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Comparative Study Between Sleeve Gastrectomy with Cruroplasty and Roux-en-Y Gastric Bypass in Morbid Obese Patients with Gastro-Esophageal Reflux Disease

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Abstract---Background: Obesity is a worldwide pandemic and one of the most serious public health issues and causes a lot of complications to obese patients as gastroesophageal reflux disease (GERD). Bariatric surgery proves more effectiveness for morbid obese patients to lose weight and is demonstrated to include significant and long term remission of obesity related comorbidities. Methods: This a controlled clinical trial study involved 50 patients, who are diagnosed as a morbidly obese patients with GERD grade(A) and (B) by endoscopy according to their BMI (>40) or >35 with one or two of obesity related co-morbidities such as diabetes mellitus. Patients were divided into 2 groups, group (A) (25 patients) underwent LSG with cruroplasty, and group (B) (25 patients) underwent LRYGB. Results: There was no statistically significant difference found between the two studied groups regarding EBW loss percentage at 1 month while there was statistically significant increase in the EBW loss percentage at 3 months, 6 months and at 1 year in LRYGB group than LSG with cruroplasty group.

Keywords---gastroesophageal, laparoscopic, reflux disease, Roux-en-Y gastric bypass, sleeve gastrectomy.

Introduction

Obesity is linked to many serious comorbidities such as increased cardiovascular risk, osteoarthritis, diabetes, cancer, and gastroesophageal reflux disease (GERD) (Must et al., 1999). Weight loss procedures have been popular in the last years with sleeve gastrectomy being the most common. Also patients with Gastroesophageal reflux disease have been offered these procedures especially Roux-en-Y gastric bypass and sleeve with cruroplasty, but Roux-en-Y gastric bypass is considered the best choice (Wang et al., 2018).

The effect of laparoscopic sleeve gastrectomy (LSG) on gastroesophageal reflux disease (GERD) is controversial. Although concomitant cruroplasty at the time of LSG is common and advocated by many surgeons, there are few data on the outcomes of GERD symptoms in these patients (Eisenberg et al., 2013; Schwartz et al., 2013). Our aim is to compare between laparoscopic sleeve gastrectomy (LSG) with cruroplasty and laparoscopic Roux-en-Y gastric bypass (LRYGB) for management of morbid obesity associated with gastroesophageal reflux disease (GERD) to assess symptoms improvement with 1 year follow up after operation.

Material and Methods

This is a prospective controlled clinical trial study conducted in department of surgery Ain-Shams University Hospitals during the period from December 2019 to December 2021 with follow up at 1 month, 3months, 6months, and 1 year post surgery. Involved 50 morbidly obese patients (BMI (>40) or >35 with one or two of obesity related co-morbidities such as diabetes mellitus, hypertension, dyslipidemia, osteoarthritis, infertility, and severe sleep apnea) with gastroesophageal reflux disease grade (A) and (B) by endoscopy. We excluded patients <18 and >69 years old, unfit for general anesthesia, previous abdominal surgeries (intra-abdominal adhesions), abdominal ventral hernia, Barrett's esophagus or hiatus hernia by endoscopy, Pregnant, and patients with major psychiatric illness. Patients who met the inclusion criteria were recruited and controlled subdivided to receive either LSG with cruroplasty or LRYGB. Ethical approval was taken from Ain Shams University ethical committee (No. IRB 0006379) and written consent was taken from every patient after explanation of all details of the operation, advantages, disadvantages, diet habits after surgery, realistic expectations and with the possibility of conversion to open surgery and all the possible intra-operative, early and late post-operative complications. Surgeries were done by the same surgical team throughout the study.

A comprehensive assessment program was carefully structured so that a disciplined routine is followed in each patient. All patients were pre-operatively and post-operatively evaluated. Pre-operative preparation of the patients included history taking focusing on age, sex, dietary habits, history of previous operations, GERD symptoms, obesity duration, medical history, family, and past surgical history. All the patients underwent full general examination and general pre-operative laboratory investigations, upper GI endoscopy evaluating the grade of reflux using Los Angeles classification of endoscopic grades of GERD and excluding BARRET'S esophagus or hiatus hernia, and pelvi-abdominal ultrasound for intra-abdominal and pelvic pathologies.

