



Long-term outcomes of laparoscopic sleeve gastrectomy from the Indian subcontinent

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Abstract

Background Laparoscopic sleeve gastrectomy (LSG) is the most commonly performed metabolic surgery worldwide. There are few mid- to long-term studies for LSG, especially from the Indian subcontinent.

Objective The primary outcome of the study was percent total weight loss (%TWL), and secondary outcomes included type 2 diabetes mellitus remission (T2DM) rates, comorbidity resolution rates, revisional surgeries, and complications related to LSG, 3 and 5 years after surgery.

Method The study was a single-center, retrospective analysis from patients who underwent primary as well as revisional LSG between January 2012 and December 2013 from a tertiary care center in India. We included patients who completed a minimum follow-up of 5 years. Details of the patients were collected from outpatient and inpatient case sheet records, during their follow-up.

Results Out of a total of 284 patients, 57% were females. Mean baseline body mass index (BMI) was 44.9 ± 7.9 kg/m². The diabetic population comprised 14.8% of the total patients. Mean %TWL at 5 years was $26.0 \pm 9.9\%$. T2DM remission at 1, 3, and 5 years were 78.5%, 71.4%, and 66.6%, respectively. Preoperative BMI ($p = 0.02$), glycosylated hemoglobin (HbA1c) ($p = 0.04$), duration of diabetes in years ($p = 0.04$), and preoperative insulin usage ($p = 0.04$) were the preoperative predictors for T2DM remission. Early (< 30 days) and late (> 30 days) complications were seen in 4.5% and 0.7% of the population, respectively.

Conclusion Weight loss after LSG was maintained in the majority of the patients, while a small proportion has significant weight regain at 5 years. T2DM resolution and other comorbidity resolutions were well supported after LSG.

Keywords Sleeve gastrectomy · LSG · Long term · Weight loss · Type 2 diabetes mellitus · Comorbidity resolution · Revisional surgeries · Complications · Predictors of success

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Introduction

LSG is the most common bariatric surgery performed worldwide, having the advantage of technical ease, with consistently good results, pertaining to outcomes of weight loss and comorbidity resolution, well proven in many studies in the existing literature [1–11]. There are only a few long-term studies reporting all aspects of bariatric surgery especially from Asia.

Asians have peculiar, body composition, lifestyle, and disease patterns. The Indian population differs from the western community in terms of the type of nutrition intake, body composition, lower lean body mass, increased visceral body fat mass, and different metabolism when compared to the white population [12–14].

It has already been established that for the same BMI, Asians had higher visceral fat compared to their western

counterparts [12]. The increased amount of visceral fat led to insulin resistance, more metabolic syndrome, and overall, an increased incidence of cardiovascular disease among the Asian population [13–15]. Various metabolic alterations combined with differences in lipid profiles such as hypertriglyceridemia and low levels of high-density lipoprotein (HDL) associated with abdominal visceral obesity were noted in different ethnic groups, as suggested by the HERITAGE family study and also various other studies [16, 17].

There are a sizeable number of diabetics in India who are predisposed to diabetes-related complications. These complications not only lead to subsequent increased morbidity and mortality but also affects the economic burden of society. In the Asian population, B-cell dysfunction sets in early in the disease process [18]. Earlier B-cell dysfunction led to the conversion of pre-diabetic state to diabetic state and insulin resistance at an earlier stage. It also led to difficulty in reversal to normal glucose regulation with adequate lifestyle measures as compared to the white population [14]. Based on the above facts, including YY paradox and early B-cell dysfunction in Indian society, extrapolating the data from the western literature might not be suitable.

In this study, we aimed to understand the effects of LSG concerning weight loss, comorbidity resolution, and also the predictors of its success in the long term in Indian patients.

Methods

Study Design and Setting

The authors retrospectively analyzed the data from a prospectively maintained database. Patients who had undergone LSG or revisional LSG and completed a minimum of 5-year follow-up were included in the study. This study was performed in obesity and metabolic surgery department, at a tertiary care teaching institute in Southern India. More than 250 bariatric procedures are performed every year in this center. The Institutional Review Board had approved the study. The patients were evaluated by a multi-disciplinary team of doctors, dedicated to bariatric surgery, including surgeons, medical gastroenterologists, dieticians, and psychologists. All patients were counseled before surgery regarding the indications, merits, and demerits associated with the same. All the surgical procedures were performed by a team of only two bariatric surgeons.

Patient Selection

Patients with BMI > 35 kg/m², with or without any comorbidities or BMI > 30 kg/m², with comorbidities or metabolic syndrome, were considered for surgery [19]. Severity of gastroesophageal reflux disease (GERD) was clinically classified

according to Montreal classification and preoperative upper GI endoscopy. Patients with significant symptoms of reflux and patients with features of hiatus hernia in the upper GI endoscopy or significant GERD changes, like Barrett's esophagus, were not advised LSG [20]. Patients who were not candidates for surgery were discouraged from getting an LSG, but those patients who still preferred a LSG against our advice were excluded from the study.

The ultimate decision for the surgery was based on the patient's preference. After a thorough process of investigations, the best bariatric surgical option, merits, and demerits of each bariatric surgical procedures were explained to the patients.

The surgical choice, after having revealed the details, however, was left to the discretion of the patients, depending upon their individual decisions.

Procedure

Preoperatively all patients were subjected to a liquid (low-calorie) liver shrinkage diet for a minimum period of 2 weeks. The preoperative diet comprised either a partial or complete formula-based diet or meal replacement and a food-based diet, with an overall low amount of carbohydrate. Low molecular weight heparin (enoxaparin, with a dosage ranging from 40 to 60 mg, as once or twice the daily frequency, based on patient's weight) was given to the patients an evening before the surgery and was continued for a minimum of 1 week following surgery [21, 22]. Gradual pneumatic compression stockings were applied to the patients for DVT prophylaxis. LSG was done in the standard five-port technique, with a 10-mm supraumbilical camera port, 5-mm sub-xiphoid liver retraction port, and two 5-mm right hand working ports, while a 13-mm port (Multiport; Olympus Corp., PA, USA) directed toward the pylorus fires the stapler. Greater-omentum division was done cranially, exposing the left crus completely, and caudally up to 4 to 5 cm proximal to the pyloric ring. Posterior gastropancreatic attachments were released to free the stomach completely. After the mobilization of the stomach, linear staplers were fired and sleeve created. Proximal one third of the stomach was reinforced with surrounding omentum after imbrication of anterior and posterior wall of the stomach. Air leak test was done intraoperatively. Port closures were done for all ports greater than 10 mm.

