

TWO YEARS OUTCOME OF LAPAROSCOPIC SLEEVE GASTRECTOMY IN OBESE PATIENTS IN A GOVERNMENT HOSPITAL OF CENTRAL INDIA(2017-2019) WITH REVIEW OF LITERATURE

ABSTRACT

Background

Bariatric surgery is an established mode of weight loss which has metabolic effects in addition to weight loss. Laparoscopic sleeve gastrectomy is a restrictive procedure which entails creation of gastric sleeve laparoscopically by using laparoscopic staplers.

Materials and methods

The present study was carried out in the Department of Surgery in Government Medical College and Hospital on 50 patients admitted in different surgical wards from July 2017 to November 2019. They were evaluated for weight loss and co-morbidity resolution in addition to studying the clinical profile.

Objectives

To study the safety and effectiveness of the sleeve gastrectomy as a bariatric procedure

Results

The mean age of participants in this study is 38.8 years. The youngest participant is 18 years old. The oldest participant is 58 years old. The male to female sex ratio is 1:1.94. Out of 50 (22%) patients belonged to the middle class and remaining 39 out of 50 patients (78%) belonged to the lower socioeconomic scale according to 2019 revised Kuppuswamy scale. The lowest Body Mass Index (BMI) operated was 33 kg/m². The mean BMI operated was 38.81 kg/m². The most common group of patients belonged to the group of BMIs between 35-39.9kg/m². %EWL at 2 years is 81.83. Percentage of complete resolution of DM, HTN, OSA and hypothyroidism is 61.53%, 70.59%, 90% and 66.67%.

Conclusions

Laparoscopic sleeve gastrectomy is a safe and effective form of bariatric surgery with comparable weight-loss and co-morbidity resolution.

Keywords

Obesity, laparoscopic sleeve gastrectomy, bariatric surgery, co-morbidity resolution, hypertension, diabetes mellitus, obstructive sleep apnea.

INTRODUCTION

It is a known fact that obesity is a global epidemic.¹ Previously considered to be a disease of the affluent class, it is now seen in the developing countries like India- spread across all the strata of the society. Low cost of calorie rich food and upward social mobility are few important causes of rising obesity in India. According to Ahirwar et al², the prevalence of obesity in India has become 16.9%-36.3%. **The prevalence of diabetes in India is an alarming**³.

The rise of non-communicable diseases in India has seen a rise. Diseases like hypertension, diabetes mellitus, osteoarthritis have been directly linked to obesity. Hampered mobility and body image issues are often associated with obesity.³ Many individuals have

difficulty in leading their normal sex life in the form of erectile dysfunction and loss of libido. Bariatric surgery has proven to be an effective treatment against obesity related comorbidities achieving high rate of remission in disease such as type 2 DM^{4,5} or hypertension^{6,7} among others.

Brief history of Laparoscopic sleeve gastrectomy

Laparoscopic sleeve gastrectomy (LSG) was introduced initially as a first stage of the biliopancreatic diversion with duodenal switch (BPDDS) for severely obese patients.⁸ Due to its greater efficiency and low complication rate LSG has become more widely accepted as a definitive treatment for morbidly obese patients.⁹ In LSG stomach is divided vertically, while removing complete fundus of the stomach and preserving the continuity of digestive tract.¹⁰

METHODS

The study was carried out in the Department of Surgery in a Government Medical college and hospital on patients admitted in different surgical wards from July 2017 to November 2019. Approval from the institutional ethics committee was obtained. 50 patients were admitted and were between 18 and 60 years of age with BMI >32.5 kg/m² with 2 or more comorbidities or >35 kg/m² without comorbidities who understood the risks and benefits of Laparoscopic sleeve gastrectomy. (International Federation for the surgery of Obesity: Asia-Pacific Chapter (IFSO-APC: 2011))¹¹

After collection of basic information of the patients, physical examination was done and were subjected to haematological and biochemical lab investigations, along with pulmonary function test, sleep study and 2D echo.

