Laparoscopic Gastric Plication; Comparative Study between Modified Enteric Bypass and Loop Bipartition.

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Abstract:

Background: Laparoscopic gastric plication (LGP) is emerging as a safe and effective bariatric procedure. A comparative study between the efficacy and complications of LGP with modified enteric bypass and LGP with loop bipartition, which are still an investigational bariatric procedure. The objective of this study to compare safety and efficacy of LGP with enteric bypass and LGP with loop bipartition in the treatment of morbid obesity in a one-year follow-up study.

Methods: A prospective study between February 2016 to December 2017, conducted on 80 morbid obese patients who were candidates for laparoscopic gastric plication, with either loop bipartition or modified enteric bypass surgery were randomly assigned to receive either LGP modified enteric bypass (n = 40) or LGP with loop bipartition (n = 40). Early and late complications, body mass index (BMI), excess weight loss, and obesity-related co-morbidities were determined at the 1-year follow-up.

Results: Operative time and mean length of hospitalization were shorter in the LGP with modified enteric bypass group than LGP with loop bipartition; (110 minutes versus 120 minutes, P<.001, and 2 days versus 3 days; P<.001, respectively). The mean percentage of excess weight loss (%EWL) at 12 months follow-up was (79.5%) in the LGB with modified enteric bypass group and (74.1%) in the LGP group (P = 0.03). Improvement was observed in all co-morbidities in both groups.

Conclusion: Both LGP and LGB are effective weight loss procedures. LGP enteric bypass proved to be a simpler and less costly procedure compared with LGP with loop bipartition with a lower risk of stomal ulcer during one year follow up.

Keywords: Laparoscopy, Stomach, Bariatric, Plication.

Introduction:

Obesity is one of the greatest public health problems in industrialized countries [1, 2]. In the US, UK, and Australia, for instance, the prevalence of obesity (body mass index (weight (kg)/ (height (m) 2)>30) has more than doubled in the past 25 years [2]. Currently, (67%) of the US population is either overweight or obese, and in most European countries the prevalence ranges between (40%) and (50%) [3]. Obesity is associated with an increased risk for type 2 diabetes, hypertension, dyslipidaemia, cardiovascular diseases, musculoskeletal disorders (such as osteoarthritis), certain types of cancer, and mortality [4]. This entails huge healthcare costs due to obesity [5].

Treatment options for obesity include non-surgical treatment and bariatric surgery. The non-surgical treatment is usually a multicomponent approach comprising behavioral therapy, dietary changes with the main aim of reducing energy intake, increasing physical activity, and various pharmacotherapies [6]. Influence of diet and exercise in

morbid obese patients is about (10%) in long term period; thus, in case of lifestyle modification failure, bariatric surgery could be considered [12] RYGB, sleeve gastrectomy.

Recently, many studies compared the efficacy of bariatric surgery (laparoscopic Roux-en-Y gastric bypass or laparoscopic sleeve gastrectomy) with medical treatment among patients with uncontrolled type 2 diabetes [17, 18]. New research has found that bariatric surgery is effective in abating the symptoms of type 2 diabetes in the short term as well as causing remission of diabetes in the long term [19]. In fact, observational evidence suggests that bariatric surgery is associated with a (60%-80%) diabetes remission rate among morbid obese persons [20].

The culprit of developing DM and obesity are associated with the imbalance of foregut and hindgut alimentation (hyper alimentation of foregut and hypo alimentation of hindgut) due to over ingestion of high-calorie, high-glycaemic index diet in modern society [21]. All current metabolic procedures such as gastric bypass, duodenal switch (DS) and ileum interposition address and reverse this imbalance and their principles are based on the foregut or hindgut theory or the combination of both. Santoro et al. has recently reported his long-term data regarding sleeve gastrectomy with transit bipartition (SG + TB), which is a similar operation to DS but without complete exclusion of duodenum in order to minimize nutritional complications [22].

Recent surgical procedure is the laparoscopic greater gastric curvature plication (LGCP). It is a procedure that reduces the gastric volume using sutures that invaginates the greater curvature, avoiding stapling or gastric resection, and aiming to reduce the gastric volume by plication of the greater curvature of stomach [10].