The patients were made to ambulate on the day of surgery and were started on a clear liquid diet at 30 ml/h. A dye study using water-soluble contrast (30–50 ml of diatrizoate meglumine) was done on POD 01. Patients were discharged when they met the discharge criteria (Table 1) on the second or third postoperative day. Follow-ups for the patients were scheduled at 2 weeks, 3 months, 6 months, 9 months, 12 months, and annually after that.

Table 1 Discharge criteria post-LSG patients

Sample number	Criteria
1	Pain score ≤ 1 (Visual Analog Scale)
2	Pulse < 90 /min
3	Temperature ≤ 37.6 °C
4	Respiratory rate < 20 /min
5	Patient ambulatory
6	Drank at least 1 l of fluid in 24 h
7	Uneventful procedure
8	No complications

Data Collection

All records were collected in pre-designed proforma. Details of intra-op and post-op results were obtained from the inpatient and outpatient case sheet records during the admission or follow-up of the patients. Various

$$\%EWL = [(Initial\ weight) - (Post\text{-}op\ weight)] / [(Initial\ weight) - (Ideal\ Weight)] \text{ (in which ideal weight is defined by the weight corresponding to a BMI of } 23 \text{ kg/m}^2\text{)}.$$

Diabetes

T2DM was classified according to American Diabetology Association (ADA) [25].

Remission was defined as HbA1c $\leq 6.5\%$, in the absence of anti-diabetic medications for a minimum of 1 year. Improvement in T2DM was identified as a statistically significant reduction in HbA1c and fasting blood sugar (FBS), not meeting criteria for remission, or decrease in anti-diabetic medication requirement.

Hypertension

HT was defined when blood pressure was persistently at or $> 140/90$ mmHg, but not at the average level which was defined as 100–140 and 60–90 mmHg for systolic and diastolic pressure, respectively. Remission in HT was defined as blood pressure $< 140/90$ mm of Hg, off any anti-hypertensive medications post-surgery [26].

Obstructive Sleep Apnea

Screening of obstructive sleep apnea (OSA) was done by STOP-BANG score [27]. The score helped in categorizing the patients who needed sleep study (polysomnography). Scores were then categorized into low, intermediate, or high risk, depending upon the polysomnography results based on the severity of the apnea/hypopnea index (AHI). High-risk

demographic features, onset, progression, and the outcome of comorbidities along with detailed records of medications in the pre-op and post-op settings were collected. Complications were categorized into early (< 30 days) and late (> 30 days). On follow-up, patients were evaluated for weight loss, change in comorbidities like type 2 diabetes mellitus (T2DM), hypertension (HT), obstructive sleep apnea (OSA), fatty liver, dyslipidemia, and gallstone disease (GSD).

Definitions

Weight Loss

The percent total weight loss (%TWL) was derived from the following formula: (weight loss/initial weight) $\times 100$.

Similarly, percent excess weight loss (%EWL) was calculated using the standard method [23, 24]:

patients were subjected to optimization with preoperative use of CPAP/B-Pap for a minimum period of 2 weeks for a minimum of 4 h/night [28].

Statistical Analysis

Statistical analysis was done using SPSS version 20.0 (SPSS Inc., IL, USA). For continuous variables, results were shown as mean \pm standard deviation (SD). For continuous variables, paired *t* test was used, while χ^2 test was done for categorical variables. Correlation between data was done using Pearson's correlation coefficient (*r*). Linear and logistic regression analyses were performed after obtaining univariate results to evaluate the effects of various variables on outcomes under consideration. Significance was considered when the *p* value was < 0.05 .

Results

Demographic and Preoperative Variables

The total number of LSGs done during this period was 284, of which females ($n = 159$) slightly outnumbered the male population. Majority of the population who underwent LSG were in the fourth decade. Percentage of LSG during the years 2012 and 2013 were 38.4% and 61.6% of the total patients who had undergone

bariatric surgery, respectively. The mean weight was 118.5 ± 24.4 kg, and the majority of the population belonged to class 3 BMI. Sixty-six patients (23.2%) were categorized as super-obese (>50 kg/m²).

The number of diabetic patients included during this period was 42 (14.8%). Most of the diabetic patients included in the group were in the fourth decade (48.6 ± 10.9), and the majority (57.1%) were males ($n = 24$). Mean duration of T2DM was 7.3 ± 7.9 years.

Twelve patients (4.2%) had GSD, which was diagnosed preoperatively, and all patients were subjected to concomitant laparoscopic cholecystectomy with LSG. Almost half ($n = 144$) of the patients (50.7%) had varying severity of OSA, out of which around a quarter ($n = 74$) of the patients (26%) were diagnosed with severe OSA and had to undergo C-Pap treatment for optimization, at least for 2 weeks prior to surgery, for a minimum of 4 h/night. Demographic details of the population studied are depicted in Table 2.

