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Wight Loss And Type II Diabetes Mellitus Control After Laparoscopic Sleeve Gastrectomy In An Early Post-Operative Period- A Prospective Cohort Study

Shailesh Kumar[1] (Corresponding Author), Md Abu Masud Ansari[2], Umakant Verma[3], Naveen Kumar[4], Arun Kumar Gupta[5], A.S.N Rao[6]

[1](Professor Of Surgery, Pgimer, Dr. Rml Hospital New Delhi, India Mob. +919810477114, E-Mail [2](Assistant Professor Of Surgery, Pgimer, Dr. Rml Hospital New Delhi, India. Mob. +919718490092, [3](Junior Surgical Resident, Pgimer, Dr. Rml Hospital New Delhi, India.)
[4](Senior Surgical Resident, Pgimer, Dr. Rml Hospital New Delhi, India.)
[5](Professor Of Surgery, Pgimer, Dr. Rml Hospital New Delhi, India)
[6](Professor Of Surgery, Pgimer, Dr. Rml Hospital New Delhi, India)

Abstract:
Introduction: *Obesity has reached epidemic proportions worldwide India rank 3rd after USA and China. The health consequences range from increased risk of premature death due to serious chronic illness like Hypertension and DM which reduces the overall quality of life. LSG produces long lasting control of Obesity as well as DM*
Material and Methods*: A prospective cohort study was conducted between the periods of January 2015 to March 2016. The criteria for selection were BMI ≥ 40 kg/m2 or BMI ≥ 35 kg/m2 with co-morbidities. All the patients were screened by a multidisciplinary team. All the patients were operated by the same surgeon to avoid any procedural biasness. At each follow-up visit, weight loss and glycemic control status were evaluated.*
Results: *Out of 60 patients operated for morbid obesity, Our focus were on those 18 patients who were morbidly obese having Diabetes as the only co morbidity .Rest were having either no co-morbidity or multiples co-morbidity. Post operatively all patients were followed up and were given same diet plan for the first three months of the follow up. Post-operatively on follow up, there was significant change in all the parameters like the weight reduction, BMI, Fasting Blood sugar level, Post prandial Sugar level.*
Conclusions: *LSG is simple, effective and reproducible surgical method to treat obesity as well as DM2.*
Keywords: *Diabetes Mellitus, Laparoscopic Sleeve Gastrectomy, Morbid obesity,*
Abbreviations: *LSG – Laparoscopic Sleeve Gastrectomy, BMI – Body Mass Index, FBS – Fasting Blood Sugar, PPBS – Post Prandial Blood Sugar, DM – Diabetes Mellitus, EWL –Excess Weight Loss.*

I. Introduction

Obesity is defined by WHO as a chronic multisystem disease resulting from complex interaction between the human genotype and the environment. It has reached epidemic proportions worldwide. There are more than one billion overweight adults, of which at least 400 million are clinically obese [1]. More than 2.8 million adult die each year as a result of being overweight or obese. Overweight and obesity attributes 44 % of diabetic, 23% of Ischemic heart disease and 7-41 % of cancer burden [2].

In Indian population, cross sectional study in Pune showed prevalence of obesity was 43 % in adult population with statistically significant association between BMI >25 kg/m^2 and diabetes and hypertension[3]. Several studies suggest that there is growing need to redefine morbid obesity in Asian population and also the Asians develop obesity related comorbid conditions at relatively younger age than their western counterparts [4]. Obesity has reached epidemic proportion in India [3].

The health consequences of obesity range from increased risk of premature death due to serious chronic illness like Hypertension and DM which reduces the overall quality of life [3] India a developing country is one of the capitals of diabetes and cardiovascular diseases. Development causes urbanization and reduction in physical activity leading to overweight and obesity.

Therapeutic interventions for the treatment of obesity range from lifestyle and diet modifications to pharmacologic and surgical therapy [5]. However, studies showed that the non-operative interventions for sustained weight loss usually fail to provide real benefits and are usually insufficient and not sustainable in co-morbidly obese patients[6,7] Dietary, behavioral, and medication treatments for obesity are often unsuccessful for consistent weight loss[8].