The mean EWL in different forms of restrictive methods is almost the same [14, 15, 16, 17]. Although adequate weight loss always occurs, patient's cooperation is the key factor for its effectiveness. Long term results showed that weight regain only occurs in a few cases due to temporary effect of restrictive methods and discontinuing diet and exercise [18, 19]. Malabsorptive method has longer effect on weight loss but the risk of late complications due to vitamin deficiency and anemia is noticeable [20].

The primary aim of this study was to assess short-term metabolic effects of bariatric surgery in a type 2 diabetic other obesity related metabolic diseases of patients and to identify predictive factors for long-term diabetes remission and recurrence. The secondary aims were to compare the metabolic effects of different bariatric procedures and to assess the EBW loss in 1 year follow up in a subgroup of gastric plication and loop bipartition and gastric placation with enteric bypass patients.

Materials and Methods:

This prospective study was conducted on 80 morbid obese patients who were candidates for laparoscopic gastric plication, with either loop bipartition or modified enteric bypass surgery. This trial was done from Feb/ 2016 to December 2017 at Soran Hospital Erbil-Iraq. The technique of LGP was performed according to the standard method based on the last paper of the author for all patients [22].

Any patient with BMI over 40 or 35 with co morbidity was selected for procedure.

All patients underwent thorough preoperative evaluations including history and physical examination, nutritional status and psychiatric status evaluations, and specialty consultations as indicated. Preoperative evaluations also included complete blood count, urinalysis, serum chemistries, levels of fasting lipids including total cholesterol and triglycerides, electrocardiogram and abdominal sonogram. Patients were considered "lost to follow-up" if no current contact information was available or if they did not respond to multiple inquiries by phone, e-mail, or mail or if they were unable or unwilling to provide outcome data.

Characteristic data was taken using standard questionnaire and patients were interviewed to evaluate their psychological issues and motivation. Anthropometric measures were recorded and informing consent was taken.

The operation combined restrictive procedure with sort of malabsorptive procedures either modified enteric bypass or loop bipartition. The procedure modified by performing a loop rather than Roux-en-Y bipartition reconstruction in Santoro's operation and laparoscopic gastric placation instead of sleeve gastrectomy and loop bipartition (SG + LB) in the treatment of other morbidity associated with obesity.

Lower limb bandage, prophylactic heparin, proton pump inhibitor and antibiotic therapy were advised in all cases. Position of patients was supine with 30-degree reverse trendelenburg. The procedure was performed by minimally invasive approach with five ports (12 mm at umbilicus, 1 mm × 5 mm at right upper quadrant, 1 mm × 10 mm and 1 mm × 5 mm at left upper quadrant and 1 mm × 5 mm ports at epigastrium for liver retraction). The greater curvature of stomach including the posterior fundus was mobilized by using LigaSureTM or Ultracision completely from prepylorus up to almost 2 cm to His angle preserving the anatomy of His angle and sacrificing left and right gastroepiploic artery. The aim of procedure was restriction of or ideally packing as much space of stomach as possible via folds plicated from its own wall. Using two-row plication. 00 prolen or nylon. Sutures were seromuscular, so that it was far away from region of gastric acid secretion. To assure the best site for suture intraluminal guide (No. 36) was used primarily. For loop bipartition, A loop gastroileostomy 250 cm from the ilececal valve was created at the dependent part of the antrum using Endo-GIA stapler 60mm covedien and the opening hand sewn continues seromuscular by V –lock 2.0 The resultant stomach tube has two outlets, one to the first part of duodenum through the pylorus and one to the terminal ileum through the gastroileostomy. Regarding modified enteric bypass, 30cm from DJ junction anastamosis with 100 cm from. Ileocecal valve using Endo- GIA stapler covedien 60mm, closing the opening with V-lock sutures continues seromuscular 2.0.The operation time was 110-130 min with blood loss less than 500ml and no need for blood transfusion.

