Concomitant Obesity & GERD; Is LSG Still Considered the Best Option? Clinical and Endoscopic Evaluation.

Introduction:

Obesity is a real worldwide problem. About one billion people are suffering from obesity all over the world. Two-thirds of this community are adults, then the remaining one-third are children and adolescents^{1–3}.

Finding a solution to this problem is a growing discussion over the last years. Approaching this disease with a surgical intervention was found to have a solid and reliable outcome⁴. Previously more complicated interventions as Roux-En-Y gastric bypass (R-E-Y GB) were planned for obesity control, while Laparoscopic Sleeve Gastrectomy (LSG) was considered as only a preliminary step before a definitive procedure. Later, LSG was found to be an effective standalone simple procedure, and no need to add a further complex procedure⁵.

Obese patients especially those with central obesity are showing an incidence of 20-50% for preexisting Gastro-Esophageal Reflux Disease (GERD)^{1,2,5,6}. This high association was attributed to high intraabdominal pressure that may increase intragastric pressure, delayed gastric emptying, weak lower esophageal sphincter pressure, more frequent lower esophageal relaxations, and associated hiatus hernia (HH)¹. The presentation and endoscopic findings of this superadded problem vary from a silent condition (10-25%), erosive esophagitis (4-34%), Barrette's esophagus (15%), and even esophageal adenocarcinoma in 0.5%³. In the same context, a preexisting HH in morbidly obese patients was found to reach 37-50%⁷.

On the other hand, LSG was found to be a Refluxogenic procedure. This finding was explained by the high pressure in the gastric tube, Crural dissection, disturbed angle of His, and de novo hiatus hernia due to migration of gastric tube toward chest cavity^{1,3}. Many papers reported variable degrees de novo GERD and de novo HH after LSG. Patients after LSG developed de novo GERD

in 11-70%, de novo HH in 16-73%, and persistence of preexisting GERD in about 75-100% of cases^{1,2,6,8-10}.

Evaluation of GERD and HH is accomplished through many parameters as clinical symptoms, pH monitoring, esophageal manometry, contrast imaging studies, and upper GI endoscopy².

The axis of relationship between (Obesity/GERD/Bariatric operations) was studied in many papers but still, there is a strong debate with wide variations in its results that can be clearly demonstrated in having no consensus around many items in this topic. This paper is trying to define the relationship between these items in obese patients in our community through clinical and endoscopic evaluation.

Patients and Methods:

This prospective study was conducted at department of surgery, Benha University Hospitals after approval from local ethical committee and after fully informed written consent signed by the patients.

This study involved patients who were scheduled for bariatric procedures from November 2018 to May 2020. All patients were invited to answer a GERD questionnaire and to do upper GI endoscopy twice; once preoperative and second time one year postoperatively. Sixty-one patients fulfilled these steps. Demographic data, BMI, GERD-Health Related Quality of Life (GERD-HRQL) questionnaire, PPI dependency and upper GI endoscopy findings were collected and analyzed.

The decision for operation was tailored according to many items. BMI was an important item. Patients with BMI > 45 were offered to have R-E-Y GB operation. Other patients were advised to have LSG.

Patients with high grade of GERD symptoms, pre-operative evidence of HH, and/or intraoperative diagnosis of HH were asked to approve additional step of Crural repair. So we have 3 groups with three different interventions; LSG, LSG with Crural repair and R-E-Y GB.

GERD symptoms were evaluated according to GERD-HRQL questionnaire11. Preoperative diagnosis of HH that required Crural repair depended on endoscopic evaluation of distance between Z-line and Crural indentation to be more than 5 cm. Cases showed this distance to be 2-5cm were defined to have small HH. While other cases with distance less than 2cm are considered physiologic esophageal migration. Small HH can be ignored without repair⁶.

Some cases were not diagnosed to have HH preoperatively, but intraoperative findings of Crural separation more than 2 cm plus hernial sac was diagnostic for HH⁸.

PPI dependencies were defined to have regular PPI intake 5 times per week for more than 3 months⁸.