Operative details

- Group (A) underwent Laparoscopic sleeve gastrectomy (LSG) with cruroplasty: (Figure 1-3)
Standard operation techniques followed in Ain Shams university hospital were followed. For LSG, we used a 36-Fr bougie along the lesser curvature for calibration of the gastric tube. Both crura were then approximated using nonabsorbable sutures placed in an interrupted fashion after dissection of both crura to expose the hiatus hernia.
- Group (B) underwent Laparoscopic Roux-en-Y gastric bypass (RYGB): (Figure 4-7)
We measured about 100 cm of small intestine from the D-J junction to create the Roux limb then forming the gastrojejunostomy after creation of the gastric pouch using calibration tube 36 French bougie. Then a 100 cm long biliopancreatic limb was chosen for jejunojejunostomy. We close the sites of internal herniations.

Statistical analysis

Data were collected, revised, coded and entered to the Statistical Package for Social Science (IBM SPSS) version 23. The quantitative data were presented as mean, standard deviations and ranges. Also qualitative variables were presented as number and percentages. The qualitative data was done by using Chi-square test and/or Fisher exact test when the expected count in any cell found less than 5.

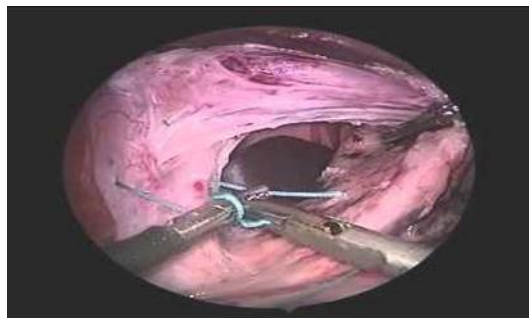


Figure 1. Dissect the hernial sac and repair of the crura of the diaphragm

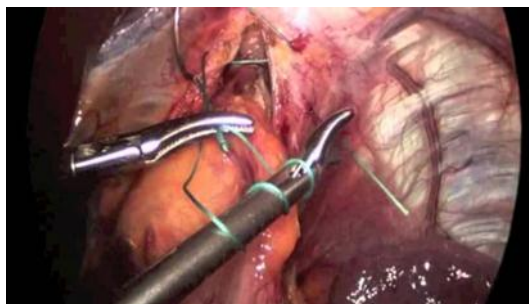


Figure 2. Repair of the crura of the diaphragm with sutures



Figure 3. Sleeve gastrectomy done after repair of hiatus hernia repair

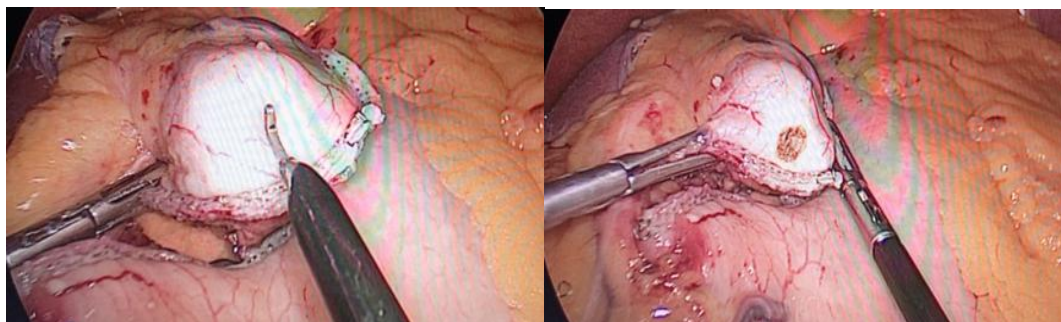


Figure 4. Creation of the gastric pouch



Figure 5. Completed gastrojejunostomy

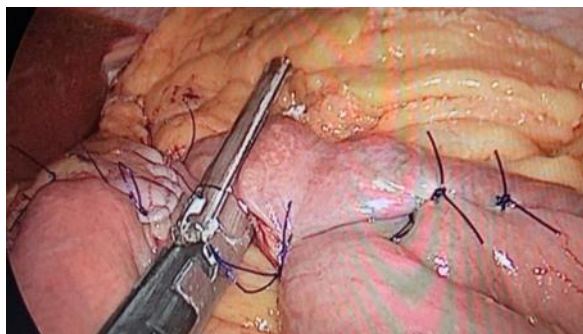


Figure 6. The staple line of the divided jejunum

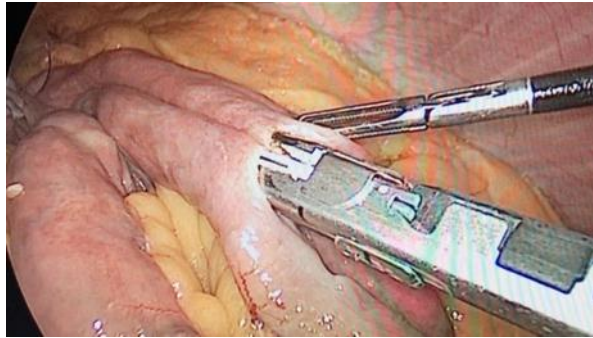


Figure 7. Creation of the entero-enterostomy

Results

After 1 year of follow-up, 50 patients met our inclusion criteria. Table (1) shows baseline characteristics of patients in both groups. There is a significant difference between the two groups regarding gender and DM, as the more diabetic patients underwent LRYGB. Table (2) shows the pre-operative GERD symptoms in both groups. LRYGB patients had more severe pre-operative GERD compared to LSG group, $p=0.798$

