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General Surgery

EFFECT OF LAPAROSCOPIC SLEEVE GASTRECTOMY ON GLYCEMIC CONTROL OF OBESE PATIENTS WITH TYPE 2 DIABETES MELLITUS

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ABSTRACT

INTRODUCTION: Obesity has risen to epidemic level worldwide in the 21st century. It is associated with a number of disease such as diabetes, cardiovascular diseases, osteoarthritis, some cancers (endometrial, ovarian, colon, etc.). Currently, bariatric surgery is the best known treatment for obesity and its related co morbidities. Here we studied the effect of laparoscopic sleeve gastrectomy on the glycaemic control of obese patients with type 2 diabetes mellitus undergoing surgery.

MATERIALS AND METHOD: We conducted a prospective observational study and report on the weight loss and glycaemic control results of our first consecutive 30 patients with a complete follow up of 3 months.

RESULTS: In our study, the mean weight of the patients was 109.7 ± 15.56 Kg in the pre op period. The mean weight after 2weeks, 1 month and 3 months reduced to 107.6 ± 15.44 kg, 105.03 ± 15.27 kg and 97.63 ± 14.59 kg respectively, all of which are statistically significant (p value <0.05). The percent mean excess weight loss (%EWL) at the end of 3 months after surgery was 25.41 ± 5.11.

The HbA1c levels reduced from a pre op level of 8.11 ± 1.10 to 7.01 ± 1.10 three months after surgery. In our study out of 30 patients, 11 patients were taking only oral hypoglycaemics to maintain their blood sugar levels, while 19 were taking insulin with or without oral hypoglycaemics. At the end of three months after surgery, 10 patients achieved diabetes remission.

Out of the 19 patients taking insulin, 9 patients (47.36%) were able to stop their insulin therapy at the end of three months after surgery and maintain blood sugar levels only with oral hypoglycaemics. There was 53.21% reduction in the insulin dose of the other 10 patients in the same period.

CONCLUSION: We would recommend that laparoscopic sleeve gastrectomy should be promoted in the morbidly obese patients with diabetes mellitus.

KEYWORDS : Obesity, Diabetes Mellitus, Sleeve Gastrectomy, Diabetes Remission

INTRODUCTION

Obesity is defined as abnormal or excessive fat accumulation that may impair health. Worldwide obesity has nearly tripled since 1975. In 2016, more than 1.9 billion adults, 18 years and older, were overweight. Of these over 650 million were obese.[1]

Body mass index (BMI) is a simple index of weight-for-height that is commonly used to classify overweight and obesity in adults. It is defined as a person's weight in kilograms divided by the square of his height in meters (kg/m^2).[1]

BMI = Weight (in kg)/Height (in m^2)

Morbid obesity is defined as a BMI > 40 kg/m2 or BMI > 35 kg/m2 with obesity-associated comorbid conditions such as diabetes, hypertension, cardiovascular diseases, etc.[2] These BMI values are age independent and same for both sexes. The risk associated with BMI are continuous and graded and begin at a BMI above 25.[1]

Increased insulin resistance (IR) and deteriorated insulin secretion are considered the main mechanisms in type 2 diabetes mellitus development. Evidence has indicated that increased β-cell function maintains the glucose equilibrium in individuals with increased IR. However, overt diabetes eventually develops after the failure of β-cell secretion compensation. Obesity is positively related to high IR and contributes to high β-cell function. This increased β- cell mass and resulting increased insulin secretion might be because of the compensatory reaction to high IR.[3]

Insulin resistance is a central abnormality of the metabolic syndrome, or syndrome X, originally hypothesized by Reaven to describe a constellation of metabolic abnormalities, including hyperglycemia, hyperinsulinemia, hypertension, dyslipidemia with increased triglycerides, and decreased HDL.[4-6] Insulin resistance correlates with the degree of obesity, notably abdominal obesity, and is a strong predictor for the development of Type 2 diabetes.[4,5]

In addition to hyperinsulinemia, several other factors in the metabolic syndrome have been implicated in endothelial dysfunction.[4]

MANAGEMENT OF OBESITY

The primary goal of treatment is to improve obesity related comorbid condition and reduce the risk of developing future co-morbidities. The decision of how aggressive treatment the patient needs and which modality to use depends on the initial BMI, risk status and available resources.[7]

Lifestyle Modifications

- Dietary Control
- Physical Activity

Pharmacotherapy

Medications for obesity have traditionally fallen into two major categories: appetite suppressants or anorexiants, and gastrointestinal fat blockers. The 6 most commonly used antiobesity medications are phentermine, orlistat, phentermine/topiramate extended release, lorcaserin, naltrexone sustained release (SR)/bupropion SR, and liraglutide.[8]