Statistical methods

Data management and statistical analysis were done using SPSS version 25. (IBM, Armonk, New York, United States). Quantitative data were assessed for normality using the Shapiro-Wilk test and direct data visualization methods. According to normality testing, numerical data were summarized as means and standard deviations or medians and ranges. Categorical data were summarized as numbers and percentages. Quantitative data were compared between study groups using one-way ANOVA or Kruskal Wallis test for normally and non-normally distributed numerical variables, respectively. Categorical data were compared using the Chi-square or Fisher's test, if appropriate. Post hoc analyses were done using Bonferroni's method. All statistical tests were two-sided. P values less than 0.05 were considered significant.

Results:

In this study, 61 patients were involved, 11 males (18%), and 50 females (82%). No significant differences were noted between the study groups regarding age (P = 0.178) and gender (P = 0.746) (Table 1).

Table (1) Demographic characteristics in the studied groups

			LSG	LSG + CRURA	RYGB	
			(n = 41)	(n = 8)	(n = 12)	P-value
Age (years)	Mean ±SD)	36 ±9	38 ±4	41 ±8	0.178
Gender	Males	n (%)	7 (17.1)	1 (12.5)	3 (25.0)	0.746
	Females	n (%)	34 (82.9)	7 (87.5)	9 (75.0)	

One-way ANOVA was used for age. Chi-square test was used for gender

Pre-& post-operative BMI & GERD score

Pre-operative BMI showed an overall significant difference between the study groups (P < 0.001). Post hoc analyses revealed that it was significantly higher in those who underwent RYGB (48.4) than those who underwent LSG (42.9) or LSG + CRURA (42.6). Post-operative BMI showed an overall significant difference between the studied groups (P = 0.04). It was significantly higher in those who underwent RYGB (33.7) than those who underwent LSG (31.7) or LSG + CRURA (31.2). Post-operative percent change in BMI showed an overall significant difference between the studied groups (P = 0.031). Post hoc analysis showed that the percent decrease was significantly higher in those who underwent RYGB (-31.5%) than LSG (-26.4%).

Pre-operative GERD score showed an overall significant difference between the study groups (P = 0.004). Post hoc analysis revealed that it was significantly higher in those who underwent LSG+CRURA (21) than those who underwent LSG (11) or RYGB (15). Post-operative GERD score showed an overall significant difference between the studied groups (P = 0.033). It was significantly higher in those who underwent LSG (14.0) than those who underwent RYGB (12). Post-operative percent change in GERD score showed an overall significant difference between the studied groups (P < 0.001). Post hoc analysis showed that the percent change was significantly

worse in those who underwent LSG (27.3%) than those who underwent LSG + CRURA (-36.3%) or RYGB (-44.9%) (Table 2&figure 1).

Table (2) Pre- and post-operative BMI and GERD score in the studied groups

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	LSG (n = 41)	LSG + CRURA (n = 8)	RYGB (n = 12)	P-value
-	-	-	-	· -
Mean ±SD	42.9 ±3 ^a	42.6 ±3.9 ^a	48.4 ±1.3 ^b	<0.001
Mean ±SD	31.7 ±2.6 ^a	31.2 ±3.1 ^a	33.7 ±1.7 ^b	0.04
Median (range)	-26.4 (-34.24.4) ^a	-26.6 (-32.522.8) ^{a,b}	-31.5 (-36.124) ^b	0.031
Median (range)	11 (3 - 25) ^{a, b}	21 (16 - 24) ^a	15 (6 - 25) ^b	0.004
Median (range)	14 (9 - 26) ^a	13 (10 - 16) ^{a, b}	12 (3 - 18) ^b	0.033
Median (range)	27.3 (-47.1 - 533.3) ^a	-36.3 (-47.822.2) ^b	-44.9 (-57.1 - 66.7) ^b	<0.001
	Mean ±SD Median (range) Median (range) Median (range)	Mean \pm SD 42.9 \pm 3 a Mean \pm SD 31.7 \pm 2.6 a Median (range) -26.4 (-34.24.4) a Median (range) 11 (3 - 25) a, b Median (range) 14 (9 - 26) a	(n = 41) (n = 8) Mean ±SD 42.9 ±3 a 42.6 ±3.9 a Mean ±SD 31.7 ±2.6 a 31.2 ±3.1 a Median (range) -26.4 (-34.24.4) a -26.6 (-32.522.8) a,b Median (range) 11 (3 - 25) a, b 21 (16 - 24) a Median (range) 14 (9 - 26) a 13 (10 - 16) a, b	(n = 41)(n = 8)(n = 12)Mean \pm SD 42.9 ± 3^{a} 42.6 ± 3.9^{a} 48.4 ± 1.3^{b} Mean \pm SD 31.7 ± 2.6^{a} 31.2 ± 3.1^{a} 33.7 ± 1.7^{b} Median (range) $-26.4 (-34.24.4)^{a}$ $-26.6 (-32.522.8)^{a,b}$ $-31.5 (-36.124)^{b}$ Median (range) $11 (3 - 25)^{a,b}$ $21 (16 - 24)^{a}$ $15 (6 - 25)^{b}$ Median (range) $14 (9 - 26)^{a}$ $13 (10 - 16)^{a,b}$ $12 (3 - 18)^{b}$

