

Prospective Study to Compare the Efficacy and Safety of Gastric Banding (LAGB) and Sleeve Gastrectomy (LSG) in Obese

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Abstract

Background: Obesity is abnormal or excessive accumulation of fat in the body which may impair health. Body mass index (BMI) is a simple index that is used to classify obesity in adult population. BMI is calculated by following method $BMI = \text{weight in kg} / \text{height in meters}^2$. Obesity is defined as $BMI > 30 \text{ kg/m}^2$. Morbid obesity is defined as a $BMI > 35 \text{ kg/m}^2$ with associated co morbid conditions or a $BMI > 40 \text{ kg/m}^2$. A $BMI > 25 \text{ kg/m}^2$ is defined as overweight. The present study has been designed to evaluate the surgical outcomes in terms of weight loss and resolution of co-morbidities in two different bariatric surgical procedures, namely laparoscopic adjustable gastric banding (LAGB) and laparoscopic sleeve gastrectomy (LSG). **Method:** The prospective, interventional comparative study was conducted in the at Maulana Azad Medical College and Associated hospitals, New Delhi. Study includes 50 Motivated patients knowledgeable about the sequel of the procedure, age between 18 and 65 years, attending the surgical out-patients department with $BMI > 33 \text{ kg/m}^2$ with significant obesity-related co morbidities. Patients divided into Group A and Group B, each group comprising of 25 patients each. Group A comprising of 25 patients treated with LAGB. Group B comprising of 25 patients treated with LSG. All the patients were followed up at 6 month, 9 month and 12 months period for evaluation of excess weight loss,

resolution of co-morbid conditions and for any late complications. **Results:** Mean duration of surgery was more in group B (148 min) as compared to group A (108 min). Mean value of percentage of excess body weight loss (EWL) was more in LSG (53.761 %) than in LAGB group (40.842) with the significant difference of p value of 0.05. Mean value of change in BMI was also seen to be more in LSG group with p value 0.001 (< 0.05). Resolution of hypertension was more in LSG group (98%) as compared to LAGB Group (87.5%). Resolution of DM type 2 was also more in LSG group (92%) as compared to LAGB group (80%). **Conclusion:** With our experience, we are of the opinion that sleeve gastrectomy (LSG) seems to be the preferred procedure in Indian population due to better post operative excess weight loss (EWL) and resolution of co-morbidities.

Keywords: LABG; LSG; Resolution of Comorbidities; Excess Weight Loss.

Introduction

Obesity is abnormal or excessive accumulation of fat in the body which may impair health. Body mass index (BMI) is a simple index that is used to classify obesity in adult population. BMI is calculated by following method $BMI = \text{weight in kg} / \text{height in meters}^2$. Obesity is defined as $BMI > 30 \text{ kg/m}^2$. Morbid obesity is defined as a $BMI > 35 \text{ kg/m}^2$ with associated co morbid conditions or a $BMI > 40 \text{ kg/m}^2$. A $BMI > 25 \text{ kg/m}^2$ is defined as overweight.

Overweight and obesity are the fifth leading risk for global deaths [1]. Atleast 2.8 million adults die each year as a result of being overweight or obese, 44% of diabetes burden, 23% of ischemic heart disease

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burden and 7% to 41% of cancer burden is attributable to overweight and obesity [1]. Obesity has reached epidemic proportions in India in 21st century, with morbid obesity affecting 5% of the population [2]. In Indian population, a cross sectional study at Pune showed, prevalence of obesity was 43% in adult population with statistically significant association between BMI>25 and diabetes and hypertension [3]. Indians are genetically susceptible to weight accumulation especially around waist, and now unhealthy processed food has become much more accessible following India's increasing integration in global food markets [3]. Obesity has reached epidemic proportions in India [3]. The health consequences of obesity range from increased risk of premature death to serious chronic illness like hypertension and diabetes which reduce the overall quality of life [3]. Obesity involves a complex interaction of metabolic, genetic, psychological and social issues and has become the second leading cause of preventable death in the developed countries after smoking [2]. Trends in the prevalence of malnutrition in female population between National Family Health Survey (NFHS-2) and NFHS-3 show a slight decrease from 36% to 33% in the population who were too thin in contrast to the increase in the percentage of overweight or obese population from 11% to 15% [4]. More than one quarter of female population in Punjab, Kerala and Delhi are overweight or obese. Tamil Nadu and Goa also have a high prevalence of overweight and obesity (more than 20%). Obesity (BMI>30) is highest in Punjab (9%) and Delhi (8%) [4].