Laparoscopic sleeve gastrectomy is an evidence based treatment of morbid obesity with proven, sustained weight loss and improvement in comorbidities [9,10,11]. The aim of this study was to evaluate the

efficacy of Laparoscopic sleeve gastrectomy in morbidly obese patients in terms of weight loss and remission of DM.

Bariatric surgery is an effective and safe treatment for morbid obesity. The efficacy of bariatric procedures in the induction and maintenance of weight loss largely superior to that obtainable by current medical therapies and that has been confirmed by large meta-analyses [12-14]. This sustained weight loss has a profound impact on obesity-related comorbidities particularly type2 diabetes.

There has been a substantial progress in the study of obesity and in the development of laparoscopic techniques of bariatric surgery Many types of operative procedures for morbid obesity have been popularized over the past three decades and are continuously evolving which range from restrictive to malabsorptive or combination of the two. It is difficult to identify the most effective option based on patient characteristics and comorbidities The LSG which removes 75-80 % of the stomach is relatively easy, safer, less invasive and almost equally effective procedures for weight control and remission of DM2 as compared to Roux–en-Y gastric bypass.

II. Materials and Method

A prospective cohort study was conducted at PGIMER & Dr R.M.L Hospital New Delhi between the periods of January 2015 to march 2016. Patients included were of either sex of age 18 -60 who had tried for weight loss for atleast 6 months by dietary restriction and life style modification but failed to maintain sustained weight loss. The criteria for selection were BMI ≥ 40 kg/m2 or BMI ≥ 35 kg/m2 with co-morbidity. All the patients were screened by a multidisciplinary team consisted of the surgeon, / nutritionist / cardiologist / endocrinologist / chest physician and a psychologist. All the patients were thoroughly evaluated and explained every concern including the risks and benefits of the procedures.

Diagnosis of T2DM was made according to the American Diabetes Association guidelines. T2DM remission was defined as a fasting plasma glucose level below 126 mg/dl, PPBS < 200 mg/dl, and Hb1Ac < 6.5% in the absence of hypoglycemic drugs [10, 15]

The % of Excess weight loss was measured on each follow up visit. The BMI upto 25 were taken as the Normal weight and beyond that were taken as the Excess weight.

2.1 Preoperative preparation:

All routine investigations including Upper GI Endoscopy**,** echocardiography and psychological assessment for conducting LSG were done on every patient. Patients were started on liver shrinkage diet one week prior to surgery. Deep venous thrombosis (DVT) prophylaxis with DVT Pump during surgery and subcutaneous LMWH was given to all patients 12 h before and continued for 7-10 days after the surgery.

2.2 Surgical Method:

A standardized procedure of LSG was performed using classical 5 ports under General Anaesethesia. All surgeries were done by the same surgeon to minimize the biasness. Omentolysis were started 3-5 cm from the pyloric junction up to the G-E Junction using ultracision. We cut sleeve over 36fr gastric calibration tube using Green cartridge for first two fires, rest all blue. Hemostasis was secured using metallic clips wherever required. Per-Operative leak test were performed using air inflation test in all patients. We routinely put 24Fr.drain along the sleeve. Specimen was removed and all ports > 10mm were closed using transfascial suture.

2.3 Postoperative period:

Patients were observed in the high-dependency unit for the first night after the procedure. Patients were encouraged to sit out of bed and chest physiotherapy using Incentive spirometry on the evening after surgery in order to minimize postoperative atelectasis. Patients were allowed clear liquid on post op day 1 along with Maintenance intravenous fluid. Antibiotic and pro-kinetics were continued for a period of 5 days and 14 days respectively. Patients were discharged and followed up at 1st week, 2^{nd}, 4^{th} week, and 12^{th} week. At each follow-up visit, weight loss and glycemic control status (FBS, PPBS, HbA1c and hypoglycemic treatment) were evaluated.