One-way ANOVA or Kruskal Wallis test was used. Post hoc analyses were done using Bonferroni's method. Different letters indicate significant pair

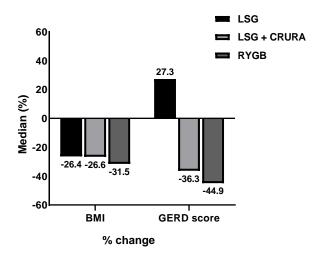


Figure (1): post-operative % change of BMI and GERD score

Endoscopy findings & use of proton pump inhibitors pre and post procedures

Pre-operative esophagitis showed a significant association with the studied groups (P = 0.001); It was significantly higher in LSG + CRURA (100.0%) compared to LSG (29.3%) and RYGB (50.0%). Post-operative esophagitis showed no significant association with the studied groups (P = 0.127). The improvement showed a significant association with the studied groups (P = 0.005); It was significantly higher in those who underwent LSG+CRURA or RYGB (37.5% for each) than those who underwent LSG (3.2%).

Pre-operative hiatus hernia showed a significant association with the studied groups (P < 0.001); It was significantly higher in those who underwent LSG + CRURA (87.5%) compared to LSG (17.1%) and RYGB (33.3%). Post-operative esophagitis showed no significant association with the studied groups (P = 0.395). The post-operative improvement of hiatus hernia showed a significant association with the studied groups (P = 0.047); It was significantly higher in those who underwent LSG+CRURA (100.0%) than those who underwent LSG (46.7%) or RYGB (66.7%).

Pre- and post-operative gastritis showed no significant association with the studied groups (P = 0.068 and 1.0, respectively).

Pre-operative use of proton pump inhibitors showed a significant association with the studied groups (P = 0.001); It was significantly higher in those who underwent LSG + CRURA (100.0%) compared to LSG (29.3%) and RYGB (50.0%). Post-operative use and discontinuation rate of PPI showed no significant associations with the studied groups (P = 0.395) (Table 3,4 & figure 2).

Table (3) Pre- and post-operative endoscopy findings & use of proton pump inhibitors

		LSG	LSG + CRURA	RYGB	
		(n = 41)	(n = 8)	(n = 12)	P-value
Esophagitis					
Pre-operative	n (%)	12 (29.3)	8 (100.0)	6 (50.0)	0.001
Post-operative	n (%)	30 (73.2)	5 (62.5)	5 (41.7)	0.127
Improvement	n (%)	1 (3.2)	3 (37.5)	3 (37.5)	0.005
Hiatus hernia					
Pre-operative	n (%)	7 (17.1)	7 (87.5)	4 (33.3)	<0.001
Post-operative	n (%)	8 (19.5)	0 (0.0)	2 (16.7)	0.395
Improvement	n (%)	7 (46.7)	7 (100.0)	4 (66.7)	0.047
Gastritis					
Pre-operative	n (%)	6 (14.6)	4 (50.0)	2 (16.7)	0.068
Post-operative	n (%)	2 (4.9)	0 (0.0)	0 (0.0)	1.0
Proton pump inhibitor	rs				
Pre-operative	n (%)	12 (29.3)	8 (100.0)	6 (50.0)	0.001
Post-operative	n (%)	15 (36.6)	4 (50.0)	3 (25.0)	0.518
Discontinued PPI	n (%)	5 (25.0)	4 (50.0)	4 (57.1)	0.253

