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Short Term Outcomes of Laparoscopic Roux-En-Y Gastric Bypass Versus Laparoscopic One Anastomosis Gastric Bypass in Super Obese Patients: Randomized Clinical Trial

Mahmoud El Ghoneimy Abd El-Sadek, Ahmed Ibrahim Swelam, Hamdy Sedky Abdallah, Gamal Ibrahim Moussa, Osama Helmy El Khadrawy

General Surgery Department, Faculty of Medicine, Tanta University, Tanta, Egypt

Email address:
Mahmoud.elghoneimy@med.tanta.edu.eg (M. El G. A. El-Sadek), ahmed.swelam@med.tanta.edu.eg (A. I. Swelam), hamdy.abdallah@med.tanta.edu.eg (H. S. Abdallah), gamal.mousa@med.tanta.edu.eg (G. I. Moussa), osama.elkhadrawy@med.tanta.edu.eg (O. H. El Khadrawy)

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Abstract: *Background*: One anastomosis gastric bypass (OAGB) has several apparent advantages over Roux-En-Y Gastric Bypass (RYGB). However, symptomatic biliary reflux and its potential risks have prevented its widespread adoption. The aim of this study was to assess the short term outcomes of LOAGB in comparison to LRYGB in treatment of patients with super obesity regarding weight loss, resolution/improvement of co-morbidities and impact on patients' quality of life (QoL). *Methods*: One hundred adult patients with super obesity were randomly divided into 2 matched groups, 50 patients each; group I underwent LRYGB and group II underwent LOAGB. *Results*: The operative time was significantly longer in LRYGB (176.4±27.29 vs. 110.5±14.13 minutes, $p<0.05$). The frequency and severity of the early postoperative complications were comparable between both groups. No mortality or re-admission was reported in both groups. There are no patients lost to follow-up. Although, the mean Excess weight loss percent (EWL%) was 57% vs 64.7% and 69.7% vs 75.5% at one and two years follow-up in group I and II respectively, the differences were statistically insignificant. T2DM remission/improvement rates at 12^{th} month were 88.9% and 94.1% in group I and II respectively without a statistically insignificant difference. In comparison to the preoperative Qol score, the postoperative score showed a statistically significant improvement (from 0.31 to 6 and from 0.41 to 6.32 in group I and II respectively). *Conclusions*: LOAGB had a shorter operative time and a tendency towards a higher EWL%, a better remission of obesity-related comorbidities and improvement in the patients QoL with comparable short term operative and postoperative complications. Thus, LOAGB can be considered an acceptable alternative to LRYGB in management of super obese patients.

Keywords: Laparoscopic Roux-en-Y Gastric Bypass, Laparoscopic One Anastomosis Gastric Bypass, Super Obesity

1. Introduction

Currently, bariatric surgery is the only efficient treatment option leading to sustainable weight loss and reduction in obesity-related comorbidities [1].

Laparoscopic Roux-En-Y Gastric Bypass (LRYGB) is regarded as the gold standard treatment of morbid obesity. It achieves durable long-term weight loss and improves obesity-related comorbidities [2]. Laparoscopic one anastomosis gastric bypass (LOAGB) has several apparent advantages over RYGB including single anastomosis, fewer internal defects for herniation and ease of construction, and revision. However, concerns relating to symptomatic biliary reflux and its risk on the stomach and esophagus have prevented its widespread adoption [3].

The aim of this study was to assess the short term outcomes of LOAGB in comparison to LRYGB in treatment of patients with super obesity regarding weight loss, resolution/improvement of comorbidities and impact on patients' quality of life (QoL).

2. Material and Methods

2.1. Methodology

This randomized clinical trial was conducted at the gastrointestinal and laparoscopic surgery unit, general surgery department, Tanta university hospitals, Egypt during the period from September 2018 to December 2020 on 100 patients with super obesity. The study protocol was approved by the local research ethics committee and an informed written consent was obtained from every patient before being enrolled in the study.

2.2. Selection Criteria

The study included patients from both genders, age 18-60 years with super obesity (BMI $\geq$ 50 kg/m^2) with or without comorbidities. Exclusion criteria included previous bariatric surgery, secondary obesity, American Society of Anesthesiologists class III and IV, liver cirrhosis, mentally instability, drug and/or alcohol abuse and pregnancy. Selected patients were randomly divided into 2 groups using the closed envelope method; group I included 50 patients who underwent LRYGB and group II included 50 patients who underwent LOAGB.

