

LONG-TERM OUTCOMES OF LAPAROSCOPIC SLEEVE GASTRECTOMY FOR MORBID OBESITY SINGLE CENTER EXPERIENCE

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Abstract

Background: Good outcomes are usually reported by patients after laparoscopic sleeve gastrectomy (LSG), especially during the short- and intermediate-term follow-up. The long-term outcome is insufficiently in literatures. We conducted this study to determine the long-term outcomes of LSG regarding weight loss, weight regain, and the effect on obesity-associated comorbidities.

Patients and methods: This retrospective study presents the data of 517 patients who underwent LSG between 2012 and 2020. Data were collected regarding weight loss, weight regains, and changes in obesity-associated comorbidities at 2, 4, 6, 8, and 10 years after the procedure.

Results: The maximum weight loss was obtained at two-year follow-up. The mean %EWL had mean values of 69.14%, 63.71%, 58.86%, 53.13%, and 47.3% at the scheduled follow-up visits, respectively. The resolution and improvement of hypertension and diabetes showed good outcomes at the initial two follow-up visits. Nonetheless, recurrence of both diseases was notedat the subsequent visits. The incidence of worsening symptoms continued to increase throughout the follow-up visits. Revisional surgery was performed in 45 patients (8.7%), after a mean period of 5.98 years following the primary LSG procedure. The indications were weight regain (73.33%), failure of comorbidity resolution (20%), and intractable reflux (6.67%).

Conclusion: Although LSG is associated with great weight loss and comorbidity resolution at the short- and intermediate-term follow-up, long-term follow-up showed a weakening of these effects manifested in decreased %EWL, recurrence of comorbidities, weight regain, and need for revisional procedures.

Keywords: Sleeve gastrectomy; Long-term outcomes

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1. INTRODUCTION

Obesity is one of the main public health issues in Egypt, as about one-third of the adult Egyptian population suffers from obesity, according to the recent "100 million health" survey [1]. Laparoscopic sleeve gastrectomy (LSG) is one of the most common bariatric procedures performed in Egypt [2].

LSG was initially described as the first stage of biliopancreatic diversion with a duodenal switch procedure. It was originally indicated as an initial tool for decreasing weight before the second stage [3, 4]. Surprisingly, that operation was associated with effective weight loss and significant improvement of obesity-associated comorbidities. Also, it is technically easier and has less morbidity compared to other procedures [5]. The previous advantages have made LSG a primary bariatric procedure and one of the most commonly performed procedures for obesity around the world [6, 7].

Although LSG yields good outcomes in the shortand intermediate-term follow-up, the durability of its effectiveness is questioned in the long term [8]. Also, the existing studies handling long-term follow-up have low follow-up rates [9].

As there is an obvious lack of Egyptian studies handling the long-term outcomes after LSG, we conducted the current study to determine the longterm outcomes of LSG as a treatment for morbid obesity regarding weight loss, weight regain, and its effect on obesity-related comorbidities.

2. PATIENTS AND METHODS

This retrospective cohort study was conducted at Gastrointestinal Surgical Center, Mansoura University, Egypt following the approval from the Institutional Review Board of our university. The study included the data of all patients that underwent LSG in the period between January, 2012 and January, 2020. All study cases0 were called for follow up at our outpatient clinics. This provided a 2 to 10-year follow up after performing this laparoscopic procedure. Patients with less than 2 years of follow up and whom we could not contact at follow-up time were excluded.

Before the procedure, all patients were clinically, endoscopically, and biochemically assessed. The LSG was performed over a 38-Fr bougie, starting 4 – 6 cm from the pylorus, with complete excision of the gastric fundus. An intraoperative leak test was done to ensure staple line integrity. Operative time and intraoperative blood loss were recorded.Patients were transferred to the ward after the operation, and oral fluid intake was often allowed on the first postoperative day unless complications were encountered.Early complications leakage, as bleeding, or wound infectionwere recorded. The patients were discharged with dietary recommendations and vitamin supplementation as recommended [10, 11].