Using the upper GI endoscopy, we compared the pre-operative reflux grade between both groups LSG with cruroplasty group and LRYGB group, $p=0.024$. Patients' reflux grades, using upper GI endoscopy, were followed at 6 and 12 months, respectively. Reflux was graded as no reflux, Grade (A) or Grade (B). there is a statistically significant difference between two groups at both 6 and 12 months with p -value=0.002 and 0.039, respectively, (Table 3). Table(4) shows that there was no statistically significant difference found between the two studied groups regarding EBW loss percentage at 1 month with p -value = 0.851 while there was statistically significant increase in the EBW loss percentage at 3 months, 6 months and at 1 year in LRYGB than LSG with cruroplasty group with p -value < 0.001, < 0.001 and < 0.001 respectively.

Table (5) shows that there was no statistically significant difference found between the two studied groups regarding GERD severity at 1 month with p -value = 0.105 while there was statistically significant difference found between the two studied groups regarding GERD severity at 3 months, 6 months and 1 year with p -value = 0.034, 0.003 and 0.035 respectively. Finally, table (6) shows that the improvement from reflux symptoms was higher in LRYGB group than LSG with cruroplasty at 1 month, 3 months, 6 months and 1 year with p -value = 0.001, 0.024, 0.031 and 0.012 respectively.

Table 1
Baseline characteristics of both groups, LSG with cruroplasty group and LRYGB group.

		LSG with cruroplasty group	LRYGB group	Test value	P-value	Sig.
		No. = 25	No. = 25			
Gender	Females	15 (60.0%)	22 (88.0%)	5.094*	0.024	S
	Males	10 (40.0%)	3 (12.0%)			

Age (years)	Mean ± SD	42.48 ± 9.23	44.36 ± 8.81	-0.737•	0.465	NS
	Range	22 – 58	27 – 59			
Weight (kg)	Mean ± SD	124.74 ± 22.67	127.80 ± 23.23	-0.471•	0.639	NS
	Range	91 – 183	91 – 178			
Height (cm)	Mean ± SD	169.12 ± 8.25	165.32 ± 7.24	1.731•	0.090	NS
	Range	158 – 184	149 – 180			
BMI (kg/m ²)	Mean ± SD	43.38 ± 5.45	46.52 ± 6.21	-1.899•	0.064	NS
	Range	36 – 58	36 – 59			
EBW (kg)	Mean±SD	52.71 ± 16.73	59.62 ± 19.09	-1.362•	0.179	NS
	Range	29.2 – 94.5	31.9 – 99.3			
DM		0 (0.0%)	10 (40.0%)	12.500*	0.000	HS
HTN		7 (28.0%)	7 (28.0%)	0.000*	1.000	NS
Obstructive sleep apnea (OSA)		1 (4.0%)	2 (8.0%)	0.355*	0.552	NS
Hyperlipidemia		3 (12.0%)	1 (4.0%)	1.087*	0.297	NS
Non-alcoholic steatohepatitis (NASH)		2 (8.0%)	0 (0.0%)	2.083*	0.149	NS

Table 2
Comparison between LSG with cruroplasty group and LRYGB group regarding GERD severity preoperative

		Sleeve group	ROUX N Y group	Test value	P-value	Sig.
		No. = 25	No. = 25			
GERD pre	No symptoms	0 (0.0%)	0 (0.0%)	0.450*	0.798	NS
	Mild	7 (28.0%)	6 (24.0%)			
	Moderate	13 (52.0%)	12 (48.0%)			
	Severe	5 (20.0%)	7 (28.0%)			