Technique of laparoscopic sleeve gastrectomy.

Laparoscopic sleeve gastrectomy (LSG) was performed in all cases. Procedures were performed in dedicated bariatric operating rooms fitted with appropriate equipment. The patient is placed in a split leg position over a dedicated bariatric table with capacity to accommodate a patient up to 350kg. Surgery is performed in a steep reverse Trendelenburg position. Usually 4 ports were used. Pneumoperitoneum is created using Veress needle through the Palmer's point. The first 12mm optical trocar is inserted under guidance with a 0degree laparoscope. In somecases in which Liver was small 3 ports were used.

The surgery begins by the division of the gastrocolicomentum 4-6 cm proximal to pylorus to preserve the pyloric function and proceeds up to the angle of His completely freeing the greater curvature. The short gastric vessels are identified and divided. Dissection is performed up to the left crus of the hiatus by dedicated 45cm long bariatric laparoscopic instruments and all attachments are released to completely mobilize the fundus posteriorly.

The gastric sleeve is created using sequential firings of a 60-mm linear Endo GI stapling device. The staplers are applied alongside a 40-Fr calibrating tube positioned against the lesser curve so as to avoid stenosis and to obtain a narrow gastric tube. The calibration tube is withdrawn, and a leak test is performed using intraoperative methylene blue dye occluding the pylorus. Haemostasis is ensured in cases of staple line bleeding by vascular clips or by burying the stapler line with barbed suture of dyed polydioxanone 2-0. A simultaneous cholecystectomy and incisional hernia repair are performed in patients with a preoperative diagnosis of gallstones and ventral hernia. Abdominal drain (24 Fr) is placed selectively, and port sites are closed. All port sites were infiltrated with 0.5 % Bupivacaine, just before closure of port sites.

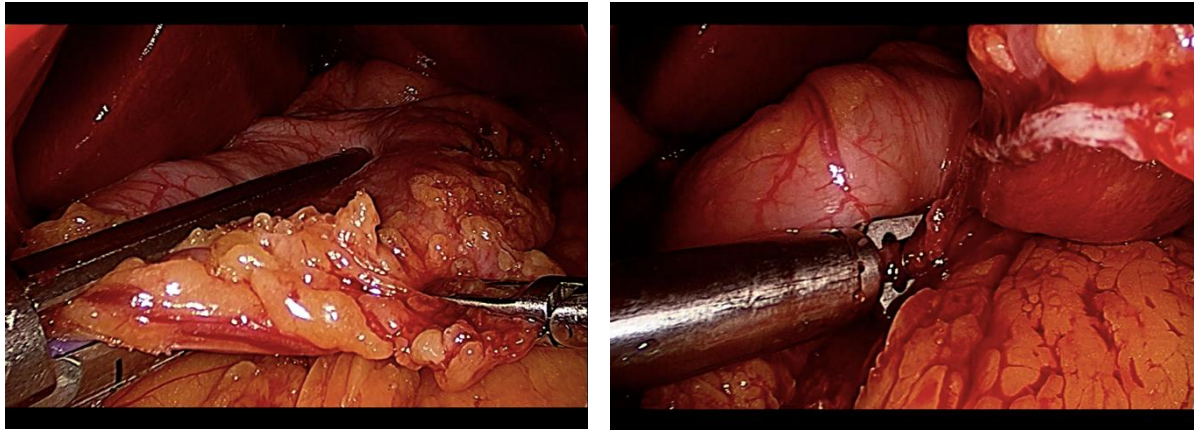


Image 1: Creation of gastric sleeve.

Postoperative management

Patients are monitored overnight in the surgical ICU. Ambulation is performed within 4 to 8 hours after surgery and chest physiotherapy is started in the immediate postoperative period. Clear liquids are started after 24 hours. The patient is discharged once oral intake of 1500–2000 ml/24 h is established. A liquid diet is given for 1 week, a pureed/soft diet for next 3 weeks, and normal diet of restricted, high protein low sugar, low fat diet after 1 month. Dietary counselling is provided and a normal consistency, low-calorie, high-protein diet is advised at 2 months from surgery. Patients are followed up at 3, 6, 12, 18 and 24th post-operative months. Patient will be followed up in surgical OPD during post-operative period and thereafter up to 2 years as per the needs of the patients and the weight, BP, thyroid function test, HbA1c and assessment of Obstructive Sleep apnoea done.