Bariatric surgery

Evidence from decades of weight loss research indicates that lifestyle interventions and pharmacotherapy often fail to help severely obese people lose enough weight to improve their health and quality of life in the long term. Currently, bariatric surgery is the best known treatment for obesity, and multiple meta-analyses have shown bariatric surgery to be more effective for treating obesity than diet and exercise or pharmacologic treatment.[9]

Types of Bariatric Surgery

Malabsorptive

Jejunoileal bypass

Restrictive

Vertical banded gastroplasty
Laparoscopic adjustable gastric banding (LAGB)
Laparoscopic sleeve gastrectomy (LSG)

Both

- **Largely Restrictive, Moderately Malabsorptive**
  Roux-en-Y gastric bypass (RYGB)
- **Largely Malabsorptive, Mildly Restrictive**
  Biliopancreatic diversion (BPD)
  Duodenal switch (DS)[10]

Laparoscopic Sleeve Gastrectomy

Initially laparoscopic sleeve gastrectomy was advocated as the first step of a two-staged procedure for high-risk patients, with the intention of reducing co-morbidities and operative risk, and to be followed by either BPD-DS or laparoscopic Roux-en-Y gastric bypass (LRYGB). However, often, satisfactory weight loss was achieved after LSG, and second-stage procedures were found to be unnecessary.[11] Therefore, LSG is now recognized as a primary procedure. As a primary procedure, the surgeon takes down the entire greater curvature, leaving intact the tissue within 3 cm of the pylorus and up to the angle of His and exposing the left crus of the diaphragm. Then, with use of a 32 Fr to 40 Fr bougie, the stomach is divided from the antrum to the angle of His by sequential firings of the stapler.

According to a study it was found that the 1-year EWL was highest for the patients undergoing laparoscopic RYGB (69%), intermediate for LSG (60%), and lowest for LAGB (34%; $P < .0001$).[10]

Advantages of the LSG are the technical simplicity of the procedure, preservation of the pylorus (avoidance of dumping), metabolic reduction of ghrelin levels, no need for serial adjustments (as for the LAGB), reduction in internal hernias (seen after laparoscopic RYGB), reduction in malabsorption (seen with laparoscopic RYGB), and ability to later modify the gastric sleeve to either a laparoscopic RYGB or a DS configuration in a second stage of the operation. [10]

MATERIALS AND METHOD

A prospective observational study was conducted in Department of Surgery, PGIMER & DR. RML Hospital, New Delhi on 30 patients who fit the inclusion criteria. Laparoscopic sleeve gastrectomy was performed on these patients after the consensus of a multidisciplinary team, consisting of a surgeon, endocrinologist, cardiologist, chest physician and psychiatrist. Thereafter the efficacy of the above procedure was assessed in diabetic patients for change in glycemic control and oral hypoglycemic agents & insulin requirement before and after laparoscopic sleeve gastrectomy. Patients included in the study were patients with Type2 Diabetes mellitus with BMI>35kg/m^2, aged >18years and <70 years and psychologically stable patient. Patient with Type1 Diabetes mellitus, BMI >50kg/m^2 and patients unfit for general anesthesia due to cardiac, respiratory or any other reason were excluded from the study.

STATISTICAL ANALYSIS

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean ± SD and median. Normality of data was tested by Kolmogorov-Smirnov test. If the normality was rejected then non-parametric test was used.

The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

RESULTS AND DISCUSSION

In our study, most of the study participants who underwent laparoscopic sleeve gastrectomy were under the age of 40 years (44%). The mean age of the patients was 43.30 ± 10.86 years. This is comparable to studies done by Matthew M. Hutter et al, 2011[12]; Hoyuela C, 2017[13], the mean age of patients being 46.52 years and 43.2 ± 13.1 years respectively. While Wang X et al, 2016[14] performed the study in a younger cohort with a mean age of 30.33 ± 8.61 years.

In our study, there were 7 (23%) male patients and 23 (77%) female patients, which is similar to the study reported by Hoyuela C, 2017[13]. They had 25.7% male and 74.3% female patients in their study. The cohort of Slater BJ et al, 2011[2] comprised of 79% males and 21% females in their study. While Wang X et al, 2016[14] and Zhang F et al, 2011[15] had almost similar number of male and female patients in their studies (57.14% male, 42.86% female patients and 42% male and 58% female patients respectively).

In our study, the mean weight of the patients was 109.7 ± 15.56 Kg in the pre op period. The mean weight after 2weeks, 1 month and 3 months reduced to 107.6 ± 15.44 kg, 105.03 ± 15.27 kg and 97.63 ± 14.59 kg respectively, all of which are statistically significant (p value <0.05). The proportions of patients having successful weight loss were 100%. The percent mean excess weight loss (%EWL) at the end of 3 months after surgery was 25.41 ± 5.11.