Standard follow-up included visits to the outpatient clinic at 3-month intervals during the first postoperative year. Later follow-up visits were scheduled at 2, 4, 6, 8, and 10 years after the procedure. The data were either collected from the electronically preserved patient sheets or by a telephone call to the patient. Data regarding the percentage of excess weight loss (%EWL), weight regain, and comorbidity changes were collected. Weight regain was defined as an increase of body weight of > ten kg from the nadir [12, 13].

Diabetes and hypertensive outcomes were defined as complete remission, partial remission, improvement, unchanged, and recurrence, while GERD assessment was subjectively classified as complete resolution, improvement, unchanged, or worsening. The previous definitions were previously published by Brethauer and his colleagues [14]. Denovo GERD was established when the patient developed reflux symptoms after the operation despite its absence before it, as reported by **Casella et al.** [15].

Our primary outcome was long-term weight loss and comorbidities outcomes. Secondary outcomes included early postoperative outcomes, weight regain rate and the need for revisional procedures.

The collected data were organized in SPSS software. Categorical variables were expressed as numbers and percentages, while numerical data were expressed as mean and standard deviation (if normally distributed) or median and range (if abnormally distributed). To compare data at different time points, we used the marginal homogeneity test for the former, while the repeated measures ANOVA was applied for the latter. In addition, McNemar's test was done for paired nominal data. A p-value less than 0.05 was considered statistically significant.

3. RESULTS

During the study period 604 patients underwent LSG as primary bariatric procedure, from them 87 patients were excluded because they had a follow up less than 2 years. Finally the study population comprised 517 patients.The mean age of the included cases was 36.82 years. Females represented 58% of the study population, whereas the remaining participants were men. Their mean preoperative body mass index (BMI)was 55.54 kg/m2. Regarding obesity-related comorbidities, diabetes mellitus was present in 67 patients (13%), while hypertension was present in 107 cases, whereas gastroesophageal reflux disease (GERD) was reported in 79 cases (15.3%) **Table (1)**.

Items	Study subjects n=517
Age (years) Mean ± SD	36.82 ± 12.26
Sex	
Males	217 (42%)
Females	300 (58%)
$\frac{BMI (Kg/m^2)}{Mean \pm SD}$	57.26 ± 12.37
Comorbidities	
Diabetes	67 (13%)
Hypertension	107 (20.7%)
GERD	79 (15.3%)

Table (1): Basic sociodemographic data among the studied cases

The mean operative time was 105.49 minutes, while mean blood loss was 257.06 ml. regarding early postoperative complications, internal haemorrhage was encountered in 2.3% of cases,

while leakage was encountered in 3.5% of them. In addition, port site infection occurred in 3.1% of cases **Table (2)**.

Items		Study subjects n=517
Operative time (min)	Mean \pm SD	105.49 ± 43.35
Blood loss (ml)	257.06 ± 188.22	
Early postope	ons	
Internal hemorrhage		12 (2.3%)
Leak		18 (3.5%)
Wound infection		16 (3.1%)

Table (2): Operative data among the studied cases.

As shown in **Table (3)**, the maximum weight loss was obtained at the two-year follow-up. The mean %EWL had mean values of 69.14%, 63.71%, 58.86%, 53.13%, and 47.3% at two, four, six, eight,

and ten-year follow-up visits, respectively. It was evident that the efficacy of LSG regarding weight loss significantly decreased with longer follow-ups.

Table (3): EWL	changes in the	study cases
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	EWL at 2 years (N=517)	EWL at 4 years (N=361)	EWL at 6 years (N=190)	EWL at 8 years (N=89)	EWL at 10 years (N=25)	
Mean ± SD	69.14 ± 10.63	63.71 ± 10.36	58.86 ± 10.02	53.13 ± 9.29	47.30 ± 9.14	
P ₁		< 0.001**	< 0.001**	< 0.001**	< 0.001**	
P ₂			< 0.001**	< 0.001**	< 0.001**	F= 63.454
P ₃				< 0.001**	< 0.001**	P < 0.001**
P ₄					< 0.001**	

F: Repeated measures ANOVA; P1: Significance in relation to 2 years value; P2: Significance in relation to 4 years value; P3: Significance in relation to 8 years value; P4: Significance in relation to 10 years value.