Table 2 Demographic and baseline clinical characteristics of individuals undergoing LSG

Age	41.08 ± 12.02 years
Gender (female)	159 (56%)
Height	162.13 ± 9.9
Weight	118.5 ± 24.4 kg
BMI	44.9 ± 7.9 kg/m ²
FBS	115.3 ± 39.8
Pre-op FC pep	3.1 ± 1.2
HbA1c	6.8 ± 1.7
Insulin requirement	10(23.8%)
Number of OHA	1.25 ± 0.7
Cholesterol	182.9 ± 38.6
TGS	126.8 ± 59.2
LDL	119.1 ± 34.6
HDL	42.08 ± 10.2
VLDL	25.4 ± 12.06
SGOT	24.4 ± 10.1
Protein	7.3 ± 0.4
Albumin	4.47 ± 0.3
HTN	134 (47.09%)
DM	42 (14.8%)
Fatty liver	192 (67.7%)
GSD	12 (4.2%)
OSA	144 (50.7%)

LSG laparoscopic sleeve gastrectomy, BMI body mass index, FBS fasting blood sugar, Pre-op FC pep preoperative fasting C peptide, HbA1c glycosylated hemoglobin, OHA oral hypoglycemic agent, TG triglyceride, LDL low-density lipoprotein, HDL high-density lipoprotein, VLDL very low-density lipoprotein, SGOT serum glutamic oxaloacetic transaminase, HT hypertension, DM diabetes mellitus, GSD gallstone disease

Operative Details

All operations were performed laparoscopically. The mean duration of surgery was 52 ± 17.8 min. Mean blood loss during the surgery was 31.9 ± 13.1 ml. The average blood loss was measured by taking the mean value of the whole blood collected in the suction apparatus at the end of each surgical procedure, which was usually documented. There were no conversions during any of the surgeries done. Concomitant LSG, along with intraperitoneal mesh repair, was done in 39 patients (13.7%), and concomitant cholecystectomy was done in 12 patients (4.2%). The mean duration of stay in the hospital was 2.6 ± 1.2 days. There was no mortality.

Complications

The overall complications observed during the period were 5.2% (15/284) out of which early complications (<30 days) were 4.5% (13/284) and late (>30 days) complications were 0.7% (2/284). Major complications which required surgical intervention were 1.7% (5/284). Minor complications were 3.5% (10/284), which were managed conservatively and included staple line bleed and contained hematoma ($n = 4$). Surgical site infections from the left (13 mm) port were reported in five patients, which were managed with culture-specific antibiotics. One patient had deep vein thrombosis (DVT), which required prolonged anticoagulant treatment (enoxaparin with a dosage of 60 mg twice daily for 2 weeks). Complications that required surgical intervention included one patient with sleeve leak, which was detected 10 days post-surgery, for which a revisional Roux en-Y gastric bypass (RYGB) was done. Another patient presented with gastro-bronchial fistula 7 months following surgery. The patient was managed with suture occlusion of the fistula tract along with revisional RYGB. Both the patients recovered uneventfully after that. A lower esophageal peptic stricture was observed 5 years following LSG. An endoscopic dilatation followed by revisional RYGB was performed for the case. Two patients required relook laparoscopy because of hemodynamic instability. Vessel bleeder at stapled margin was found in one patient, while the second patient had a diffuse ooze from the staple line. Both cases were controlled after suture repair.

Follow-Up Records

Follow-up rate during the first, third, and fifth years were 87.7% ($n = 249$), 68.3% ($n = 194$), and 52.8% ($n = 150$), respectively.

Weight

The preoperative, 1-year, 3-year, and 5-year post-operative weights were 118.6 ± 24.4 , 80.7 ± 15.1 , 89.5 ± 14.8 , and 86.9 ± 16.7 kg, respectively (Fig. 1).

BMI

The BMI during preoperative, 1-year, 3-year, and 5-year post-operative period were 44.9 ± 7.9 , 30.7 ± 5.9 , 32.6 ± 5.6 , and 33.2 ± 6.3 , respectively.

Excess BMI loss (%EBMIL) was maximum during 1 year (76.03%), followed by 3 years (68.8%) and least at 5 years (61.2%), respectively (Fig. 2).

Percentage total weight loss (%TWL) was maximum during the first year, being 31.3 ± 8.9 , which gradually decreased during the third year and fifth years to $30.9 \pm 9.3\%$ and $26.0 \pm 9.9\%$, respectively (Fig. 3).

Percentage excess weight loss (%EWL) at 1-year, 3-year, and 5-year postoperative period was 76.3 ± 25.5 , 73.1 ± 26.0 , and 62.4 ± 25.8 , respectively (Fig. 4).

Patients with %EWL of < 50% from the baseline weight were 9.6% ($n = 24/249$ patients) at 1 year, 6.1% ($n = 12/194$) at 3 years, and it gradually increased to 41.3% ($n = 62/150$) at 5 years.

Weight Regain

Fifty patients (17.6%) had weight regain of 4.1 ± 2.5 kg after 3 years, whereas at the end of 5 years, weight regain gradually increased to 6.4 ± 7.6 kg, respectively, in 111 patients (39.1%).

Using multivariate regression analysis (Table 3), we found that none of the factors (age, gender, preoperative weight, preoperative BMI, and presence or absence of T2DM) had significant predictive value for postoperative %TWL, at 3 years and 5 years, respectively.

Diabetes Mellitus

HbA1c and Fasting Blood Sugar

Mean HbA1c in the preoperative, 1-year, 3-year, and 5-year postoperative period were 6.82 ± 1.7 , 6.06 ± 1.2 , 5.66 ± 1.09 , and 5.85 ± 0.9 , respectively. There was a significant reduction of HbA1c, between preoperative and 5 years ($p < 0.001$) (Fig. 5).

Fasting blood sugar(FBS) at preoperative, 1-year, 3-year, and 5-year postoperative period were 115.3 ± 39.8 , 99.2 ± 23.9 , 95.9 ± 14.2 , and 100.5 ± 22.1 , respectively. There was a significant decrease in the values in the long-term follow-up (5 years), FBS ($p < 0.001$).

Diabetes Remission and Improvement

Thirty-three patients (78.5%) had complete remission in T2DM, while there was an improvement in the remaining nine patients (21.4%) at the end of the first year. At the end of 3 years, the percentage of remission came down in 30 patients (71.4%) while improvement was found in 8 patients (17.8%). Four patients (9.5%) had static diabetic status. At the end of 5 years, remission was further reduced to 28 patients (66.6%) while improvement was found in 14 patients (33.3%) (Table 4).