Treatment of obesity consists of various dietary modifications, behavioural modifications, changes in lifestyle, medical therapy and surgical treatment [5,6,7]. Data suggest that non surgical treatments for weight loss are ineffective and that bariatric surgery is the most sustainable and effective treatment for weight loss, improve comorbidities, and prolong survival in the morbidly obese [8-17].

There has been a substantial progress in the study of obesity and in the development of laparoscopic techniques of bariatric surgery. Our experience at Artemis Hospital, Maulana Azad Medical College showed that a large number of patients coming for various surgical procedures, and patients attending medical and surgical outdoor for associated comorbid conditions, fall in the category of morbidly obese. The present study has been designed to evaluate the surgical outcomes in terms of weight loss and resolution of co-morbidities in two different bariatric surgical procedures, namely laparoscopic adjustable gastric banding and sleeve gastrectomy

Materials and Methods

The prospective, interventional comparative study was conducted in the Department of Surgery, Maulana Azad Medical College and Associated hospitals, New Delhi. Study includes 50 Motivated patients knowledgeable about the sequel of the procedure, Age between 18 and 65 years, attending the surgical out-patients department with BMI > 33 kg/m² with significant obesity-related co morbidities. The Co-morbid conditions included for the present study are type 2 Diabetes Mellitus, latent Diabetes Mellitus (detected by glucose tolerance test), hypertension, dyslipidemia, atherosclerotic heart disease, sleep apnea syndrome, Gastro-oesophageal reflux disease. Patients divided into Group A and Group B, each group comprising of 25 patients each. Group A comprising of 25 patients treated with LAGB. Group B comprising of 25 patients treated with LSG. All the patients were followed up at 6 month, 9 month and 12 months period for evaluation of excess weight loss, vomiting, abdominal fullness, patient satisfaction, resolution of co-morbid conditions and for any late complications. Postoperative evaluation: Immediate post operative complications, post operative pain based on visual analogue score, Time to return to routine daily activity (TADL), Time to return to work (TRTW), Time of discharge. The data has been expressed by mean and standard deviation. Mean values of pre-operative weight, pre-operative BMI, pre-operative waist to hip ratio has been compared with their respective post-operative values. Percentage of excess body weight loss also evaluated. Comparison was made between the pre operative and post operative parameters in the same group and between the two groups, namely group A and group B. The significant difference between the two means for paired value has been observed by Wilcoxon signed rank test (nonparametric). Qualitative non-parametric data; pre-operative hypertension status has been compared with postoperative hypertension status. The significant difference between the two has been computed using the binomial McNemar test. P value less than 0.05 has been taken as significant (S), <0.01 as highly significant (HS) and values <0.001 as very highly significant (VHS)

Results

Comparison of excess body weight loss between group A and group B:

Mean value of percentage of excess body weight loss was more in LSG (53.761 %) than in LAGB group

(40.842 %) with a p value 0.05.

Mean value of change in BMI was also seen to be more in LSG group, p value 0.001 (<0.05).

Waist Hip Ratio

Waist hip ratio, pre operative values (mean 1.06) and post operative values (mean 1.03) were significant in group A p value 0.014 (<0.05), similarly values were significant in group B, pre operative mean value 1.06, post operative mean 1.02 with p value 0.001

(<0.05). Comparison between group A and group B was found to be significant p value 0.001

Comparison between Group A and Group B

Mean values of percentage of excess weight loss is 40.842 % for group A and 53.761% for group B. the difference is significant with a p value of 0.05 (table 1). Change in mean values in BMI was also significant with a p value of 0.001 (<0.05). -Change in mean values of waist hip ratio was also significant in two groups with a p value of 0.001.