Chi-square or Fisher's exact test was used

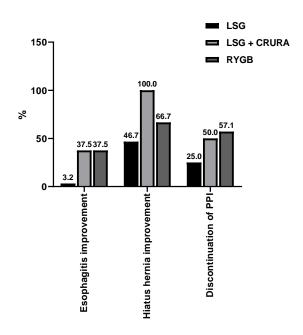


Figure (2): post-operative improvement of endoscopy findings & discontinuation of PPI

Table (4) Pre- and post-operative endoscopy grading of esophagitis:

	LSG (n = 41)		LSG + CRURA (n = 8)		RYGB (n = 12)	
	Preoperative	Postoperative	Preoperative	Postoperative	Preoperative	Postoperative
Grade A	2	14	1	4	0	3
Grade B	6	10	2	1	2	2
Grade C	2	4	1	0	1	0
Grade D	2	1	4	0	3	0
Barrette's	0	1	0	0	0	0
Total	12	30	8	5	6	5

Discussion:

Obesity is no more just a cosmetic problem. Obesity is a metabolic disease that responds well to surgical control. This area of research is rapidly growing with rapidly cumulating data that can act as a guide toward the proper management.

In this study, our protocol for obesity treatment was tailored according to BMI, GERD symptoms, endoscopic evidence of esophagitis and/or HH, and patient choice.

Group of R-E-Y GB have BMI 48.4 \pm 1.3, while other 2 groups of LSG and LSG plus Crural repair have BMI of 42.9 \pm 3 and 42.6 \pm 3.9 respectively.

Patients in LSG group showed the preoperative median GERD score to be 11 (3-25) and postoperative score was 14 (9-26). These scores reflected slight worsening of GERD conditions after LSG. On the other hand, preexisting esophagitis in 12 patients (29.3%), one case improved postoperatively, while 11 cases continue to suffer from esophagitis plus 19 cases developed de novo esophagitis.

Patients in LSG group showed 7 cases with small HH that disappeared postoperatively but other 8 cases developed de novo hiatus hernia.

Twelve patients (29.3%)of LSG group were defined as PPI dependent preoperatively, 5 cases(12.2%) succeeded to discontinue PPI drugs while another eight cases (19.5%) started to complain from de novo PPI dependency.

Overall results in LSG were running toward worsening of GERD symptoms and subsequent effects as esophagitis and PPI dependency.

The above results are matching with what reported by Jorge et al ⁸, Halim ¹, and Ramon et al ³ that patients after LSG have factors that enhance de novo GERD such as lost angle of His, Crural dissection, disturbed sling fibers, excised pad of fat, increased intragastric pressure, delayed gastric emptying, weak LES, and possible migration of gastric tube toward negatively pressured thoracic cavity. On the other hand, some patients after LSG may show some benefits in GERD and/or HH improvement. This also can be explained by decreased intraabdominal pressure after weight loss, improved gastric emptying in some cases, and decreased the ability of acid production³.

Patients of the second group that received LSG plus Crural repair were selected due to preoperative diagnosis of big HH. All cases of these group suffered from esophagitis. Half of these cases showed grade IV esophagitis preoperatively. Post operative cure of HH was found in 100% of cases. 5 cases (62.5%) of them are still showing the picture of esophagitis but shifting of its degree toward lower grades was noticed. Fifty percent of patients in this group succeeded to discontinue PPI medications. The above results are going with previous reports upon simultaneous LSG & Crural repair 12–15. On the contrary, Lewis et al 16 and Masoud et al 17 reported that adding the step of Crural repair to LSG was considered as adding more risk without gaining significant benefits as real prevention of post operative GERD.

Patients in the third group were selected on the bases of BMI higher than 45. Those patients showed improvement of esophagitis, decrease in postoperative incidence and degree. Six patients (50%) were classified as PPI dependent preoperatively. Four cases of them succeeded to discontinue PPI medication one patient started postoperative de novo PPI dependency. These results agree with that reported by Zaina et al⁷ that R_E_Y GB is a feasible option used more frequently to treat bariatric cases with concomitant GERD and/or HH.

Conclusion:

Treating obesity in patients with concomitant GERD should be taken carefully. LSG operation seems to be truly a Refluxogenic procedure, while LSG plus Crural repair and R_E_Y GB should

be considered as better alternatives to avoid postoperative worsening of GERD and degree of esophagitis. Further studies with bigger number of cases is recommended to stabilize this concept.

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