2.4 Statistical Analysis:

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean ± SD and median. Statistical tests were applied as follows-

1Quantitative variables were compared using unpaired t-test/Mann-Whitney Test (when the data sets were not normally distributed) between the two groups.

2Qualitative variables were correlated using Chi-Square test /Fisher's exact test. The P value of <0.05 was considered statistically significant.

The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0. All of the results are presented as 2-tailed values with statistical significance defined as *P* values < 0.05.

III. Results and Observations

A total of 60 patients were operated for morbid obesity of the age ranging from 27 to 55 years with a mean of 41.53 ±8.89 years and the male to female ratio is 3:7. The LSG were done on all patients by the same surgical team. The patients were selected randomly who came to our OPD. All patients were thoroughly investigated to rule out any reversible causes of obesity as well as any psychiatric, cardiac and respiratory problems including OSA Syndrome.

Our study focuses on those 18 patients who were morbidly obese having Diabetes as the only co-morbidity, rest were having either no co-morbidity or multiples co-morbidity. Post operatively all patients were strictly followed up as per the research protocol and were given same diet plan for the first three months of the follow up.

The mean weight of the all morbidly obese patients pre-operatively was 111.03±8.78 Kg (ranging from 100-130) and the mean height was 1.6m (ranging from 1.5-1.73) On follow up, the mean weight at 1^{st} week, 2^{nd} weeks, 4^{th} weeks and 12^{th} weeks reduced to 109 ± 8.23 kg, 107.2± 7.88kg, 103.37 ± 7.81 kg and 96.63 ± 7.06kg respectively. On statistical analysis it was found to be significant (P value <0.05).

The Mean BMI of all the patients were 43.68 ± 3.75 kg/m^2 Pre-operatively and on follow up the mean BMI reduced to 42.9 ± 3.52 kg/m^2, 42.09 ± 3.26 kg/m^2, 40.55 ± 3.14 kg/m^2 and 38.01 ± 2.31kg/m^2 at 1^{st} week, 2^{nd} weeks, 4^{th} weeks and 12^{th} weeks respectively. All these observations were analyzed and found statistically significant (P value <0.05)

Table 1: correlation of Weight and BMI with post op period
Fig.1: Weight and BMI trends following LSG

Fasting blood sugar

Out of 60 patients 18 patients had diabetes as the only co-morbidity. Their mean fasting blood sugar was 127.78± 12.76 mg/dl. At 1st week, 2^{nd} weeks, 4^{th} weeks and 12^{th} weeks, the mean value decreased to 118 ± 6.24 mg/dl, 116.44 ± 4.88 mg/dl, 109.89 ± 5.62mg/dl, 105.44 ± 6.62mg/dl respectively. All these observations were statistically significant (P value<0.05)

Post prandial Blood Sugar

The mean post prandial blood sugar of all 18 diabetic patients were recorded separately pre-operatively and subsequent follow up and it was 208.11±19.37mg/dl pre-operatively and 194.78±18.36mg/dl, 187.89±14.92mg/dl, 177.78±13.28mg/dl and 167.56±12.69 mg/dl after 1^{st}week, 2^{nd} week, 4^{th} week and 12^{th} week respectively. On statistical analysis theses were found significant (P value <0.05).

Table 2: Correlation of FBS & PPBS with post op period
Fig. 2: FBS & PPBS trends with post op period

Serum HbA1C:

The mean serum HbA1c of all 18 patients was 8.06 ± 0.63%. After 1 week the mean value decreased to 8.01 ± 0.69% which was statistically not significant. Subsequently at 2^{nd} weeks, 4^{th} weeks and 12^{th} weeks, the mean value decreased to 7.72 ± 0.8%, 7.34 ± 0.58% and 6.88 ± 0.44% respectively. All of these were statistically significant. (P value<0.05)

Table 3: Correlation of HbA1c level with post-op period
Fig. 3: HbA1c trends with post-op period

EWL: The % of Excess weight loss were measured at each follow up visits and were recorded as 4.316%, 8.143%, 16.287% and 30.618% at 1^{st} week, 2^{nd} week 4^{th} week and 12^{th} week respectively.
Fig. 4: % EWL trend with post-op period