Similar to the trend of drop in %EWL over time, weight regain also increased progressively during follow-up. Weight regain was present in 4.06 % at 2 years, 9.69 % at 4 years, 29.42 % at 6 years, 47.19% at 8 years and 76 % at 10 years as shown in **Figure (no.1).**

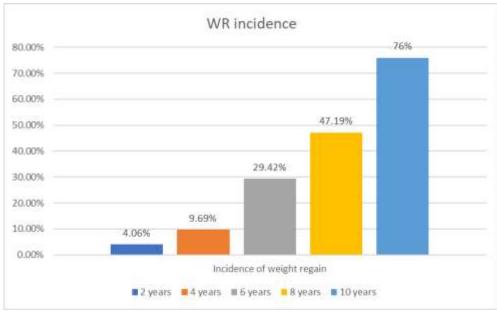


Figure (1): A chart showing the incidence of WR at the scheduled follow-up visits.

Diabetes remission and improvement showed good results at both two- and four-year follow-ups. However, at the subsequent visits, 15% and 20% of diabetic cases who presented at follow-up showed recurrence of their diabetic manifestations at sixand eight-year follow-up visits, respectively. Only three diabetic patients completed their ten-year follow-up, with no recurrence reported, mostly due to the limited patient sample (**Table 4**).

Long-Term Outcomes of Laparoscopic Sleeve Gastrectomy for Morbid Obesity Single Center Experience

	At 2 years (N=67)	At 4 years (N=42)	At 6 years (N=20)	At 8 years (N=10)	At 10 years (N=3)	
Complete remission	27 (40.3%)	12 (28.6%)	4 (20%)	2 (20%)	1 (33.3%)	
Partial remission	10 (14.9%)	9 (21.4%)	3 (15%)	2 (20%)	0 (0%)	MH= 2.548
Improvement	13 (19.4%)	9 (21.4%)	4 (20%)	1 (10%)	1 (33.3%)	P=0.136
Unchanged	17 (25.3%)	12 (28.6%)	6 (30%)	3 (30%)	1 (33.3%)	
Recurrence	0 (0%)	0 (0%)	3 (15%)	2 (20%)	0 (0%)	

Table (4): Changes in diabetes mellitus in the study cases with pre-existing diabetes

MH: Marginal homogeneity test.

The resolution and improvement of hypertension showed good outcomes at the initial two follow-up visits. Nonetheless, recurrence of the hypertensive state was noted in 4.5%, 25%, and 28.6% of patients at the subsequent three follow-up visits, respectively **Table (5)**.

Table (5): Changes in hypertension in the study cases with pro-	e-existing hypertension
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	At 2 years (N=107)	At 4 years (N=77)	At 6 years (N=44)	At 8 years (N=20)	At 10 years (N=7)	
Complete remission	21 (19.6%)	13 (16.9%)	4 (9.1%)	2 (10%)	0 (0%)	
Partial remission	20 (18.7%)	18 (23.4%)	13 (29.5%)	2 (10%)	1 (14.3%)	MIL 2.099
Improvement	23 (21.5%)	12 (15.6%)	8 (18.2%)	3 (15%)	0 (0%)	MH= 2.988 P= 0.092
Unchanged	43 (40.2%)	34 (44.2%)	17 (38.6%)	8 (40%)	4 (57.1%)	1 - 0.092
Recurrence	0 (0%)	0 (0%)	2 (4.5%)	5 (25%)	2 (28.6%)	

MH: Marginal homogeneity test.

Although some patients reported resolution or improvement of their GERD symptoms at the initial follow-up after the operation, the incidence of worsening symptoms continued to increase throughout the follow-up visits. The incidence of worsening GERD was 30.4%, 32.1%, 35.7%, 37.5%, and 67.7% at two, four, six, eight, and tenyear follow-up visits, respectively Table (6). Worsening of GERD was in the form of increased frequency of symptoms, incidence of extraesophageal symptoms such as hoarseness of voice, and need for antacids or proton pump therapy. An endoscope was done at 2 years and every 2 years thereafter in patients with GERD revealed no esophagitis, grade I or grade II esophagitis with no Barrett's diagnosed in all patients. All cases were controlled with medical treatment except 3 cases that underwent revisional surgery.