Table 1: Comparison of weight loss between group A and group B

| | Mean Pre operative wt | Mean Post operative wt | Mean % of excess wt loss |
|----------------|-----------------------|------------------------|--------------------------|
| Group A (LAGB) | 106.4 | 87.30 | 40.842 % |
| Group B (LSG) | 116.03 | 82.80 | 53.761 % |

Resolution of hypertension was more in group B (LSG) about 98%, resolution of diabetes was also found to be more 92% in group B (LSG). Average time for resolution of hypertension was seen to be more in LSG group. Mean values of percentage of excess weight loss is 40.842 % for group A and 53.761% for group B. the difference is significant with a p value of 0.05. Change in mean values of pre operative and post operative BMI was also significantly more in

group B, with a p value of 0.001. Change in mean values of waist hip ratio was also significant in two groups with a p value of 0.001. Mean duration of surgery was more in group B (148 min) as compared to group A (108 min). No post operative complication was seen in group B patients, while in group A, two patients had port site infection. Both these patients belonged to low socioeconomic strata and had poor compliance and hygiene.

Table 2: Comparison of resolution of co-morbidities between group A and group B

| | Resolution of Hypertension | Resolution of DM type 2 |
|----------------|----------------------------|-------------------------|
| Group A (LAGB) | 87.5% | 80% |
| Group B (LSG) | 98% | 92% |

Conclusion

Specific Conclusions

Intra Operative Parameters

- Duration of surgery:** Mean duration of surgery in group A (LAGB) was 108 minutes (range 90-130 minutes). Mean duration of surgery in group B (LSG) was 148 minutes (90-240 minutes). Difference was not significant (p value 0.472) but LAGB was a relatively shorter duration surgery.
- Intra operative complications:** There was no intra operative complication in group A, while in group B there was a blood loss of 100 ml caused by liver retractor in one patient and clips were applied on staple line bleed in 3 other patients.
- Conversion to open surgery:** No conversion to open surgery was done in both the groups.

Both the procedures were found safe in terms of intra operative complications, with LAGB being associated with lesser complications in comparison to LSG.

Post Operative Parameters

- Time to start orally:** Both the groups were started orally after 24 hours after confirming a normal upper GI gastrograffin study. Both groups accepted orally well from post operative day 1.
- Duration of hospital stay:** Mean duration of hospital stay was more in group B (LSG).
- Time to return to daily work:** Mean time to return to daily work was same for both the groups (5 days), but patients in group A (LAGB) started ambulation earlier than the patients in group B (LSG).
- Complication:** In group A patients, incidence of vomiting, fullness, wound infection and patient satisfaction was poor. There was no post

operative complications in group B patients.

- e. *Weight loss parameters:* Mean values of percentage of excess body weight loss was significantly better in group B (LSG =53.761%) than in group A (LAGB=40.842%) with a p value of 0.05. The fall in mean values of BMI in group B, LSG (44.82→33.85) was also significantly better (P value 0.001) than in group A, LAGB (38.49→33.56). Similarly change in waist hip ratio was also significantly better in group B, LSG (1.06 →1.02) than in group A, LAGB (1.06→1.03).
- f. *Resolution of comorbid conditions:* Resolution of hypertension was more in LSG patients with 98% of patients becoming normotensive in comparison to LAGB patients where 87.5% patients became normotensive. Resolution of diabetes was 92% in Group B and 80 % in Group A.
- g. With our experience, we are of the opinion that LSG seems to be the preferred procedure in Indian population.

General Conclusions

- 1) Pre-operatively patients who went through a structured weight loss program, who lost a minimum of 5 kg after their enrollment in the program and attended the metabolic surgery clinic regularly, had better post-operative compliance and results.
- 2) All the patients who received very low calorie diet, starting atleast 2 weeks prior to surgery, had shrunken left lobe of liver thus decreasing the operative difficulty.
- 3) All the patients were given DVT prophylaxis in the peri-operative period. In our study Low molecular weight heparin was started 1 day prior to surgery and was continued for a period of 5 days post-operatively. Pneumatic compression stockings were applied to the patient through out the surgery and were continued for a period of 48 hrs. Early patient ambulation was also done.
- 4) Liver injury caused by liver retractors (5 mm tri-flange retractor and 10 mm retractor) could be avoided with Nathanson's liver retractor.
- 5) Patients undergoing Laparoscopic Sleeve Gastrectomy underwent gastrograffin upper GI study in post-operative day 1 and were allowed liquids orally if the study was normal. However in patients undergoing Laparoscopic Gastric Banding, patients may be allowed liquids orally

after about 6 hrs post surgery. Gastrograffin upper GI must be done in the post-operative day 1.

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