RESULTS

This is a prospective interventional study carried out in 50 patients of obesity. This study is designed to assess clinical profile of the patients like age, sex, co-morbidities, socio-economic status and resolution of weight and co-morbidities over a period of 2 years and to study the complications associated with laparoscopic sleeve gastrectomy.

The mean age of participants in this study is 38.8 years. The youngest participant is 18 years old. The oldest participant is 58 years old. The most common age group of patients belonged to that between 41-50 years which was 22 out of 50 (44%). The least common age group of patients was between 18 and 20 years of age which was 3 out of 50 (6%).

The participants between age group of 61-65 are placed upto 65 as the age limit was chosen as per the according to International Federation for the surgery of Obesity: Asia-Pacific Chapter (IFSO-APC: 2011)¹¹

17 patients were males and 33 patients were females. The sex ratio was 1:1.94. None of the patients belonged to the upper class, 11 out of 50 (22%) patients belonged to the middle class and remaining 39 out of 50 patients (78%) belonged to the lower socioeconomic scale according to 2019 revised Kuppuswamy scale.¹²

The lowest Body Mass Index (BMI) operated was 33 kg/m². The lowest BMI in males was 33 kg/m². The lowest BMI in females was 33.2 kg/m². The highest BMI operated was 55.5 kg/m². (as per OSSI Guidelines ²⁶)

^BMI RANGE	MALE	FEMALE	TOTAL	PERCENTAGE
32.5-34.9 Obese Class I	2	3	5	10%
35-39.9 Obese Class II	11	22	33	66%
40-49.9 Obese Class III	3	7	10	20%
50-60 Super Obese	1	1	2	4%

Table 1: BMI distribution of the participants.

The clinical definition of hypertension is Blood Pressure of >140/90mmHg.⁵The clinical definition of diabetes mellitus is Fasting Blood Glucose level of >126mg% or HbA1C of >7%.⁵The clinical definition of Hypothyroidism is when patient is on oral thyroxine or has elevated Thyroid stimulating hormone.⁵Clinically Obstructive Sleep Apnea (OSA) is defined by the occurrence of daytime sleepiness, loud snoring, witnessed breathing interruptions, or awakenings due to gasping or choking in the presence of at least 5 obstructive respiratory events(apneas, hypopnea or respiratory associated arousals) per hour of sleep.⁵

The incidence of diabetes among the study participants was 13(26%), out of which 5(10%) were males and 8(16%) were females.The incidence of hypertension among the study participants was 17(34%), out of which 7(14%) were males and 10(20%) were females.The incidence of hypothyroidism among the study participants was 6(12%), out of which 0(0%) were males and 6(12%) were females.The incidence of Obstructive Sleep Apnea among the study participants was 15(30%), out of which 10(20%) were males and 5(10%) were females.

	TOTAL NO OF PATIENTS	PERCENTAGE
DIABETES MELLITUS	13	26%
HYPERTENSION	17	34%
OBSTRUCTIVE SLEEP APNEA	15	30%
HYPOTHYROIDISM	6	12%

Table 2: Incidence of comorbidities

Out of the 13 diabetic patients, 8 (61.53%)patients had complete remission of Diabetes mellitus and 2 patients (15.38%) of them had partial remission and remaining 3 patients(23.07%) had improvement in their Diabetes mellitus. Out of the 17 hypertensive

patients, 15 (88.23%) patients had complete remission of hypertension and 1 patient (5.88%) of them had partial remission and remaining 1 patient (5.88%) had improvement in their hypertension. Out of the 6 hypothyroid patients, 4 (66.6%) patients had complete remission of hypothyroidism and 2 patients (33.3%) of them had partial remission. Out of the 20 OSAS patients, 15 (75%) patients had complete remission of OSAS and 5 patients (25%) of them had partial remission.

