there is a potential superiority of the LRYGB and MGB over the LSG in obtaining diabetes remission.

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