Post operation, Intravenous infusion of liquid (3-4 liters of dextrose half saline daily) was advised after operation and increase the potential of mobilization to reduce risk of thromboembolic problems without using anticoagulation post operative. Patients did not have Foley

catheter or NGT after operation and they were mobilized after about 4 hours of operation. ICU admission was not routinely advised. Patients were discharged a 2-3 days observation. The average time of follow up was 1 years (1 month to 12 years). During first 6 postoperative weeks no solid food which was soft-liquid (2Weeks), semi-liquid (2Weeks) and semi-solid food (2Weeks) were advised until the patient able to eat normal meal.

Data management and statistical analysis:

Data will be recorded on a specially designed questionnaire, collected and entered in the computer and then analyzed using Statistical Package for Social Sciences (SPSS) version 22 and the results will be compared between patients with different variables, with a statistical significance level of < 0.05. The results will be presented as rates, ratio, frequencies, percentages in tables and figures and analyzed using T-test and Chi square tests.

Ethical consideration:

1. This study was submitted to the scientific council of Kurdistan Board of Medical specialties for scientific and ethical approval.
2. This study was explained for each patient, both procedure was explained there outcomes and post operative periods and a verbal and writing consent was obtained from each patient or his/ her guardian. Confidentiality of data will be ensured. Procedures were selected after taking patients consideration and there past medical and surgical history, as those with past medical history of peptic ulcer diseases were offered LGP with modified enteric bypass.

Results:

A total of 80 patients enrolled in the study. 32 of them were male while 48 were female participants. The male to female ratio was 0.6:1 and females constituted most of both groups A and B. Majority of both groups did not have cardiovascular diseases, hypertension, diabetes mellitus, asthma, depression and disability, while most of the patients (regardless of their groups) had sleep apnea. (55%) of group A participants had positive surgical history in contrary to (55%) of the group B patients who had negative surgical history.

The average age of group A patients was 38.8 years group B was 38 years. Group A mean BMI was 46.7 kg/m^2 while mean BMI of group B was 43.9 kg/m^2. Patients of group A had (61.5%) excess body weight, in reverse to group B participants who had (53.7%) excess body weight on average, figure (1).

The results of table (2) show that there were non-significant statistical associations between surgical procedures (A and B) and the different parameters, except for stomal ulcer. More than (90%) of patients from both groups did not develop post operative complications including bleeding, leak, infection, respiratory problems and thromboembolism, majority of them did not undergo bariatric surgery previously and improved after six and 12 months completely. Chi square test were done and P–values were more than 0.05. Stomal ulcer perforation was developed in (10%) of group B patients in reverse none of group A participants developed stomal ulcer perfoaration as diagnosed by endoscopy. Pearson Chi square test was done and P–value was 0.04.

According to Figure 1, the average excess body weight loss at six months for Group A was (49.59%) while for group B was (46.53%). The difference was statistically not significant. T – test was performed and P – value was 0.11. After 12 months of operation, the mean excess body weight loss for Group A was (79.5%) while it was (74.1%) for group B. The difference was statistically significant. T – test was done and P – value was 0.03.

Table (1): Descriptive data of group A and B patients.

Variables	Categories	Surgical procedure *		Total
		Group A	Group B	
Gender	Male	18	14	32
		45%	35%	40%
	Female	22	26	48
		55%	65%	60%
CVD	Positive	2	8	10
		5.0%	20.0%	12.5%
	Negative	38	32	70
		95.0%	80.0%	87.5%
Hypertension	Present	15	20	35
		37.5%	50.0%	43.8%
	Absent	25	20	45
		62.5%	50.0%	56.3%
Diabetes mellitus	Present	13	6	19
		32.5%	15.0%	23.8%
	Absent	27	34	61
		67.5%	85.0%	76.3%
Sleep apnea	Present	30	27	57
		75.0%	67.5%	71.3%
	Absent	10	13	23
		25.0%	32.5%	28.7%
Asthma	Present	2	3	5
		5.0%	7.5%	6.3%
	Absent	38	37	75
		95.0%	92.5%	93.8%
Depression	Present	6	9	15
		15%	22.5%	18.8%
	Absent	34	31	65
		85%	77.5%	81.3%
Disability	Present	1	0	1
		2.5%	0%	1.3%
	Absent	39	40	79
		97.5%	100%	98.8%
Past surgical history	Positive	22	18	40
		55%	45%	50.6%
	Negative	17	22	39
		45%	55%	49.4%
Total		40	40	79
		100%	100%	100%