IV. Discussion

World Health Organization (WHO) Reveals in its report that obesity is one of the most common, yet among the most neglected, public health problems in both developed and developing countries [1]. According to Wild et al the prevalence of diabetes is expected to double globally from 171 million in 2000 to 366 million in 2030 with a maximum increase in India [3]. It is also predicted that by 2030 diabetes mellitus may afflict up to 79.4 million individuals in India only, while China (42.3 million) and the United States (30.3 million) would

also see significant rise in those affected by the disease [3,4] Obesity is strongly associated with other co-morbidity including diabetes, hypertension, dyslipidemia, cardiovascular disease and even some cancers [2].

There is a growing consensus that bariatric surgery is the predominant treatment option available for the management of morbid obesity and its associated co-morbid conditions. Diet therapy, medical treatment and different exercise & yogas are relatively ineffective in treating morbid obesity in the long term [16]. Recently, the laparoscopic sleeve gastrectomy has emerged as a stand-alone procedure for the treatment of morbid obesity, and unlike the Roux-en-Y gastric bypass, the LSG does not bypass the foregut [17, 18].

The mechanisms of action of LSG are mechanical restriction and hormonal modulation. Ghrelin, a hunger-regulating peptide hormone, produced by P/D1 cells that are found mainly in the fundus of the stomach are removed, thus reducing plasma Ghrelin levels and subsequently, the feeling of hunger. Ghrelin regulation is also disturbed following the sleeve gastrectomy procedure. LSG was also reported to have a hindgut effect with increasing levels of glucagon-like peptide 1 and peptide YY due to the increased transit time after LSG [19].The % loss of excess weight at one year is 62% and 72% at two years [20-23]. In our study the % loss of excess weight was 4.316%, 8.143%, 16.287% and 30.618% at 1st week, 2nd week, 4th week and 12th week respectively which is significant and is consistent with the other studies. Similarly the mean BMI also reduced substantially in accordance with the earlier studies. It is expected that the loss of excess weight may be even more if patients follow the nutritional guidelines strictly, which is high protein low calorie diet and regular exercise.

A recent 3-year study of diabetic patients after LSG demonstrated an improvement in all comorbidities in 70% of patients [24]. Significant improvement /remission of diabetic markers like Blood sugar level Fasting as well as PP), HbA1c is commonly observed after bariatric surgery [25-27]. Improvement of comorbid conditions was observed after LSG in more than half of the patients with type 2 diabetes [28, 29]. A remission of type 2 diabetes after LSG in 51% of patients after 4 months and 84% after 12 months as reported by Vidal et al [30,31].

Similarly in our study, there are marked improvement in all the markers of the diabetes likes Blood sugar level (Fasting as well as PP), HbA1c and showed positive and significant change. Our results also observed that the improvement in diabetes occur early in the postoperative course. It was also observed that while these changes occur early, they are also durable [24]. The findings are also comparable with a recent review of 27 studies of sleeve gastrectomy; in that 66% resolution of diabetes with a mean follow up of 13 months [25]. In our study there was remarkable improvement of diabetes in all patients with reduction of diabetic medications after 2 wks of surgery.

The exact mechanism responsible for remission of diabetes after LSG has not yet been elucidated and necessarily excludes the bypass of the foregut theory, as has been suggested for the gastric bypass [31] As reported by others and supported by the results in this study, a significant reduction in diabetes markers and diabetic medications precedes maximal weight loss [32]. A systematic review of the existing literature showed that SG results in T2DM resolution ranging from 80% to 96% in morbidly obese subjects [33] a range similar to that in patients following RYGBP [34].

It is obvious from our study that positive change in all parameters of the DM started in the very first week and become statistically significant from the following week which continued till the last follow up visit in all Patients. The most probable cause of remission are removal of gastric hormones, including Ghrelin and peptide YY presents in the resected portion of the stomach has been found to be significantly reduced after LSG compared to gastric bypass [33]. There might be some changes in the milieu of other gut hormones which may play some role in remission. It is also not clear whether there is any change in the function of pancreatic endocrine and insulin resistance and further studies are needed in this direction.