2.3. Data Collection

Preoperative evaluation included history taking with a questionnaire for assessing the QoL suggested by Oria and Moorehead [4]. Obesity-related comorbidities and presence of metabolic syndrome were documented. Diabetic Remission (Diarem) score proposed by Still et al., [5] was calculated. Anthropometric measurements, laboratory investigations, imaging studies and upper gastrointestinal (GI) endoscopy data were also collected. Operative data including operative time and complications were recorded. During follow-up, data were collected regarding weight loss progress, status of comorbidities, and any recorded complications.

2.4. Technical Aspects of Surgery

Both techniques were performed using the standard 5 ports approach. LRYGB included a creation of 4 cm wide lesser curve-based subcardiac pouch starting between the 2nd and 3rd gastric branches of the left gastric vessel. The whole length of the small bowel was routinely measured before division of the bowel. Then, a 3 cm long linear gastro-jejunal anastomosis (GJA) was performed creating a 50 cm long biliopancreatic limb (BPL) and 150 cm long alimentary limb ensuring that the common channel is at least 400 cm. In LOAGB, a 4 cm wide gastric pouch was created starting by dividing the lesser curve at the level of the incisura angularis, followed by creation of a 4 cm long linear GJA at 200 cm from duodenojejunal flexure (DJF). A leak test using methylene blue was performed in all cases.

2.5. End Points

The primary endpoints were weight loss in terms of EWL% and exess BMI loss percent (EBMI loss%), and remission/improvement of comorbidities while secondary endpoints included the operative time, length of hospital stay, complications, change of the patients' QoL and mortality at one year after surgery.

2.6. Statistical Analysis

Data were analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). Qualitative data were described using number and percent. The Kolmogorov-Smirnov test was used to verify the normality of distribution. Quantitative data were expressed as median and mean with standard deviation. The used tests were Chi-square test, Fisher's Exact or Monte Carlo correction, Student t-test and Paired t-test. P value less than 0.05 was considered statistically significant.

3. Results

3.1. Patients' Demographic and Preoperative Data

Both groups were comparable regarding gender, age, anthropometric measures, and distribution of comorbidities. In the subgroup of patients with T_2DM, Diarem score showed no statistically significant difference between both groups. The mean preoperative score of QoL questionnaire was 0.31±0.81 and 0.41±0.92 in group I and II, respectively, without a statistically significant difference [Tables 1 and 2].

3.2. Operative and Postoperative Data

All procedures were completed laparoscopically. The operative time (without concomitant procedures) was significantly longer in LRYGB than LOAGB (176.4±27.29 vs. 110.5±14.13 minutes, $p<0.05$). Concomitant surgical procedures included mesh repair of paraumbilical hernias in 3 patients (2 in group I and 1 in group II) and cholecystectomy in 7 patients (4 in group I and 3 in group II). The mean postoperative hospital stay was 4.38±0.59 and 4.18±0.55 days in group I and II respectively with a statistically insignificant difference.

Table 1. *Patients' demographic and Preoperative data.*

	Group I (n=50)	Group II (n=50)	P value
Female	41 (82%)	38 (76%)	NS
Mean age (mean±SD)	39.20±6.76	40.50±6.67	NS
Body weight (kg) (mean±SD)	136.9±8.45	145.2±13.01	NS
BMI (kg/m^2) (mean±SD)	56.73±4.69	59.70±4.32	NS
EBW (kg) (mean±SD)	81.98±4.53	82.60±5.31	NS
Osteoarthritis	38 (76%)	33 (66%)	NS
Metabolic Syndrome	25 (50%)	28 (56%)	NS
Dyslipidemia	22 (44%)	26 (52%)	NS

	Group I (n=50)	Group II (n=50)	P value
Hypertension	25 (50%)	21 (42%)	NS
OSA	21 (42%)	24 (48%)	NS
T2DM	22 (44%)	21 (42%)	NS
Hyperuricaemia	12 (24%)	16 (32%)	NS
Pseudo-tumour cerebri	1 (2%)	1 (2%)	NS

BMI: Body Mass Index, EBW: Excess Body Weight, OSA: Obstructive Sleep Apnea, T2DM: Type 2 Diabetes Mellitus