Comorbidity resolution was achieved as follows-

	INCIDENCE	COMPLETE RESOLUTION	PARTIAL RESOLUTION
DIABETES MELLITUS	13	8(61.53%)	2(15.58%)
HYPERTENSION	17	12(70.59%)	3(17.64%)
OBSTRUCTED SLEEP APNEA	20	18(90%)	2(10%)
HYPOTHYROIDISM	6	4(66.67%)	2(33.33%)

Table 3: Table showing resolution of co-morbidities.

The percentage of patients followed up at the following intervals along with the weight loss in 2 years is as follows-

	3 months	6 months	12 months	24 months
Percentage of follow-up	100	72	56	20
Percentage excess weight loss	59.34	72.62	78.55	81.83

Table 4: Follow-up percentage with percentage excess weight loss.

In the present study of 50 patients of morbid obesity who underwent laparoscopic sleeve gastrectomy, who also had other diseases for e.g. cholelithiasis and paraumbilical hernia, additional procedures for these diseases were performed in the same setting. In 6 patients, after proper counselling of the patients that due to the changing dynamics of the patients

abdominal wall after weight loss surgery, hernia might recur. Hence, anatomical closure of the rectus by transfascial suturing by prolene no. 1 was done.

In 2 patients of morbid obesity with associated Cholelithiasis, laparoscopic cholecystectomy was performed in the same anaesthesia. Both these procedures were done uneventfully.

Partial weight regain was seen in this study in 1 patient (2%), who initially lost 30 kg in the first 8 months, thereafter this patient started gaining weight and at the end gained 10 kgs. His nutritional evaluation and dietary counselling was done. Again he gained 2 kgs. The cause for this was evaluated by performing an upper gastrointestinal endoscopy which revealed that the fundus was retained partially and had dilated in due course and was present in the sleeve created.

1 patient (2%) developed a suture line leak on day 2. This case was encountered in the initial few cases, where in the creation of sleeve was difficult. A 24 Fr Drain was kept next to the staple line. Patient was kept nil by mouth for 24 hours. Thereafter on day 2, a contrast study revealed a leak in the staple line. A Gastroenterologist opinion was sought and a Megastent was introduced endoscopically in this patient and managed conservatively. Patient had an episode of hematemesis due to the mucosal erosion of oesophagus that was managed conservatively with proton pump inhibitors. This case also had severe regurgitation that was conservatively managed by prokinetics. The patients megastent was in situ for 3 weeks after which a contrast study was done and the staple line had healed and Megastent was removed.

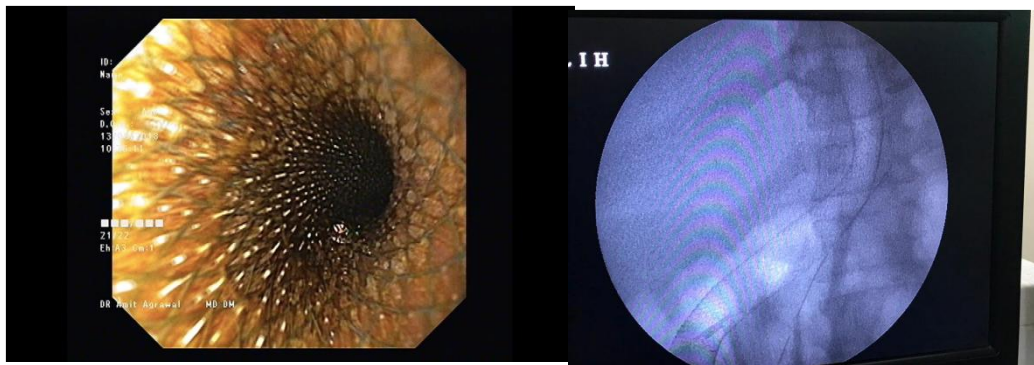


Image 2: Megastent introduction endoscopically under fluoroscopic guidance.