* Group A = LGP modified enteric bypass. Group B = LGP Loop bipartition

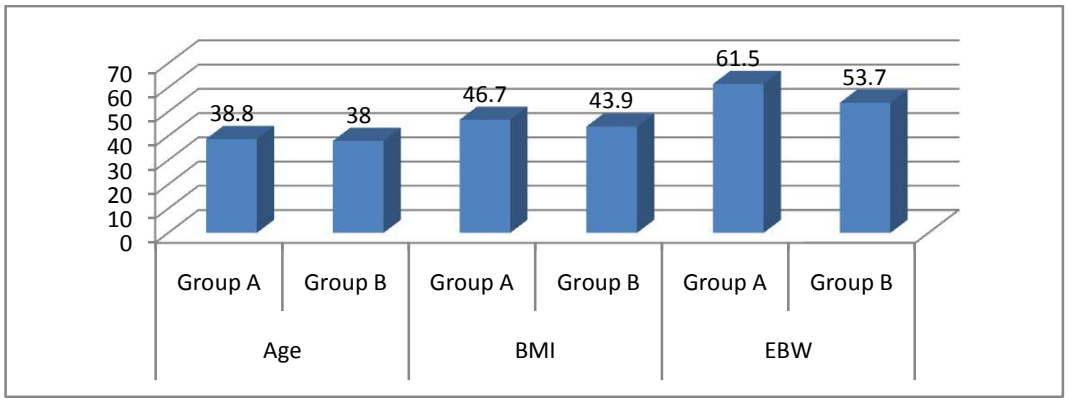

Figure (1): Average age, BMI and EBW of groups A and B participants.

Table (2): Association between surgical procedures and different parameters.

Variables	Categories	Surgical procedure *		Total	P
		Group A	Group B		
Previous bariatric surgery	Positive	3	6	9	0.28
		7.5%	15%	11.3%	
	Negative	37	34	71	
		92.5%	85%	88.8%	
Bleeding	Present	2	1	3	0.55
		5.0%	2.5%	3.8%	
	Absent	38	39	77	
		95%	97.5%	96.3%	
Leak	Present	0	1	1	0.31
		0%	2.5%	1.3%	
	Absent	40	39	79	
		100%	97.5%	98.8%	
Infection	Present	8	4	12	0.21
		20%	10%	15%	
	Absent	32	36	68	
		80%	90%	85%	
Respiratory problems	Present	4	2	6	0.39
		10%	5%	7.5%	
	Absent	36	38	74	
		90%	95%	92.5%	
Thromboembolism	Present	2	0	2	0.15
		5%	0%	2.5%	
	Absent	38	40	78	
		95%	100%	97.5%	
Medical condition after 6 months	Completely improved	33	26	59	0.06
		82.5%	65%	73.8%	
	Partially improved	7	10	17	
		17.5%	25%	21.3%	
	No change	0	4	4	
		0%	10%	5%	
Medical condition after 12 months	Completely improved	40	35	75	0.06
		100%	87.5%	93.8%	
	Partially improved	0	3	3	
		0%	7.5%	3.8%	
	No change	0	2	2	
		0%	5%	2.5%	
Stomal ulcers	Present	0	4	4	0.04
		0%	10%	5%	
	Absent	40	36	76	
		100%	90%	95%	
Total		40	40	80	
		100%	100%	100%	

