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

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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 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-morbidites. 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,


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/m² 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 pharmacological 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
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 type 2 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 at least 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 up to 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 Anaesthesia. 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, 2nd, 4th week, and 12th 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:

- Quantitative variables were compared using unpaired t-test/Mann-Whitney Test (when the data sets were not normally distributed) between the two groups.
- Qualitative 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\textsuperscript{st} week, 2\textsuperscript{nd} weeks, 4\textsuperscript{th} weeks and 12\textsuperscript{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\textsuperscript{st} week, 2\textsuperscript{nd} weeks, 4\textsuperscript{th} weeks and 12\textsuperscript{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 |

| 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\textsuperscript{nd} weeks, 4\textsuperscript{th} weeks and 12\textsuperscript{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\textsuperscript{st} week, 2\textsuperscript{nd} week 4\textsuperscript{th} week and 12\textsuperscript{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 like 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
Table 2: Correlation of FBS & PPBS with post-op period

<table>
<thead>
<tr>
<th>Duration</th>
<th>Sample size</th>
<th>Parameter</th>
<th>Mean ± SD</th>
<th>Median</th>
<th>Min-Max</th>
<th>Inter quartile Range</th>
<th>P value</th>
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<tbody>
<tr>
<td>0 Week</td>
<td>18</td>
<td>FBS</td>
<td>127.78 ± 12.76</td>
<td>128</td>
<td>108-142</td>
<td>117,250 - 137</td>
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<td>PPBS</td>
<td>208.11 ± 19.57</td>
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<td>187-240</td>
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<tr>
<td>1 Week</td>
<td>18</td>
<td>FBS</td>
<td>118 ± 6.54</td>
<td>118</td>
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<td></td>
<td></td>
<td>PPBS</td>
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<td>187-222</td>
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<tr>
<td>2 Week</td>
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<td>FBS</td>
<td>116.44 ± 4.88</td>
<td>116</td>
<td>110-126</td>
<td>112-118,500</td>
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<td>PPBS</td>
<td>187.89 ± 14.92</td>
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<td>166-216</td>
<td>176-197</td>
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<td>4 Week</td>
<td>18</td>
<td>FBS</td>
<td>109.89 ± 5.62</td>
<td>110</td>
<td>98-120</td>
<td>109,500 - 111,250</td>
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<td>PPBS</td>
<td>177.78 ± 13.28</td>
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<td>160-200</td>
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<td>12 Week</td>
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<td>FBS</td>
<td>105.44 ± 6.62</td>
<td>106</td>
<td>90-112</td>
<td>103,500 - 110</td>
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<tr>
<td></td>
<td></td>
<td>PPBS</td>
<td>167.56 ± 12.65</td>
<td>170</td>
<td>150-189</td>
<td>157,500 - 176</td>
<td>.0003</td>
</tr>
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</table>

Figure 4: % EWL trend with post-op period
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Table 3: Correlation of HbA1c level with post-op period

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<tr>
<th>Sample size</th>
<th>Mean ± Stdv</th>
<th>Median</th>
<th>Min-Max</th>
<th>Inter quartile Range</th>
<th>P value</th>
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References