	At 2 years (N=79)	At 4 years (N=53)	At 6 years (N=28)	At 8 years (N=8)	At 10 years (N=3)	
Resolution	8 (10.1%)	6 (11.3%)	5 (17.9%)	1 (12.5%)	0 (0%)	
Improvement	15 (19%)	17 (32.1%)	3 (10.7%)	1 (12.5%)	0 (0%)	MH= 3.265
Unchanged	32 (40.5%)	13 (24.5%)	10 (35.7%)	3 (37.5%)	1 (33.3%)	P=0.076
Worsened	24 (30.4%)	17 (32.1%)	10 (35.7%)	3 (37.5%)	2 (67.7%)	

Table (6): Follow-up of GERD in patients with pre-existing GERD

MH: Marginal homogeneity test.

The incidence of denovo GERD was 2.5%, 2.9%, 3.7%, 6.1%, and 18.2% at two, four, six, eight, and ten-year follow-up visits, respectively. The

incidence of this problem continued to increase throughout the long-term follow-up **Table (7)**.

 Table (7): The development of de novo GERD in patients without pre-existing GRED.

	At 2 years (N=438)	At 4 years (N=308)	At 6 years (N=163)	At 8 years (N=81)	At 10 years (N=22)	
Denovo GERD	11 (2.5%)	9 (2.9%)	6 (3.7%)	5 (6.1%)	4 (18.2%)	McN= 4.681 P= 0.005*

McN: McNamar's test.

Weight regain was reported in 22.43% of patients at follow-up. Revisional surgery was performed in 45 patients (8.7%) after a mean period of 5.98 years following the primary LSG procedure. The most common indication for revision was weight regain (73.33%), followed by failure of comorbidity resolution (20%) and intractable GERD (6.67%). The most common procedure performed was roux-en-y gastric bypass RYGB (66.7%), followed by minigastric bypass (28.9%), and resleevegastrectomy (4.4%) **Table (8)**.

Table (6). Weigh regain and revisional surgery data an	0	Study subjects
Items		n=517
Weight magin		
Weight regain		116 (22.43%)
Revision surgery		
Revision		45 (8.7%)
No revision		472 (91.3%)
Indication for revision		
Weight regain		33 (73.33%)
Failure of comorbidity improvement	9 (20%)	
• GERD	3 (6.67%)	
Type of Revision (N= 45)		-
• Roux-on -Y		30 (66.7%)
Mini gastric bypass	13 (28.9%)	
• Resleeve	2 (4.4%)	
The interval between primary surgery and revision (Years)	Mean \pm SD	5.98 ± 1.45

Table (8). Woigh ragain	and ravisional surgary	data among the studied cases
Table (o): weigh legan	i and revisional surgery	data among the studied cases.

4. **DISCUSSION**

This study was done to evaluate the long-term outcomes after LSG. As there is a paucity of Egyptian studies handling the same concept, this poses an advantage in favour of our research.

In our study, the operative time ranged between 30 and 300 minutes (mean = 105.49 minutes). Gentileschi reported that the median operative time was 102 minutes (range, 64 - 180 minutes) [16], which is near to our findings. However, **Bobowicz et al.** reported that the mean operative time was 61 min (range 30–140 min) [17], which is lower than ours. Some differences are accepted between studies regarding the previous parameter. That would differ due to surgeon experience, place ergonomics, and the performance of concomitant procedures like cholecystectomy.

Staple line leakage was encountered in 3.5% of our participants, and that incidence rate lies within the reported global incidence of leakage after LSG, which ranges between 1.1% and 5.3% [18].

Internal hemorrhage occurred in 2.3% of our patients. This incidence is in accordance with the previous range in the literature (1.16 - 4.94%) [19, 20].

Regarding surgical site infection in the current study, it occurred in 3.1% of cases. Other previous studies reported that this complication could occur in up to 4% of patients following laparoscopic bariatric procedures [21, 22], which is in line with our findings.

Regarding weight loss outcomes in our study, the % EWL had mean values of 69.14%, 63.71%, 58.86%,

53.13%, and 47.3% at two, four, six, eight, and tenyear follow-up visits, respectively. Similar to the trend of drop in %EWL over time, weight regain also increased progressively during follow-up. Weight regain was present in 4.06 % at 2 years, 9.69 % at 4 years, 29.42 % at 6 years, 47.19% at 8 years and 76 % at 10 years.