Table 3
Comparison between LSG with cruroplasty group and LRYGB group regarding pre operative and postoperative endoscopic evaluation at 6 and 12 months

endoscopic reflux grade	LSG with cruroplasty group	LRYGB group	Test value	P-value	Sig.
	No. = 25	No. = 25			
Pre operative:					
Grade (A)	10 (40.0%)	3 (12.0%)	5.094*	0.024	S
Grade (B)	15 (60.0%)	22 (88.0%)			
Post operative					
6 months:					
No reflux	4	16	12.65	0.002	HS
Grade A	8	5			
Grade B	13	4			
Post operative					
12 months					
No reflux	8	17	6.496	0.039	S
Grade A	8	4			
Grade B	9	4			

Table 4
Comparison between LSG with cruroplasty group and LRYGB group regarding excess body weight loss percentage

EBW loss (%)		LSG with cruroplasty group	LRYGB bypass group	Test value	P-value	Sig.
		No. = 25	No. = 25			
At 1 month (kg)	Mean±SD	14.19 ± 1.85	14.10 ± 1.66	0.189	0.851	NS
	Range	10 – 19.02	11.55 – 17.48			
At 3 months (kg)	Mean±SD	25.00 ± 1.43	27.73 ± 1.35	-	0.000	HS
	Range	22.51 – 28.24	25.71 – 30.5	6.963		
At 6 months (kg)	Mean±SD	39.99 ± 2.29	45.00 ± 2.20	-	0.000	HS
	Range	36 – 45.19	41.69 – 49.5	7.901		
At 1 year (kg)	Mean±SD	59.98 ± 3.43	64.44 ± 3.15	-	0.000	HS
	Range	54 – 67.78	59.72 – 70.88	4.786		

Table 5
Comparison between LSG with cruroplasty group and LRYGB group regarding GERD severity post-operative follow-up

		LSG with cruroplasty group	LRYGB group	Test value	P-value	Sig.
		No. = 25	No. = 25			
GERD symptoms (After 1 month)	No symptoms	1 (4.0%)	7 (28.0%)	6.136*	0.105	NS
	Mild	9 (36.0%)	9 (36.0%)			
	Moderate	14 (56.0%)	8 (32.0%)			
	Severe	1 (4.0%)	1 (4.0%)			
GERD symptoms (After 3 months)	No symptoms	4 (16.0%)	12 (48.0%)	8.655*	0.034	S
	Mild	9 (36.0%)	9 (36.0%)			
	Moderate	9 (36.0%)	2 (8.0%)			
	Severe	3 (12.0%)	2 (8.0%)			
GERD symptoms (After 6 months)	No symptoms	4 (16.0%)	16 (64.0%)	13.930*	0.003	HS
	Mild	9 (36.0%)	5 (20.0%)			
	Moderate	8 (32.0%)	1 (4.0%)			
	Severe	4 (16.0%)	3 (12.0%)			
GERD symptoms (After 1 year)	No symptoms	8 (32.0%)	18 (72.0%)	8.598*	0.035	S
	Mild	7 (28.0%)	4 (16.0%)			
	Moderate	2 (8.0%)	1 (4.0%)			
	Severe	8 (32.0%)	2 (8.0%)			

Table 6
comparison between LSG with cruroplasty group and LRYGB group regarding
postoperative symptomatic improvement of reflux

Improvement		LSG with cruroplasty group		LRYGB group		Test value*	P-value	Sig.
		No.	%	No.	%			
1 month	Non-Improved	16	64.0%	4	16.0%	12.000	0.001	HS
	Improved	9	36.0%	21	84.0%			
3 months	Non-Improved	10	40.0%	3	12.0%	5.094	0.024	S
	Improved	15	60.0%	22	88.0%			
6 months	Non-Improved	11	44.0%	4	16.0%	4.667	0.031	S
	Improved	14	56.0%	21	84.0%			
1 year	Non-Improved	11	44.0%	3	12.0%	6.349	0.012	S
	Improved	14	56.0%	22	88.0%			

Discussion

Bariatric surgery is a gastrointestinal surgery to help obese patients to lose weight. It offers the only realistic chance of long-term weight reduction, and resolution or improvement of co-morbidities including Type 2 DM, HTN, and GERD. Surgeons realized that many patients with morbid obesity and GERD who underwent weight loss procedures experienced symptoms improvement ([Moini et al., 2020](#); [Sturm, 2007](#)).