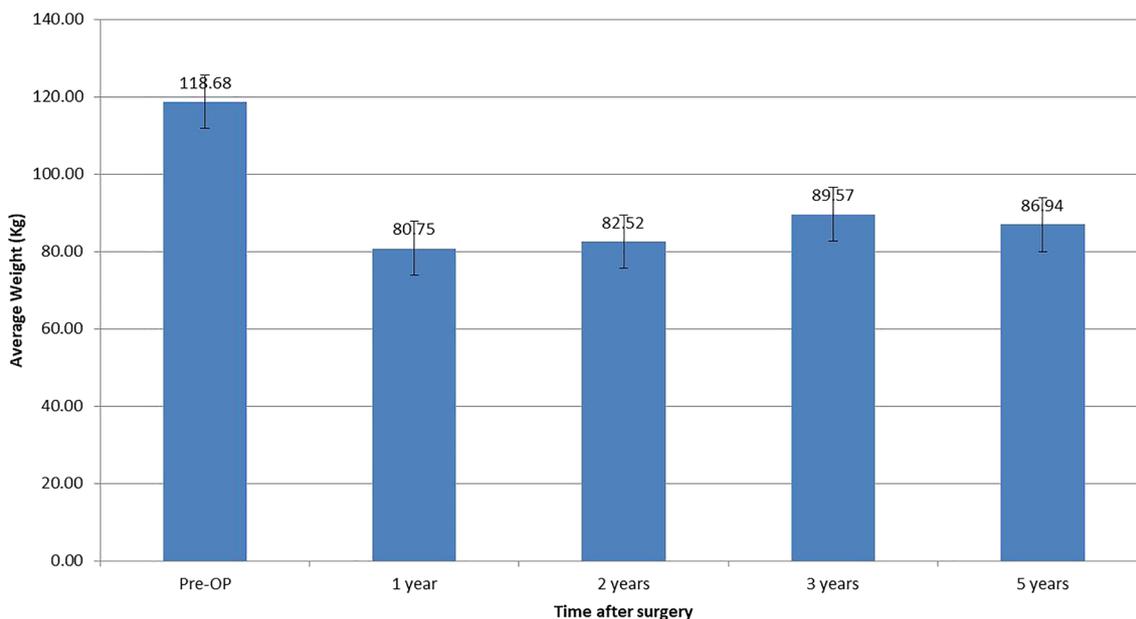


Fig. 1 Weight change following sleeve gastrectomy

Fig. 2 Percentage excess BMI loss at 1-, 3-, and 5-year follow-up

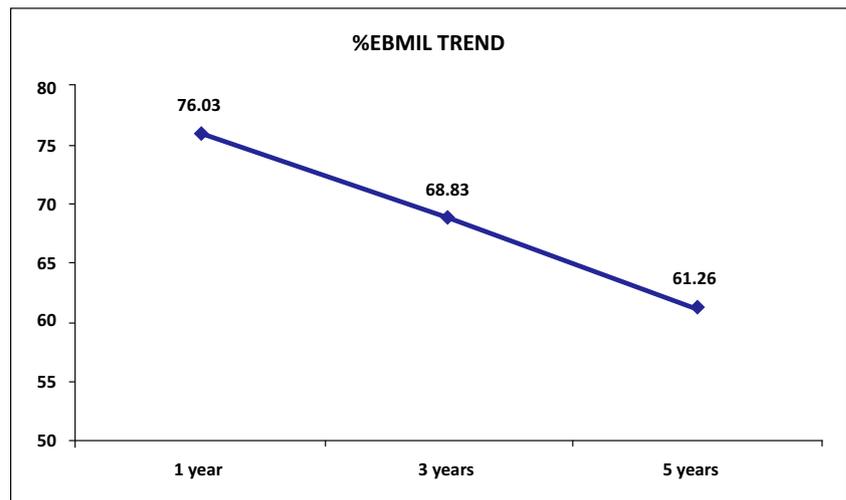


Fig. 3 Percentage total weight loss (%TWL) at 1, 3, and 5 years

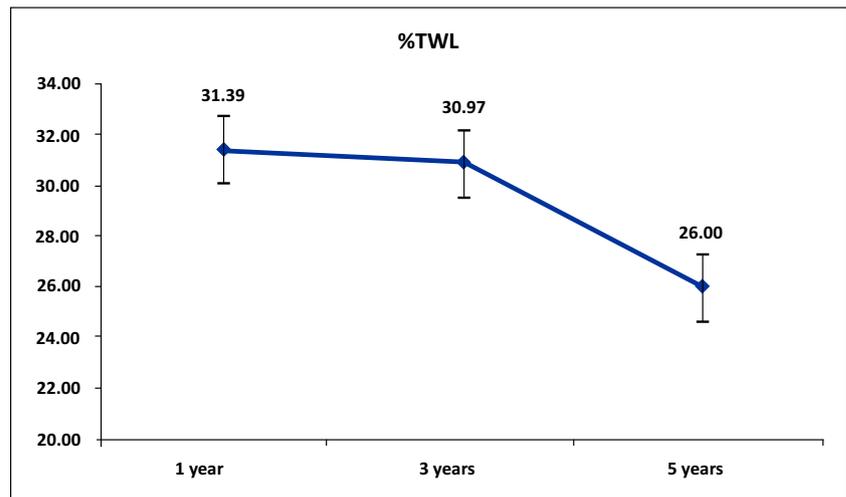


Fig. 4 Percentage excess weight loss (%EWL) at 1, 3, and 5 years

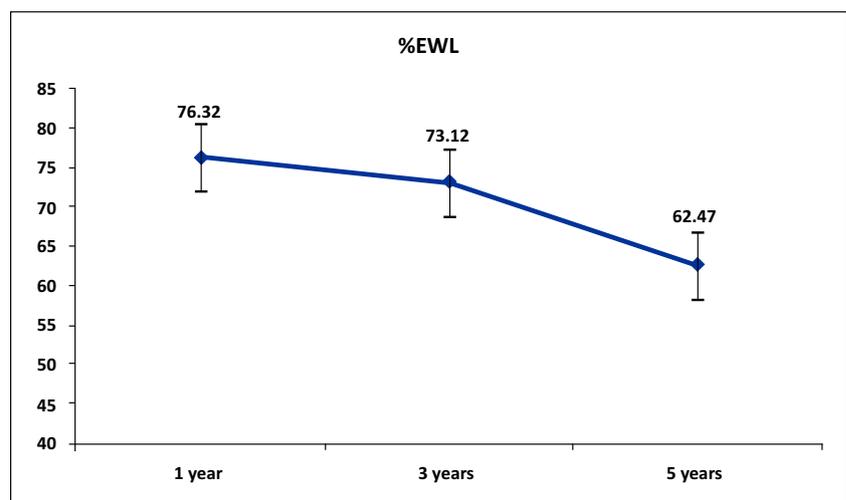


Table 3 Results of multivariate regression analysis to predict postoperative weight loss success (% TWL) at 3-year and long-term (5-year) control