It was evident that the efficacy of LSG regarding weight loss significantly decreased with longer follow-ups.

Multiple factors could contribute to the waning effects of LSG with time. These include dilatation of the gastric pouch, inadequate fundus resection, increased ghrelin secretion from the previously silent gastric glands, a sedentary lifestyle, and poor adherence to dietary recommendations [12, 23-25].

In the study conducted by **Rodríguez** and his coworkers, the % EWL had mean values of 72.7%, 66.3%, and 53.8% at three, five, and ten years following LSG [26]. Additionally, **Sarela et al.** reported an EWL of 86%, 79%, and 69% after two, three, and eight years respectively [27]. A previous systematic review including 16 previous studies handling LSG outcomes stated that the %EWL had mean values of 62.3%, 53.8%, 43%, and 54.8% after five, six, seven, and eight years after LSG, respectively [28]. Also, **Arman et al.** reported that six-and eleven-year %EWL had mean values of 75.9% and 62.5%, respectively [24].

Liu et al. reported that the proportions of patients having successful weight loss (%EWL>50 %) were 79.7, 71.7, 58.4, 55.8, and 54.5 % from 1 to 5 years respectively and similar to the trend of drop in %EWL over time, weight regain also increased progressively during follow-up. Weight regain was not evident in the first two year but was present in 1.0 % at 2 years, 11.6 % at 3 years, 19.2 % at 4 years, and 29.5 % at 5 years [10].

One could also notice the heterogenicity of reported %EWL among studies. That may denote that weight loss after LSG is also affected by other parameters, preoperative weight, postoperative including exercise, and postoperative dietary management [29]. In the current study, revisional surgery was performed in 45 patients (8.7%) after a mean period of 5.98 years following the primary LSG procedure. Indications for revision were weight regain (73.33%), failure of comorbidity resolution (20%), and intractable GERD (6.67%). The most common procedure performed was RYGB (66.7%), followed by minigastric bypass (28.9%) and resleeve (4.4%).

Lazzati et al. reported that revision rates after LSG were 4.7%, 7.5%, and 12.2% after five, seven, and ten years respectively. The revision was indicated for obesity persistence and GERD. The performed operations were RYGB (75.2%) and resleeve gastrectomy [30].

AbdEllatif et al. reported a low revision rate (4%), which was needed for inadequate weight loss after LSG. Revisional procedures included resleevegastrectomy, RYGB, and banding [31].

The change in revision rates between studies could be explained by different factors, including the difference in the incidence and definition of weight regain after LSG, the different incidence of GERD, patient seek for weight loss, and the economic status of the patient, along with insurance coverage for bariatric procedures between different countries.

Weight regain, which is the major etiology of revision after LSG, ranges from 19.2% to 75.6%, according to long-term studies in the current literature [15, 32, 33]. Our incidence of weight regain lies within the previous range.

This heterogenicity in incidence could be due to different definitions used for weight regain after such a procedure. Some authors defined it as more than 10 kg from nadir weight [12], while others defined it as rebound excess weight loss > 25% [32].

In our study, diabetes remission and improvement showed good results at both two- and four-year follow-ups. However, at the subsequent visits, 15% and 20% of diabetic cases who presented at followup showed recurrence of their diabetic manifestations at six- and eight-year follow-up visits, respectively. Likewise, **Conte et al.** reported that diabetes relapse could occur in 13 - 20% of individuals after temporary improvement following bariatric surgery [34]. Another study reported a higher relapse rate (44%) [35].

Other studies reported favorable long-term diabetic outcomes after LSG [25, 36]. **Eid et al.** reported a 40% improvement rate, along with a 37.1% remission rate at the five-year follow-up [36]. The difference in the definition of remission and improvement, as well

as the difference in the duration of follow-up, could be responsible for heterogenicity between studies.

In the current study, resolution and improvement of hypertension showed good outcomes at the initial two follow-up visits. Nonetheless, recurrence of the hypertensive state was noted in 4.5%, 25%, and 28.6% of patients at the subsequent three follow-up visits, respectively. **Rodríguez** and his associates reported improvement of hypertension in 75.8%, 68.9%, and 48.2% of their participants after three, five, and ten years following LSG [26]. One could notice the decreasing efficacy of LSG in controlling individual blood pressure over time.