Table 2. *Diarem score.*

	Group I (n=22)	Group II (n=21)	P value
Diarem Score			
1. Score (Mean±SD)	6.35±3.84	6.90±2.18	NS
2. Predictive value of remission (%)	64-88%	64-88%	
Age (years)			
1. < 40	2	4	NS
2. 40-49	17	15	
3. 50-59	3	2	
Medications			
Oral hypoglycemic	11	12	
i) Sulfonylurea or insulin sensitizing agents	9	6	NS
ii) Not Sulfonylurea or insulin sensitizing agents			
b-Insulin therapy	2	3	
HbA1C level			
1. 6.5-6.9	18	14	NS
2. 7.0-8.9	4	7	
3. >9	0	0	

Diarem score: Diabetic Remission score

Early postoperative complications (within 30 days from the operation) were comparable between both groups in respect to frequency and severity according to Clavien-Dindo classification and all were managed conservatively. No mortality or re-admission was reported in both groups.

The follow-up period ranged from 12 to 24 months with a mean of 19.10±3.38 in group I and 16.33±2.61 in group II. Late post-operative complications were recorded in 6 and 11 patients in group I and II, respectively, without a statistically significant difference [Table 3].

Table 3. *Operative data and postoperative data.*

	Group I (n=50)	Group II (n=50)	P value
Operative time (minutes)	176.4±27.29	110.5±14.13	*<0.001**
Small bowel length (M)	7.10±0.68	6.94±0.91	NS
Intra operative complications			
1. Minor liver injury	3	4	NS
2. Splenic capsule tear	1	1	
3. Stapler misfire	1	0	
Hospital stay (days)	4.38±0.59	4.18±0.55	NS
Early post-operative complications			
1. Reactionary hemorrhage	1	0	NS
2. Port-site infection	3	2	
Late postoperative complications			
1. GERD symptoms	1	3	
2. Dumping syndrome	3	1	NS
3. Aneamia	1	3	
4. Hypocalcemia	1	2	
5. Gallbladder stones formation	0	2	

3.3. Weight Loss

Although there was a higher EWL% and BMIL% in group II than in group I at 12th and 24th postoperative month, this difference failed to reach a statistical significance [Table 4].

Table 4. *Weight loss at 12 and 24 months.*

	Group I	Group II	P value
At 12 months	(n=50)	(n=50)	
1. TWL %	33.9±1.21	36.5±1.08	NS
2. EWL%	57.08±1.38	64.73±2.83	
3. EBMI loss %	51.45±1.13	55.35±2.13	

	Group I	Group II	P value
4. Δ BMI	17.1±0.73	19.8±1.28	
At 24 months	(n=27)	(n=24)	
1. TWL %	41.5±1.32	42.7±1.14	
2. EWL%	69.70±1.64	75.50±1.69	NS
3. EBMI loss %	62.90±2.23	66.75±1.16	
4. Δ BMI	24.6±1.88	27.1±1.27	

TWL %: Percent of Total Weight loss, EWL%: Percent of Excess Weight loss, EBMI loss %: Percent of Excess Body Mass Index loss, Δ BMI: Change in Body Mass Index

3.4. Outcomes of Comorbidities and Metabolic Parameters

At 12th postoperative month, the improvement and the remission rates of these comorbidities were higher in group II than group I, there was no statistically significant difference [Table 5].

The Diarem score of diabetic patients was 3-7 indicating 64-88% probability of remission in both groups. The actual postoperative remission/improvement rates of T_2DM were 88.9% and 94.1% in group I and II respectively.

Table 5. *Outcomes of co-morbidities and metabolic parameters at 12th month.*

	Group I	Group II	P value
Osteoarthritis	(n=38)	(n=33)	
1. Complete remission	15 (50%)	15 (55.6%)	NS
2. Improvement	9 (30%)	8 (29.6%)	
3. No improvement	6 (20%)	4 (14.8)	
Dyslipidemia	(n=22)	(n=26)	
1. Remission	11 (61.1%)	16 (76.1%)	NS
2. Improvement	5 (27.8%)	4 (19.0%)	
3. No improvement	2 (11.1%)	1 (5.3%)	
Hypertension	(n=25)	(n=21)	
1. Remission	13 (65.0%)	13 (76.4%)	NS
2. Improvement	5 (25.0%)	3 (17.6%)	
3. No improvement	2 (10.0%)	1 (5.6%)	
OSA	(n=21)	(n=24)	
1. Remission	10 (58.8%)	13 (68.4%)	NS
2. Improvement	5 (29.4%)	5 (26.3%)	
3. No improvemt	2 (11.7%)	1 (5.2%)	
T_2DM	(n=22)	(n=21)	
1. Remission	12 (66.7%)	13 (76.5%)	NS
2. Improvement	4 (22.2%)	3 (17.6%)	
3. No improvement	2 (11.21%)	1 (5.9%)	
Psuedo-tumour cerebri	(n=1)	(n=1)	NS
Remission	1 (100%)	1 (100%)-	