In a study by Zhang F et al, 2011 the mean body weight decreased from 161.4 ± 34.3 kg in the pre op period to 112.9 ± 25.6 kg at 1 year after surgery.[15]

In a study by Slater BJ et al, 2011 the average percent excess weight loss (EWL) in each time interval was 20% at 2 weeks postoperatively, 31% at 2 months, 47% at 6 months, and 56% at 12 months.[2]

In our study, the mean HbA1c level of the 30 morbidly obese patients in the pre op period was 8.11 ± 1.10. The mean HbA1c levels after 2weeks, 1 month and 3 months reduced to 8.02 ± 1.09, 7.53 ± 1.08, and 7.01 ± 1.10 respectively.

In a study done by Meydan C et al, 2015 the HbA1c value reduced from 7.63 in pre op period to 7.31 at 1 week and to 6.05 at the end of 3 months after surgery.[16]

In the study by Slater BJ et al, 2011 the mean HbA1c values reduced from 7.4 in the pre op period to 6.1, 1 year after laparoscopic sleeve gastrectomy.[2]

Table 1: Comparison of the HbA1c levels

Study	Pre op	Post op	Follow up	P value
Slater BJ et al, 2011[2]	7.4	6.1	12 Months	<0.05
Meydan C et al, 2015[16]	7.63	6.05	3 Months	<0.05
Our Study	8.02	7.01	3 Months	<0.05

In our study out of 30 patients, 11 patients were taking only oral hypoglycaemics to maintain their blood sugar levels, while 19 were taking insulin with or without oral hypoglycaemics. At the end of three months after surgery, 10 patients achieved diabetes remission i.e. they were maintaining their blood sugar levels without any oral or injectable treatment.

Out of the 19 patients taking insulin, 9 patients (47.36%) were able to stop their insulin therapy at the end of three months after surgery and maintain blood sugar levels only with oral hypoglycaemics. There was 53.21% reduction in the insulin dose of the other 10 patients in the same period.

In a study by Wong SK et al, 2012 after a mean follow-up of 27 months, 4 of 11 insulin-dependent patients (36%) were able to stop their insulin therapy, and 18 patients (46%) achieved remission of T2DM (HbA1c <6.5% without the use of medication).[17]

Thus we had relatively more patients who stopped their insulin therapy as compared to Wong SK et al.

Table 2: Changes the treatment in pre op and post op period

	OHA	Insulin	Both	No Treatment
Pre op	11	07	12	00
At 2 Weeks	10	07	10	03
At 1 Month	07	05	10	08
At 3 Months	10*	05	05	10

*this apparent rise in the number is because some patients were taking both OHA and insulin in the pre op period and stopped taking either of them in post op period.

The authors from American Diabetic Association agreed upon the following definitions, which are the same for type 1 and type 2 diabetes: Remission is defined as achieving glycaemia below the diabetic range in the absence of active pharmacologic (anti-hyperglycaemic medications, immunosuppressive medications) or surgical (ongoing procedures such as repeated replacements of endoluminal devices) therapy. A remission can be characterized as partial or complete. [18]

Partial remission is sub-diabetic hyperglycemia (HbA1c not diagnostic of diabetes [<6.5%], fasting glucose 100–125 mg/dl [5.6–6.9 mmol/l]) of at least 1 year's duration in the absence of active pharmacologic therapy or ongoing procedures.[18]

Complete remission is a return to "normal" measures of glucose metabolism (HbA1c in the normal range, fasting glucose <100 mg/dl [5.6 mmol/l]) of at least 1 year's duration in the absence of active pharmacologic therapy or ongoing procedures.[18]

Remission of type 2 diabetes could be attained, for example, after

bariatric/metabolic surgery or with lifestyle efforts such as weight loss and exercise. Nondiabetic glycaemia resulting from ongoing medications or repeated procedures (such as in the dynamic phase of band adjustment after laparoscopic gastric banding) would not meet the definition of remission, as these interventions are considered treatment.[18]

Table 3: Diabetes remission rates in various studies

Study	Diabetes Remission	Follow up period
Hoyuela C, 2017[13]	75%	5 Years
Zaman JA et al, 2016[19]	53.9%	12 Months
Marius Hoogerboord, 2014[20]	78%	12 Months
Slater BJ et al, 2011[2]	75%	12 Months
Matthew Hutter et al, 2011[12]	55%	12 Months
Wong SK et al, 2012[17]	46%	27 Months
Schauer PR et al, 2012[21]	37%	12 Months
Our Study	33%	3 Months

The difference in the diabetic remission rate in our study seen is because of short follow up period of 3 months, as compared to 1 year to 5 years follow up period in other studies.

CONCLUSION

Assessment of the result showed that apart from decreasing weight and BMI of the patient laparoscopic sleeve gastrectomy leads to drastic improvement in the diabetic status of the patient. Diabetes remission was seen in the 33.33% of the patients, while 47.36% of the patients were able to stop their insulin therapy at the end of three months while there was 53.21% reduction in the insulin dose of the remaining patients.

Thus based on our experience we would recommend that laparoscopic sleeve gastrectomy should be promoted in the morbidly obese patients with diabetes mellitus.

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