Variable	Three-year control			Long-term control		
	Beta	95% CI	<i>p</i>	Beta	95% CI	<i>p</i>
Age (< 45 vs. > 45)	-0.031	-0.328, 0.444	0.265	-0.014	-0.072, 0.044	0.628
Sex (male, female)	0.032	-0.085, 0.024	0.366	0.044	-0.03, 0.118	0.239
Weight (< 100, 101–125, 126–150, and > 150 kg)	-0.037	-0.009, 0.008	0.425	-0.056	-0.155, 0.042	0.256
T2DM	0.017	-0.13, 0.056	0.533	0.016	-0.041, 0.073	0.572
BMI (kg/m ²)	-0.004	-0.037, 0.07	0.352	-0.004	-0.012, 0.004	0.263

T2DM type 2 diabetes mellitus, BMI body mass index, %TWL % total weight loss

Insulin and Oral Hypoglycemic Agent (OHA) Usage

Before the surgery, there were 10 patients (23.8%) who were on insulin treatment, 36 patients (85.7%) were on treatment with one or more OHAs, whereas 12 patients (28.5%) were on therapy with both insulin as well as OHA.

Post-surgery, there had been a reduction in the usage of OHA from 1.25 ± 0.7 in the preoperative period to 0.13 ± 0.1 at 5 years (*p* < 0.001). It was also noted that 10 patients, who took insulin during the preoperative period, had significantly reduced to only one patient using insulin at the 5-year follow-up (*p* < 0.001).

Multivariate regression analysis was done to analyze the postoperative remission rate of T2DM. Variables such as age, gender (male/female), preoperative HbA1c, preoperative BMI (kg/m²), duration of diabetes in years, usage of insulin, and OHA requirement were studied during preoperative settings. It was found that higher HbA1c levels corresponded to an inferior remission rate at 3 years (*p* = 0.05) Preoperative

BMI had a direct positive relationship with the T2DM remission rate at 1 year, with higher BMI leading to better remission rates (*p* = 0.02). It was also noted that the longer the duration of diabetes, the more inferior was the remission rate, and it was significant at 1-year follow-up (*p* = 0.04).

Patients who were on preoperative insulin usage had lower remission rate, which was statistically significant at the 3-year follow-up period (*p* = 0.04). Age and gender of the patient did not have any significant correlation over the remission rates of T2DM patients. Table 5 depicts six predictive factors taken into account for the remission of T2DM.

Lipid Profile

We observed a significant difference in all (cholesterol, TG, LDL, HDL, and VLDL) the lipid profile parameters between the preoperative and at the 5-year postoperative period (Table 6).

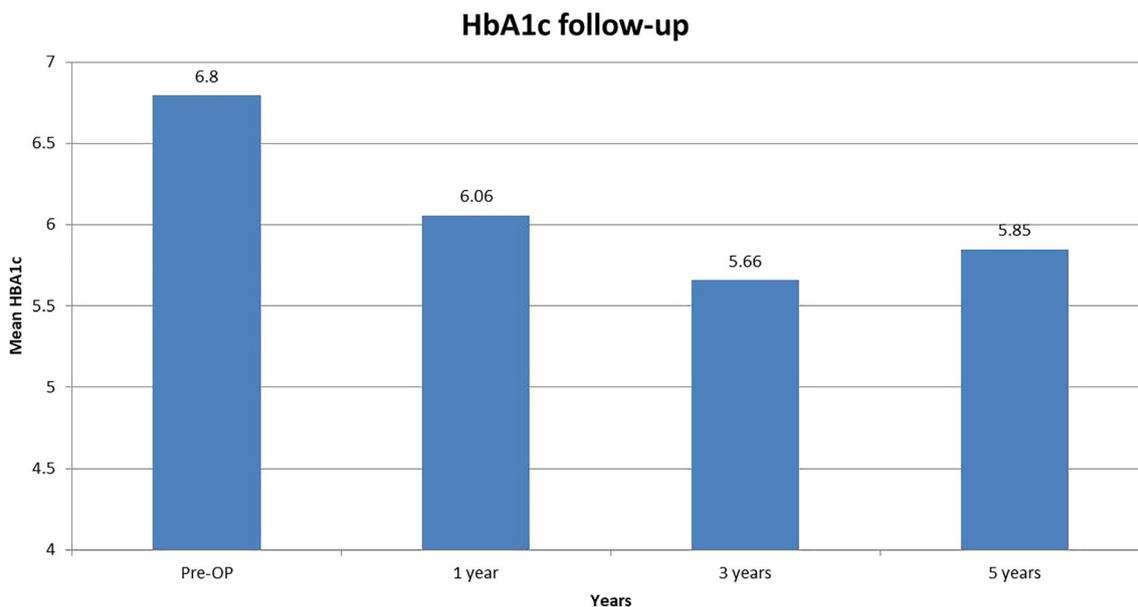


Fig. 5 Glycosylated hemoglobin (HbA1c) during 1-, 3-, and 5-year follow-up

Table 4 Remission and improvement rates at 1, 3, and 5 years of follow-up

LSG	Remission		Improved	
	n	%	n	%
One year	33	78.5%	9	21.4%
Three years	30	71.4%	8	19.0%
Five years	28	66.6%	14	33.3%

Comorbidity Resolution

The preoperative prevalence of HT, T2DM, fatty liver, GSD, and OSA were 47.0%, 14.8%, 67.7%, 4.2%, and 50.7%, respectively, while post-surgery the prevalence of the above

Table 5 Predictors of resolution of type 2 diabetes mellitus (T2DM) in LSG patients