We conducted our study on 50 morbid obese patients with GERD grade (A) and (B) by endoscopy. patients were subdivided into two groups: group (A) (25 patients) underwent LSG with cruroplasty and group (B) underwent LRYGB with follow up at 1 month, 3 months, 6 months and 1 year post-operatively. To our knowledge, this is the first study to compare LSG with cruroplasty to LRYGB in morbid obese patients with GERD. Our results, after 1 year of follow-up, showed a significant higher Excess body weight loss (EBWL) in LRYGB compared to LSG with cruroplasty at 3 ($p=0.0001$), 6 ($p=0.0001$), 12 ($p=0.0001$) months interval. Also, LRYGB showed a significant improvement in GERD symptoms during follow-up period.

Many studies reported the effect of LSG or RYGB on weight loss and obesity. Other studies had compared these two operations. In a comparative study done by [Abdel-Razik et al. \(2021\)](#), on 50 patients. They reported that RYGB was superior to LSG regarding weight loss but no significant difference was detected regarding post-operative complications and Reflux. At our study three patients had worsen GERD symptoms at LSG with cruroplasty group which goes with results of the study done by [Peterli et al. \(2018\)](#), where 117 patients were

randomized to either LSG or RYGB showed no significant difference between LSG and RYGB in excess BMI loss yet, LSG group had less GERD remission and more worsened reflux symptoms.

At Our study Patients with worsen or persistent GERD symptoms post-operative were asked for doing esophageal manometry and 24 hours PH monitoring studies and continue their medical treatment until completing the studies. On the other hand, few studies showed the effect of LSG with cruroplasty. [Samakar et al. \(2016\)](#), studied only 58 patients with LSG and cruroplasty with pre-operative reflux symptoms in 15.5%. Post-operatively, only 34.6% had resolution of symptoms and 15.6 % had new-onset reflux symptoms. However, in a meta-analysis done by [Chen et al. \(2021\)](#), a total of 18 studies (937 patients) were included. It showed a significant reduction in GERD symptoms (OR: 0.20; 95% CI: 0.10 to 0.41; P < 0.00001) with 68% incidence of GERD remission, 12% de novo GERD. No difference between LSG with cruroplasty and LSG alone in de novo GERD. [Attia \(2017\)](#), conducted a study on 53 patients who underwent LSG and cruroplasty. He reported that LSG with cruroplasty offers satisfactory weight loss with favourable outcomes in GERD symptoms, 56% remissioned and 26.4% improved symptoms of GERD.

Gastroesophageal reflux disease is very common in super obese patients . this can be explained by many factors such as increased oesophageal acid exposure and high intraabdominal pressure .also many experts consider LRYGB as the most effective surgical intervention for GERD control and also weight loss that last for long time ([Abdel-Razik et al., 2021](#)). LSG is considered to be faster, less technically demanding, and thus associated with fewer postoperative complications compared to LRYGB, which may be contributing factors to its recent popularity. While studies have found no significant difference in weight loss when compared to LRYGB. LSG is generally controversially in patients who have gastro-esophageal reflux disease (GERD). LSG may cause new onset or worsening of pre-existing acid reflux, which may increase the risk of developing Barrett's metaplasia ([Peterli et al., 2018](#)). To prevent post-operative de-novo GERD after LSG, several surgical methods have been investigated among which is Cruroplasty ([Kochkodan et al., 2018](#)), this method depends mainly on narrowing the oesophageal hiatus by using stitches to prevent reflux. The results between experts are variable some consider it effective especially when combined with absorbable mesh , but others consider no advantage for this technique in preventing reflux ([Attia, 2017](#)).

Clearly, there are contradictory data regarding LSG and cruroplasty. Surely, LSG and cruroplasty offers satisfactory weight loss and improvement of GERD compared to LSG alone. Our study is limited to its small sample size which affected distribution of GERD severity among both groups thereby more patients with severe GERD were found in LRYGB group. Many studies including RCT are needed to further evaluate and compare RYGB and LSG with cruroplasty with larger sample size and prolonged follow-up period to assess the efficacy of either in management of obesity associated with GERD.

Conclusion

LSG with cruroplasty offers satisfactory results of weight loss and improvement of symptoms and severity of GERD, although these results are inferior to LRYGB in improvement of GERD symptoms and severity in one year follow up period after surgery. So large sample studies with prolonged follow up period are needed to evaluate long term effects of both LSG with cruroplasty and LRYGB on weight loss and GERD improvement on morbid obesity associated with GERD.

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