OSA: Obstructive Sleep Apnea, T2DM: Type 2 Diabetes Mellitus

3.5. Post-operative Endoscopy

Postoperative endoscopic examination was performed for 29 symptomatic patients, 12 in group I and 17 in group II. Gastric pouchitis was found in 2 patients in group I and 4 patients in group II, while stomal ulceration was found in 2 patients of group II only. The difference between the two groups was statistically insignificant. Gastric mucosal biopsy tested positive for *H Pylori* in 2 patients in group II. All patients responded well to medical treatment. There was no endoscopic evidence of biliary reflux in examined patients.

3.6. Postoperative QoL and BAROS Score

BAROS score outcomes showed good/very good results in 80% in both groups. In comparison to the preoperative Qol score, the postoperative score showed a statistically significant improvement from 0.31 to 6 and from 0.41 to 6.32 in group I and II respectively.

4. Discussion

Since the superiority of one of the two studied procedure, LRYGB and LOAGB, over the other in terms of effectiveness and safety remains unclear, this study was conducted trying to clarify this uncertainty. Our study included 100 patients with super obesity divided randomly into 2 equal groups; group I underwent LRYGB while group II underwent LOAGB. We measured the whole small bowel length to keep the length of the common channel not less than 400 cm in all patients to avoid postoperative malnutrition which required revisional surgery in previous cases (unpublished data in our unit).

The mean operative time in the current study was 176.4±27.29 and 110.5±14.13 minutes in group I and II respectively with a significantly shorter time in group II. This coincided with Alkhalifah et al., [6] who reported 160.3±62.5 and 124.6±38.8 minutes in group I and II respectively and used to routinely measure small bowel length. Rheinwalt et al., [7] on the other hand, recorded a shorter mean operative time (103.36 and 80.28 min in their both groups respectively). This difference could be attributed to their lower initial BMI and the additional time for measuring the small bowel in our study.

Intraoperative complications were recorded in 10 patients; 5 in each group (10%) which included 9 superficial liver and splenic tears. These injuries can be explained by the super obesity and large heavy livers in those patients. Despite a lower BMI of around 40 kg/m^2 in their cohorts, Alkhalifah et al., [6] reported complication rate of 8.6% in group I and 7.3% in group II. Rheinwalt et al., [7] reported 8.7% and 4.6% operative complications in group I and II respectively.

Although, nutritional deficiencies were higher in LOAGB than LYRGB in this study, the difference failed to achieve a statistical significance. They were mild and managed medically with no need for readmission or revisional surgery. The greater length of the totally excluded bypassed limb (200 cm) in the LOAGB in comparison to RYGB in which the excluded BPL is shorter (50 cm) while the alimentary limb still shares in nutrients absorption explains this difference [17,

21]. Jammu and Sharma [8] reported a 13.1% incidence of hypoalbuminemia in LOAGB using more than 250 cm BPL and Mahawar et al., [9] found that the majority of their patients requiring revisional surgery for hypoalbuminaemia, had BPL greater than 200 cm.

Although, postoperative endoscopic examination showed marginal ulcers in 2 patients (4%) in the LOAGB group versus no patient in the LRYGB, the difference was statistically insignificant. Recent systematic reviews reported an incidence of 0.6–4% for marginal ulcers in large series which is even less than that found after RYGB (0.6 and 25%) [3, 10]. Various risk factors, independent of bile reflux have been suggested as increased acid production in an oversized pouch, *H pylori* infection and a short distance between pouch stapling and GJA stapling lines [11-13].

In our study, 1 patient (2%) in group I and 3 patients (6%) in group II developed GERD symptoms without endoscopic signs, an incidence comparable to that reported by Robert et al., [14] of 1.4% in group I and 5.6% in group II. Rheinwalt et al., [7] reported a lower incidence; 0.7% and 3.5% in both groups respectively, which may be explained by their tailoring of the length of BPL to BMI inducing marked early EWL% and decrease in the intra-abdominal pressure.