Factors	One year		Three years		Five years	
	Rem. %	p value	Rem. %	p value	Rem. %	p value
Age group						
30–40 years	66.70%	0.855	100.00%	0.461	83.30%	0.202
40–50 years	50.00%		70.00%		70.00%	
50–60 years	66.70%		66.70%		83.30%	
> 60 years	50.00%		66.70%		33.30%	
Gender						
Male	66.70%	0.311	83.30%	0.334	75.00%	0.388
Female	50.00%		68.80%		62.50%	
Pre-OP HbA1c						
< 7	83.30%	0.391	100.00%	0.050	66.70%	0.718
7–8	60.00%		70.00%		70.00%	
8–9	60.00%		100.00%		80.00%	
9–10	25.00%		25.00%		75.00%	
> 10	33.30%		66.70%		33.30%	
Pre-OP BMI						
< 35	0.00%	0.021	75.00%	0.739	75.00%	0.262
35–40	85.70%		85.70%		42.90%	
> 40	58.80%		70.60%		76.50%	
Duration of DM in years						
< 5	87.50%	0.049	100.00%	0.099	87.50%	0.440
5–10	28.60%		57.10%		71.40%	
10–15	71.40%		85.70%		57.10%	
> 15	33.30%		50.00%		50.00%	
Insulin Y/N						
Yes	28.60%	0.093	42.90%	0.043	57.10%	0.398
No	66.70%		85.70%		71.40%	
Pre-OP OHA Pre/Abs						
Required	54.20%	0.417	70.80%	0.292	66.70%	0.615
Not required	75.00%		100.00%		75.00%	

LSG laparoscopic sleeve gastrectomy, Rem remission, HbA1c glycosylated hemoglobin, BMI body mass index, DM diabetes mellitus, Y yes, N no, Pre present, Abs absent

comorbidities decreased to 28.0%, 5.2%, 6.8%, 19.5%, and 0%, respectively, with a significance of $p < 0.001$, $p < 0.001$, $p = 0.005$, and $p = 0.04$, respectively. The significance value of OSA could not be computed statistically (Fig. 6).

The overall comorbidity resolution after LSG decreased from 43.1% to 12.8% in the postoperative period.

Revisional Surgeries

There were 14 revisional surgeries performed during this period. We performed six revisional surgeries (two re-sleeve gastrectomies and four revisional RYGB) for weight regain. Two duodeno-jejunal bypasses (DJBs) and four single anastomosis duodeno-ileostomies (SADIs) had been performed for inadequate weight loss. For another case of gastro-bronchial fistula, we performed closure of the fistula followed by distal RYGB. There was also a case of benign esophageal peptic stricture as a consequence of reflux esophagitis post-LSG, for which we performed a preoperative pneumatic dilatation followed by revisional gastric bypass surgery.

Discussion

LSG is one of the most commonly performed bariatric surgical procedures performed worldwide [10, 11]. There have been many short- and mid-term studies present in the literature [29], but there are only a few long-term studies, especially from Asia. Differences exist between the western and Indian population [13–17]. Our long-term survey took into consideration all the factors related to bariatric surgical outcomes such as weight loss, weight loss predictors, remission/improvement of T2DM, its predictive factors, revisional surgeries, resolution of comorbidities, and complication rates.

Success for a weight loss surgery was usually defined as %TWL > 10% or %EWL > 50% [30]. In our study, we observed that %TWL were 31.3 ± 8.9 , 30.9 ± 9.3 , and $26.0 \pm 9.9\%$ at 1, 3, and 5 years, respectively, and %EWL were 76.3 ± 25.5 , 73.12 ± 26.0 , and $62.47 \pm 25.8\%$, respectively. Our results were in concordance to various studies done previously concerning weight loss after LSG [4–7, 31]. Boza et al. and Diamantis et al. showed a similar %EWL at 5 years (62.9% and 62.3%, respectively) [5, 31]. According to Reinhold's criteria [30, 32], percentages of patients with %EWL < 50% were 24 patients (9.6%) at 1 year, 12 patients (6.1%) at 3 years, and lastly gradually increased to 62 patients (41.3%) at 5 years. Hypothesizing that patients lost to follow-up could be secondary to poorer outcomes, it could be highly likely that the percentages of patients with < 50% EWL could even be higher than noted. Hence, strict selection criteria and better follow-up processes need to be built when LSG is contemplated. A similar failure rate of 30.4% at 5 years was observed in a study published by Sepulveda et al. and also

Table 6 Mean cholesterol, triglyceride, LDL, HDL, and VLDL profile over 5 years

	Pre Op	1 year	3 years	5 years	p value (5-0)
Cholesterol	182.9 ± 38.6	168.1 ± 38.8	178.6 ± 50.5	176.2 ± 46.2	0.028
Triglyceride	126.8 ± 59.2	96.3 ± 37.9	94.5 ± 45.3	101.4 ± 43.9	<0.001
LDL profile	119.1 ± 34.6	109.9 ± 33.9	113.4 ± 47.01	113.1 ± 38.4	0.021
HDL	42.08 ± 10.2	46.3 ± 13.5	52.9 ± 12.7	52.09 ± 12.7	0.001
VLDL	25.4 ± 12.06	19.8 ± 7.02	17.7 ± 5.8	20.9 ± 9.4	<0.001

LDL low-density lipoprotein, HDL high-density lipoprotein, VLDL very low-density lipoprotein

identical results were found in a survey done by Garg et al. [6, 7]. Weight regain post-LSG like any other bariatric surgery is a known fact [30, 33]. Weight regain could be due to various factors. It may be due to primary or secondary failure of the surgery. Primary failure is where fundus (> 250 ml) of the stomach during the index surgery was left behind. Secondary failure was seen when the stomach gradually increased in size over time, which led to an increase in appetite and therefore increase in weight. Secondary failure was seen when the stomach gradually increased in size over time, possibly due to the patient’s eating habits or due to upstream dilatation caused by narrowing at the level of incisura, which led to increased appetite and subsequent increase in weight [34].