Minor complications encountered during this study were minor wound infections observed in 2 patients (4%) treated conservatively by local wound care and post-operative nausea vomiting treated conservatively with proton pump inhibitors and prokinetics.

Sr no	Complications	No of patients	Percentage
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1	Overall mortality rate	0	0%
2	Overall complication rate	2	4%
3	Sleeve leak	1	2%
4	Partial weight regain	1	2%
5	Venous thromboembolism/ pulmonary embolism	0	0%
6	Major Hemorrhage	0	0%
7	Port site hernia	0	0%
8	Marginal ulcers	0	0%
9	Stricture/stenosis	0	0%

Table 5. Post-Operative Complications in laparoscopic sleeve gastrectomy.

DISCUSSION

In this study we present a prospective interventional study of effect of laparoscopic sleeve gastrectomy in 50 patients of obesity in a tertiary center of Government medical college. We report to you our initial experience which has had a learning curve.

In our study the mean age was 38.8 years which is comparable to *Prasad et al¹⁴*, *Kikkas et al¹⁵* and *Radu Neagoe et al¹⁶*. Despite extensive research, we could not find any mention of study of socio-economic group of the participants. Our institute being a government run hospital, usually has intake of patients belonging to the poor socio-economic strata. These patients when offered weight loss surgery do accept it and follow-up with the bariatric team after the surgery. 78% of the participants in our study belonged to the lower socio-economic strata.

The study of the co-morbidities, weight loss, comorbidity resolution was comparable to the other international studies. (*Radu Neagoe et al¹⁶*, *Ismail et al¹⁷*, *Kikkas et al¹⁵* and *Dakour et al¹⁸*) proving that there is very little difference, if any, between patients' parameters studied in literature.

We have found that this procedure is safe, having low morbidity and no mortality in our study. Our study reports no mortality, although this number could increase as the mean BMI of the sample studied increases or with presence of multiple comorbidities. Morbidity of this study was low with minor complications seen in 4% patients which was easily managed by non-operative measures.

The procedure of laparoscopic sleeve gastrectomy used in this study has been in accordance with the standard procedure stated in the literature, although modifications have been made in some cases in which instead of 4 ports, only 3 ports were utilized without any significant difference noted in duration or difficulty of the procedure.

In the literature, there are many references of reinforcement of the staple line and its role in reducing staple line hemorrhage and incidence of post-operative leak rates. This was not a part of this study, although in some patients with intra-operative staple line bleed, reinforcement sutures with barbed Polydioxanone material were taken in continuous fashion. In some patients, hemostatic clips or glue was applied at the localized site of hemorrhage.

In a few patients who also had other conditions for which operative interventions was needed, necessary associated operations were performed in these individuals. In 2 patients, laparoscopic cholecystectomy was performed with LSG and in 6 individuals, after explaining the risk of recurrence, primary closure of umbilical hernia was performed by transfascial sutures of polypropylene no 1. This has increased the duration of some procedures. *Hirth et al*¹⁹ in their study of laparoscopic sleeve gastrectomy 1 patient developed partial gastric obstruction at the incisura angularis and 1 patient had subacute leak. *Dakour et al*¹⁸ had a long-term complication in the form of hiatal hernia (1.4%), incisional hernia (2.7%), symptomatic gall stones (9.6%) and depression (4.1%) in their study.

*Hoyuela et al*²⁰ in their study. A leakage in the staple-line was detected in 2 women (1.2%). The total 30-day postoperative complication rate was 5.1%. A leakage in the staple-line was detected in 2 women (1.2%). The first woman (after oversewing the staple line) healed successfully with medical management 14 days after. The second required a laparoscopic reoperation to drain a subphrenic abscess secondary to a leak at the angle of His. No endoprosthesis or self-expanded wall stent was needed. Regarding late complications, one patient developed a gastric stricture 10 months after the LSG and submitted to a laparoscopic gastric bypass (0.6%). To date, three patients (1.9%) have developed a trocar-site hernia. Cholecystectomy due to symptomatic gallstones was performed during the follow-up in 7 patients (4.4%).