Our results showed a higher EWL%) and EBMI loss% in group II than in group I. Although, the mean EWL% was 57% vs 64.7% and 69.7% vs 75.5% at one and two years follow-up in group I and II respectively, this difference did not attain a statistical significance. These results were parallel to those reported widely in literature; Parmar et al., [15] (55.6% vs 59.6%), Kruschitz et al., [16] (59% vs 77%), Lee et al., [17] (58.7% vs 64.9%) and Spivak et al., [18] (72% vs 84.5%). In a meta-analysis including 7452 patients by Magouliotis et al., [19] a better EWL% was recorded in the LOAGB than LRYGB at 1 year with a weighted mean difference of −7.55 (P value of 0.10). Similarly, EBMI loss% in this series was higher in group II than group I; 55.35% vs 51.45% and 66.75% vs 62.90% at one and two years but without a statistically significant difference. Again our results matched those of Robert et al., [14] and Disse et al., [20]. Looking for the correlation between the length of the bypassed limbs and weight loss in LRYGB, Mahawar et al., [21] found that a range of ≤200 cm for combined length of BPL and alimentary limb gave optimum results in most patients. On performing LOAGB, Lee et al., [22] and Musella et al., [23] used a tailoring formula offering patients with a BMI of 35 kg/m^2 a BPL length of 150 cm with 10 cm per BMI point increase after that, while Noun et al., [24] started from BMI of 40 kg/m^2 and reported 0.4% incidence of revisional surgery for EWL% compared to 1% incidence reported by Lee et al., [22]. Authors such as Kular et al., [25] and Chevallier et al., [26] who used a fixed 200 cm noted a much significant lower malnutrition rate of 0.05% and 0.1%, respectively.

Remission rates of baseline comorbidities at 12^{th} month, including dyslipidaemia and systemic hypertension were higher in group II than in group I, but, without a statistically significant difference. Similar to these comorbidities, T_2DM showed a higher remission rates in group II (76.5%) than in group I (66.7%), but, without a statistically significant difference. These results coincided with those of Rheinwalt et al., [7] (69.6% and 82.8% in group I and II respectively) and Almalki et al., [27] (55.4% in group I vs 81.9% in group II). The latter authors postulated that the better weight loss achieved by LOAGB, in addition to the anti-diabetic effect of a longer BPL (200 cm vs 50 cm) were possible potential mechanisms explaining the higher remission rates in LOAGB over LRYGB.

The Diarem score was used in this study to predict the probability of remission/improvement of T_2DM. It ranged from 3 to 7 indicating 64-88% probability of remission. Our overall remission/improvement rate was 88.9% in group I and 94.1% in group II. These results matched well with the predictive value of our patients' scores indicating the accuracy of Diarem score. Similar results were reported by Lee et al., [22] (remission/improvement in 85.3% of patients who underwent LRYGB with score of 3-7) and Ahuja et al., [28] (remission/improvement in 85.1% of patients that underwent LOAGB with score of 3-7).

The 2 patients with pseudo-tumour cerebri in this study showed complete remission. In 2 systematic reviews, Friedman et al., [29] and Handley et al., [30] reported 92% remission indicating excellent results with bariatric surgery after failure of other available maneuvers.

Postoperatively, our mean BAROS score was 6.0 and 6.32 in group I and II respectively reflecting very good outcomes (>5-7) of both procedures. These results coincided with those of Robert et al., [14] who reported BAROS score with very good outcomes for 86% in the LRYGB group and 94% in the LOAGB group. Campos et al., [31] and Al Harakeh et al., [32] reported similar results in their LRYGB patients. The postoperative QoL score of our patients showed significant improvement in comparison to their preoperative baseline levels (1.9 in group I and 2.1 in group II postoperatively). Our postoperative QoL score was quiet similar to Biter et al., [33] (1.82) and Peterli et al., [34] (1.9).

Our study has some limitations which are the small sample size and the short term follow-up.

5. Conclusions

This study confirms the safety of LOAGB as a bariatric procedure. LOAGB had a shorter operative time and a tendency towards a higher EWL%, a better remission of obesity-related comorbidities and improvement in the patients QoL with comparable short term operative and postoperative complications. Thus, LOAGB can be considered an acceptable alternative to LRYGB in management of super obese patients.

Conflict of Interest

The authors declare that they have no conflict of interest.

Ethical Committee Approval

The study protocol was approved by the local research ethics committee (No. 32563/09/18).

Informed Consent

An informed written consent was obtained from every patient before being enrolled in the study.

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