V. Conclusion

LSG is simple and effective surgical procedure to achieve a significant weight loss and control of type 2 diabetes mellitus which starts in the early post-operative period. There is significant reduction in the diabetes medications hence the cost of diabetes treatment. A long term follow-up is needed to evaluate its effectiveness.

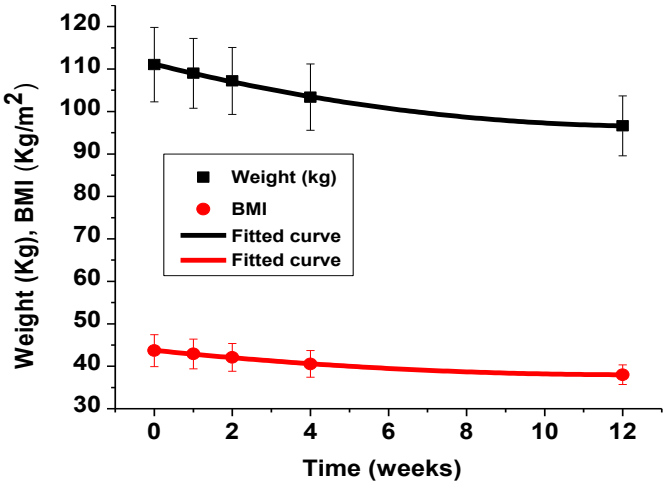

Figure 1: Weight and BMI trends following LSG

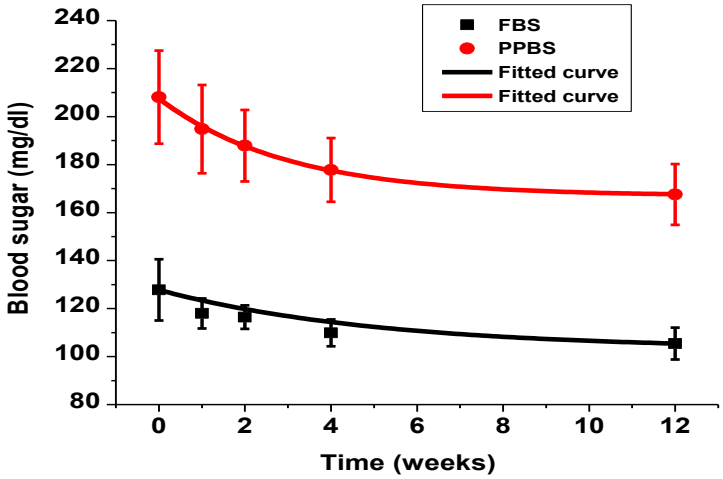

Figure 2: FBS & PPBS trends with post op period

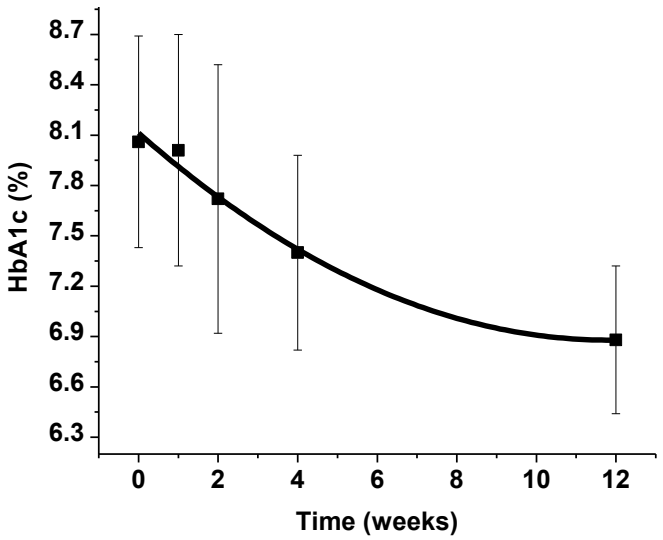

Figure 3: HbA1c trends with post-op period

Table 1: Correlation of Weight and BMI with post-op period

Duration	Sample size	Parameter	Mean ± SD	Median	Min-Max	Inter quartile Range	P value
0 Week	60	Weight (kgs)	111.03 ± 8.78	110	100-130	104 - 118	
		BMI	43.68 ± 3.75	42.82	37.63-56.44	41.400 - 45.240	
1Week	60	Weight (kgs)	109 ± 8.23	108	98-126	103 - 113	<.0005
		BMI	42.9 ± 3.52	42.24	37.63-55.55	40.620 - 43.150	<.0005
2Week	60	Weight (kgs)	107.2 ± 7.88	104.5	97-124	101 - 112	<.0005
		BMI	42.09 ± 3.26	41.43	37.26-53.33	40.130 - 42.570	<.0005
4 Week	60	Weight (kgs)	103.37 ± 7.81	100.5	94 -120	98 - 110	<.0005
		BMI	40.55 ± 3.14	39.6	36.13-51.11	38.750 - 41.870	<.0005
12 Week	60	Weight (kgs)	96.63 ± 7.06	95	84-112	92 - 100	<.0005