Increase in weight post-LSG could also be due to the intake of high calorific diet, decreased physical activity, and inappropriate dietary patterns as people in the Indian subcontinent have a preponderance of high carbohydrate and lower protein intake compared to the European or American population [34–38]. In our series, weight regain occurred at the end of 3 years; 50 patients (17.6%) regained 4.1 ± 2.5 kg, whereas at

the end of 5 years, 111 patients (39.1%) had weight regain of 6.4 ± 7.6 kg, respectively. Our results were in comparison to the study done by Noel et al., who had shown weight regain of 41.7% in the long-term follow-up [34]. Another survey by Saliba et al. showed that post-LSG, the weight regain ranged from 5.7% at 2 years to 75.6% at 6 years [36]. One of the definitions of significant weight regain was an increase in weight by greater than 10 kg from the nadir weight [39]. In our study, we noticed that significant weight regain was noted in 5 patients (1.7%) at the end of 3 years, while at the end of 5 years, 36 patients (12.6%) had significant weight regain. This correlated with the study by Bohdjalian et al., whose study had a considerable significant weight regain of 19.2% at the end of 5 years [35].

For a better patient selection and a better understanding of the post-surgical weight loss outcomes, we should have a better preoperative knowledge of the predictive factors that influence the latter. Hence, we had done a multivariate regression analysis using preoperative age, sex, weight, BMI, presence or absence of T2DM, and their effect on postoperative %TWL, and we found that there were no predictive factors

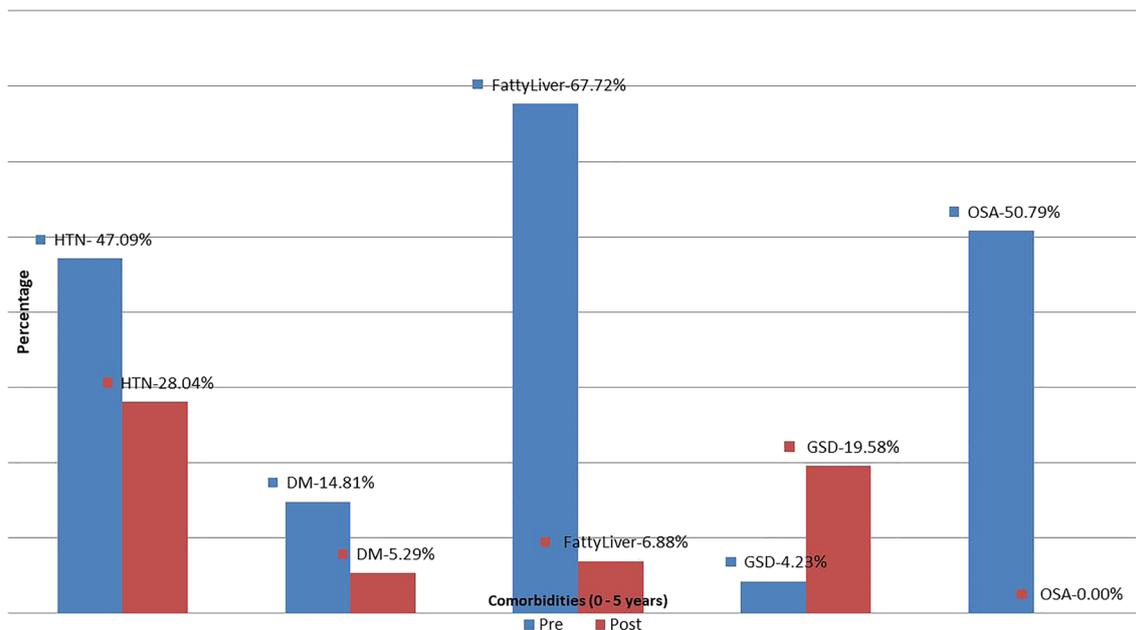


Fig. 6 Long-term (5 years) resolution of comorbidities

which had effects on the same. Many other authors had reported similar outcomes. A meta-analysis by Masha et al. showed that the only predictive factor which affects postoperative weight loss was preoperative weight loss [40]. However, we could not take the above consideration in our study.

Although LSG is a restrictive procedure, studies have shown that improvement of T2DM post-LSG could be compared to results of T2DM remission in cases of gastric bypass procedures [41, 42]. The meta-analysis by Cho et al. showed that LSG had similar outcomes of T2DM remission when compared to RYGB [43]. In our study, we found that diabetes remission and improvement at 1, 3, and 5 years were 78.5%, 71.4%, and 66.6% and 21.4%, 19%, and 33.3%, respectively. Many hypotheses explained the improvement of diabetes remission after LSG. It might be due to an increase in B-cell function or an increase in the levels of incretins. Another rationale could be due to the sharp reduction of calorie intake, which aided in the improvement of glycemic index as suggested by Lingvay et al. and Laferriere et al. [44, 45]. There were various other studies which also supported the evidence of diabetes remission and improvement rates post-LSG [9, 42, 46, 47].

Preoperative profile of the patient could help predict the diabetic outcome of the patients. After conducting multivariate regression analysis, we found that high preoperative HbA1c had a more unsatisfactory outcome in diabetes remission at 3 years ($p = 0.05$). Poor remission might be due to chronic hyperglycemia, which could have led to pancreatic beta-cell toxicity, apoptosis, and subsequent B-cell reduction as showed by Praveen et al. and Robertson et al. [48, 49]. The longer the duration of diabetes, the more inferior was the diabetes remission rate at 1 year ($p = 0.04$). Imperfect remission could be due to decreased B-cell function at the baseline with increasing duration of diabetes, as shown by English et al. [50]. Usage of preoperative insulin too had an inverse relationship with the remission of diabetes at 3 years ($p = 0.04$). In our study, it was also shown that higher BMI led to a better remission in postoperative T2DM ($p = 0.02$). Better remission in obese patients was probably due to a higher number of B cells in obese patients as compared to non-obese patients [49]. Age and gender of the patient had no significant predictive factor on diabetes remission. Various studies had supported the predictive factors for T2DM remission [9, 42, 46, 47, 51]. There was a substantial decrease in the postoperative usage of insulin and OHA usage ($p < 0.001$) which had also been seen in the study by Abelson et al. and Garg et al. [3, 7, 42].