*Radu Neagoe et al*¹⁶ in their study had 1 mortality (0.005%), minor intra op complications in the form of staple line bleeding which was locally controlled. They had post-operative complications in the form of post-operative hemorrhage which required laparoscopic intervention. 1 patient had proximal leak which was treated by performing a feeding jejunostomy and the fistula was closed endoscopically after 4 months of surgery. After surgery, 33 patients (18.4%) developed weight gain which required other interventions.

50 obese patients in our study have been observed for a period of 2 years post procedure. More comorbidities and effect over nutrition can be studied in the participants. Further studies are required involving a larger sample size with studies over a more prolonged period of time to study the long-term effects of LSG and the need of revision procedures.

Study	Mean Age in yrs	Mean BMI (kg/m ²)	% Males	Percentage incidence of comorbidities	Percentage of complete comorbidity resolution	%EWL
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				HTN	DM	OSA	Hypothy	HTN	DM	OSA	hypothy	3m	6m	12m	24m
<i>Moon han et al²¹ (2005)</i>	-	-	-	-	-	-	-	100	92.9	-	-	-	71.6	83.30	-
<i>Prasad p et al¹⁴ (2012)</i>	39.3	44.5	-	-	-	-	-	85.7	83.3	-	-	-	-	67.5	71.1
<i>Boza et al²² (2014)</i>	-	-	-	-	-	-	-	-	84.7	-	-	-	-	-	--
<i>Diamantes et al²³ (2014)</i>	45	49.2	-	-	-	-	-	-	-	-	-	-	-	-	-
<i>Hirth et al¹⁹ (2015)</i>	49	43.5	-	-	-	-	-	-	-	-	-	-	-	-	-
<i>Dakour et al¹⁸ (2016)</i>	-	49.2	-	-	-	-	-	68	87.5	-	-	-	-	-	-
<i>Radu Neagoe et al¹⁶ (2019)</i>	40.47	42.92	24%	22.9	47.4	24.5	-	65.8	65.8	70.4	-	41.8	64.1	75.33	76.0
<i>Kikkas et al¹⁵ (2019)</i>	42.1	46.5	16.3	57%	18.6	15.1	-	32.7	68.8	61.5	-	44.3	75.8	-	-
<i>Misra et al²⁴ (2019)</i>	-	44.9	-	-	14.8	-	-	-	66.6	-	-	-	-	-	-
<i>Nasta et al²⁵ (2019)</i>	-	45.8	-	-	-	-	-	-	44	-	-	-	-	87.6	-
<i>Ismail Met al¹⁷ (2019)</i>	33.7	40.2	-	-	-	-	-	-	-	-	-	-	-	-	-
<i>-Present study</i>	38.8	38.8 kg/m ²		34	26	30	12	61.5	61.5	80	66.6	59.3	72.6	78.5	81.8

Table 6: Table showing comparison of studies between age, male percentage, mean Body Mass Index, incidence of comorbidities, comorbidity resolution and percentage excess weight loss over a period of time.(BMI-mean Body Mass Index, HTN- hypertension, DM- Diabetes Mellitus, OSA- obstructive sleep apnea,Hypothyroidism, %EWL- percentage excess weight loss)

CONCLUSION

In conclusion our study shows that LSG is very good bariatric procedure with excellent results on short term follow up regarding body weight reduction, BMI and co-morbidities. The short-term follow-up period after the operation and the relatively low no. of patients included in the study were potential limitations of our study. These results were consistent with the results of other national and international study. However, results are comparable to other recently published studies.

Ethical Approval:

As per international standard or university standards written ethical approval has been collected and preserved by the author(s).

Consent

As per international standards or university standards, patient(s) written consent has been collected and preserved by the author(s).

Drawback- Further long-term studies mandatory to be better determine the benefits/risk balance after after this bariatric procedure.

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