* Group A = LGP modified enteric bypass. Group B = LGP Loop bipartition

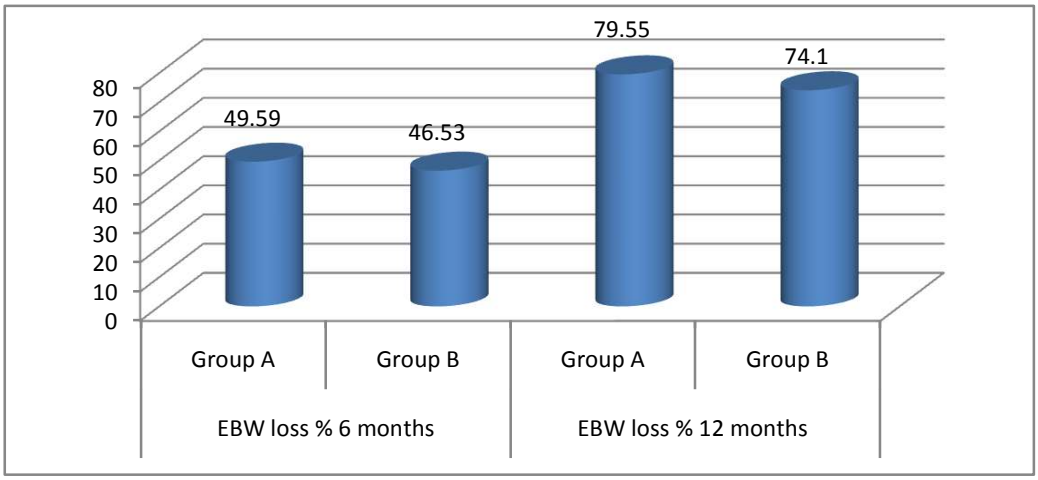

Figure (2): Difference between Groups A and B regarding EBW loss in 6 (P: 0.11) and 12 months (P: 0.03).

Discussion:

Bariatric surgery is an effective approach used to treat morbid obesity which causes long-term sustained weight loss and remission of co-morbidities such as diabetes mellitus, dyslipidemia, hypertension, and sleep apnea.

The study which compared LSG with the current gold standard in bariatric surgery, laparoscopic gastric bypass (LRYGB), both procedures were highly effective in terms of weight loss with an excessive BMI loss at 3 years of (70.9%) in the LSG group and (73.8%) in the LRYGB group. The weight loss nadir was between 1 and 2 years postop with a discrete weight regain thereafter. LRYGB showed a non significant better weight loss at each time point that is in line with most previously published series and meta-analyses [23, 24, 25, 26].

In another study which analyses 160 cases underwent A standard sleeve gastrectomy which combined with a modified jejuno-ileal bypass, showed that Excess weight loss was (78%) (IQR 70–83 %, 12 months, $n = 168$), (79%) (IQR 70–85 %, 24 months), maintained at most recent follow-up with (77%) (IQR 68–84 %, $n = 168$), and for 8 year follow-up alone (75%) (IQR 66–84 %, $n = 18$). Type 2 diabetes mellitus resolved in (80.3%) and improved in the remainder of patients, hypertension resolved in (92.3%) and improved in the rest [27].

In our study, both group A (LGP with modified enteric bypass) and group B (LGP with Loop bipartition), as a new restrictive and malabsorption methods for treatment for morbid obesity, have shown good results during one year follow up regarding excess body weight loss about 79.55 and 74.1 respectively. They are equally effective in: 1) weight loss. 2) Improvement of morbidities.

Improvements in the obesity-related co morbidities type 2 diabetes, hypertension, and hyperlipidemia were mostly reported as secondary outcomes in bariatric surgery studies. Secondary outcome analyses may be a reliable measure of an intervention's effect when studies are sufficiently powered to answer secondary questions.

Remission rates of co morbidities showed equal effects, quality of life improved significantly in both groups after surgery at 1 year compared with baseline. There was statistically significant difference in complications

within the first 1 year postop just for stomal ulcer from the group B which occur at gasto-ileal anatomized site which was successfully managed by suture and omental patch. As for group A, we didn't face any case of perforated stomal ulcer as there is no anastamosis between stomach and small bowel. We had one case of post operative bleeding from group B, which was managing by diagnostic laparoscopy in which control of bleeding done, one case from group B had leak from stomach the site of stitch which was managing by laparoscopic insertion of drain and follow up.

This study has several limitations. First, the follow up period was one year and it would be better to follow the patients for a longer period. Additionally, identifying the gut hormone levels before and after bariatric surgery may be helpful.

Conclusion:

Both procedures are effective in reduction of excess body weight and improvement of obesity related morbidity with slightly better outcomes and less serious complication for group A (LGP with modified enteric bypass) during first year follow up.

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