		BMI	38.01 ± 2.31	37.48	34.62-44.44	36.160 - 38.620	<.0005

Table 2: Correlation of FBS & PPBS with post-op period

Duration Weeks	Sample size	Parameter	Mean ± St.dev	Median	Min-Max	Inter quartile Range	P value
0 Week	18	FBS	127.78 ± 12.76	128	108-145	117.250 - 137	
		PPBS	208.11 ± 19.37	201	187-240	194	
1Week	18	FBS	118 ± 6.24	118	106-130	116 - 120	.020
		PPBS	194.78 ± 18.36	192	167-222	180 - 206.500	.0002
2Week	18	FBS	116.44 ± 4.88	116	110-126	112 - 118.500	.022
		PPBS	187.89 ± 14.92	186	166-216	176 - 197	.001
4 Week	18	FBS	109.89 ± 5.62	110	98-120	109.500 - 111.250	.001
		PPBS	177.78 ± 13.28	178	160-200	167.500 - 187	.001
12 Week	18	FBS	105.44 ± 6.62	106	90-112	103.500 - 110	.0003
		PPBS	167.56 ± 12.69	170	150-189	157.500 - 176	<.0005

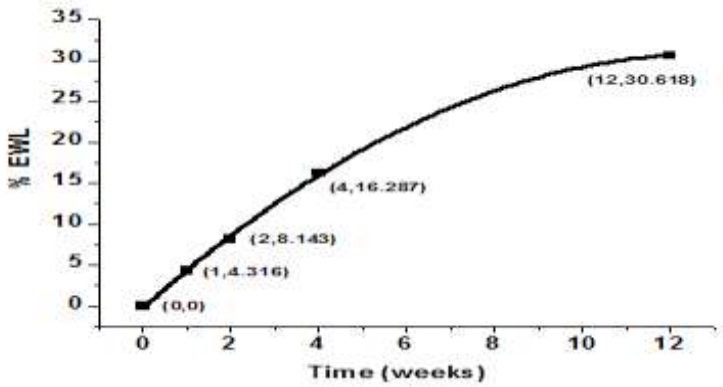

Figure 4: % EWL trend with post-op period

Table 3: Correlation of HbA1c level with post-op period

	Sample size	Mean ± Stdev		Median	Min-Max	Inter quartile Range	P value
0W	18	8.6	± 0.63	8	6.9-8.9	7.725 - 8.575	
1W	18	8.1	± 0.69	7.9	6.6-8.9	7.775 - 8.575	.586
2W	18	7.2	± 0.8	7.6	6.5-8.9	7.325 - 8.200	.005
1M	18	7.4	± 0.58	7.5	6.5-8.1	6.900 - 7.775	.0002
3M	18	6.8	± 0.44	7	5.9-7.5	6.825 - 7.025	<.0005

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