In our study, although some patients reported resolution or improvement of their GERD symptoms at the initial follow-up after the operation, the incidence of worsening symptoms continued to increase throughout the follow-up visits. The effect of LSG on GERD is still contradictory. Worsening of GERD could be explained by the formation of a highpressure tube, disruption of the angle of His, decreased ghrelin secretion, and subsequent dysmotility. However, other theories could explain improvement after LSG. Gastric resection leads to the decline of the parietal cell mass, leading to a marked decrease in acid production. Also, weight loss itself with the subsequent decline in intrabdominal pressure and enhanced gastric emptying [37].

Eid et al. reported that remission and improvement of GERD manifestations were reported in 8.96% and 22.9% of patients, respectively. Worsening was reported only in 8.6% of their participants [36].

In the current study, the incidence of denovo GERD was 2.5%, 2.9%, 3.7%, 6.1%, and 18.2% at two, four, six, eight, and ten-year follow-up visits, respectively. This is in accordance with **Pilone et al.**, who reported that denovo GERD could be encountered in up to 20% of patients after LSG [38]. Moreover, **AbdEllatif et al.** reported an incidence of 11.4% for the same complication one year after LSG. That incidence significantly declined to 2% at four-year follow-ups [31].

Additionally, in a study evaluating longterm effect of sleeve gastrectomy on GERD on a total of 315 patients, **Braghetto & Korn** exclude patients with preoperative GERD, all patients with reflux symptoms after sleeve are 'de novo' refluxers. They reported that at late follow up, (mean 7.07 ± 2.26 years) an increased incidence of symptoms was observed compared to patients evaluated early after surgery (mean 65.1% v/s 28.1%, respectively) (P = 0.0001). Only 26.9% were treated with PPIs at early follow-up while 57.7% of patients needed PPI treatment due to reflux symptoms late after surgery (P = 0.0001). These results suggest worsening of reflux symptoms with time [39].

In a review of longterm results of sleeve gastrectomy, **Felsenreich et al.** showed that short-term studies report an improvement (or even remission) of reflux symptoms in many of their patients, which may very well be caused by a decrease of intra-abdominal pressure as patients lose large amounts of weight [40]. **Spivak et al.,** for example, were able to show that reflux was cured in 73.7% of patients, who had had preoperative reflux, after 1 year [41].

Chiu et al. analyzed 15 studies with follow-ups between 6 and 60 months after SG in a systematic review and found that 4 of them reported higher rates of reflux and 7 showed improvement of reflux [42].

Mid- and long-term studies, however, show an increase in patients needing proton pump inhibitors (PPIs) and severe reflux symptoms that often stem from de novo reflux [43,44,45]. **Boza et al.**, for example, found new-onset reflux in 26.7% of their SG patients after 5years in a study of 161 patients with a follow-up rate of 70% [46]. **Himpens et al.** studied 53 SG patients at a follow-up of 6+years and 21% were suffering from new-onset reflux at that point [43]. A reason for de novo reflux at this stage may be an increased intra-abdominal pressure caused by weight regain, which often also leads to hiatal hernia development and/or intra-thoracic migration of the sleeve, which is a high-pressure system [40].

Our study has some advantages including the respectable sample size with long-term follow up. However, our study has several limitations. First, the retrospective nature of our data. Second, the follow up rate beyond 8 years was relatively low, a common problem seen in bariatric literature. Third, the impact on comorbidities was analyzed only by changes in therapy, prescribed by other physicians. Fourth, we were not able to perform invasive tests regarding GERD, could only base our results on presented symptoms, and declared pharmacotherapy. We did not assess objectively the severity and frequency of GERD symptoms. More studies including more patients from different bariatric centers should be conducted in the near future.

5. CONCLUSION

According to the previous findings, although LSG is associated with great weight loss and comorbidity resolution at the short- and intermediate-term followup, long-term follow-up showed a weakening of these effects manifested in decreased %EWL, recurrence of comorbidities, weight regain, and need for revisional procedures.

Conflict of interest: Nil.

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