There was also a significant resolution of other comorbidities like HT, fatty liver, OSA, and dyslipidemia after surgery. The overall preoperative and postoperative comorbidities were 43.1% and 12.8%, respectively. Various studies in the literature have supported improvement in HT, OSA, and dyslipidemia status post-surgery [1, 3–5, 7, 46, 52].

OSA was found in around 58% of moderate to severely obese patients [28]. Severe OSA with AHI (> 30 events/h) was associated with an increased incidence of stroke, cardiovascular diseases, and sudden death [53]. Weight loss following LSG led to an improvement in sleep-related symptomatic improvements, and improvement of OSA and its associated cardiovascular effects. Following LSG, 100% of our patients had an improvement in OSA, and C-PAP was not required postoperatively in any of the patients [28].

Non-alcoholic fatty liver disease (NAFLD) was common in obese patients. Up to 70% of the obese patients had NAFLD [54]. Post-bariatric surgery, there was a reduction in the liver volume and steatosis in 83.7% of the patients as shown in a study by Luo et al. [55]. Post-LSG, there was a significant improvement of patients affected with NAFLD. The results were supported by a randomized controlled trial (RCT) done by us in “NASHOST,” a registered prospective RCT, in which we performed a preoperative and postoperative liver biopsy in obese patients and compared histological changes in the preoperative and postoperative settings. We found a significant ($p = 0.005$) improvement in all of the histopathological components taken into consideration [54]. Other studies also supported our data, in which there was an improvement in the NAFLD score in the postoperative period when compared to the preoperative period [56].

There was an increase in the incidence of GSD post-LSG. Preoperatively, only 4.2% of the patients had GSD. Postoperatively, 19.5% of the patients developed GSD, mostly during the first year post-surgery ($p = 0.04$). A study by Hasan et al. showed the prevalence of GSD increased from 13.7% in the preoperative period to 27.5% in the post-LSG period [57]. Another study by Coupaye et al. concluded that maximum incidence of GSD post-LSG occurred during the first year post-surgery as this was the period of maximal weight loss, and frequency of cholecystectomy post-LSG was 28% [58]. A meta-analysis by Uy et al. highlighted the prophylactic use of ursodeoxycholic acid (UDCA) post-surgery, which reduced the incidence of GSD from 27.7% to 8.8% ($p = 0.01$) [59].

We had an overall complication rate of 5.2%, with early (< 30 days) complications being 4.5% and late (> 30 days) complications being 0.7%. Surgical intervention was required in 1.7% of the overall complications. Out of the complications requiring surgical intervention, two cases were of hemoperitoneum, one due to generalized ooze from the staple line and the other being a bleeder from spurting vessel at the staple line, both of which were managed by peritoneal lavage and control of the bleeder sites. There was one case of staple line leak 7 days post-LSG. On performing an oral contrast CT scan, the leak was from the proximal third part of the sleeve. We performed a revisional RYGB in the same scenario. Staple site leak mostly occurred from the proximal third of the sleeve due to the high-pressure zone and due to the ischemic changes which occurred in the proximal third of the remnant stomach

[60]. If untreated, the leak could lead to prolonged morbidity due to intra-abdominal collections, sepsis, and multi-organ failure. Conversion to RYGB, post-sleeve leaks should be contemplated and was feasible in the cases of inevitable drainage for surgical sepsis according to a series published by Saglam et al. [61]. In one of our studies, we had created an algorithm for the management of sleeve leaks. The study emphasized on the early conversions of sleeve leaks into bypass converting a high-pressure system to a low-pressure system [62]. Praveen Raj et al. had concluded the timely and early intervention in the case of sleeve leaks was required to prevent further inadvertent complications [62]. As mentioned and hypothesized previously, staple line leaks are most common from the proximal third of the sleeve. Hence, some form of reinforcement (over-sewing or buttressing) was advisable at the proximal side of the sleeved stomach [63]. Suture imbrication and omentopexy of the proximal third of the staple line was made as a part of our institutional protocol in all cases of LSG. We had encountered a case of gastro-bronchial fistula (GBF), for which suturing of the fistula site followed by a revisional RYGB was done, which served as a useful measure to reduce the GBF output and therefore helped in the healing of the fistula [64]. GBF post-LSG is a rare and a usually late complication post-LSG. The management of GBF was tailor based depending upon the condition of the patient, with initial attempts of conservative management with sequential dilatation if the state of the patient is stable, or surgical excision of the fistula tract and revisional RYGB [65]. Strictures post-LSG (0.1–3.9%) are most common at the incisura and body of the stomach [66]. We had a rare case of lower esophageal peptic stricture 5 years post-LSG for which endoscopic pneumatic dilatation followed by revisional RYGB was done, and the patient recovered subsequently. Pneumatic dilatation and revisional RYGB is the standard treatment for de novo GERD and its related complications like peptic stricture [67, 68].

Limitations

Primary limitations of our study were that this was a single-center, retrospective study. Patients had lost to follow-up over the period, which led to an overall weight regain with time. We had not used proper GERD-based questionnaires, 24-h pH studies, or manometric studies in the preoperative and postoperative settings to assess the overall effect of LSG over GERD symptoms and the development of de novo reflux. We also did not use an overall quality of life (QOL) score before and after surgery. Also, in our research, a few of the cardiovascular risk factors could not be reviewed and taken into consideration. Preoperative behavioral disorders, eating disorders, and psychological patterns on an individual basis were not taken into account. Preoperative weight loss, which served as an important predictive factor for postoperative weight loss, had also not been studied.

Conclusion

LSG provides adequate long-term weight loss, with promising results in remission and improvement in T2DM and also the resolution of other comorbidities like HT, OSA, and fatty liver disease. Careful selection of patients should be made to achieve the best results of weight loss and remission of T2DM. Meticulous follow-up of patients during the postoperative period could help in the reduction of failure rates. Comparison of other bariatric surgical procedures using case match analysis and RCTs should be made to establish the effects of LSG in the long term.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no competing interests.

Consent Consent had been attained from the patients before the surgery.

Ethical Clearance The institutional ethical committee had approved the study.

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