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Original Research Article

EFFECT OF LAPAROSCOPIC SLEEVE GASTRECTOMY ON GLYCEMIC CONTROL IN TYPE 2 DM PATIENTS

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ABSTRACT

Introduction: Sleeve Gastrectomy has become popular as a standalone procedure, but its usefulness as an efficacious metabolic procedure for glycemic control and remission of diabetes is still under investigation. Many studies have shown benefits following LSG, although its long-term efficacy both as a bariatric and a metabolic procedure is yet to be established. This study was carried out to have a comprehensive picture of the effects on various parameters following LSG in obese populations with T2DM in the Indian scenario.

Aim: The effect of Laparoscopic Sleeve Gastrectomy (LSG) on the usage of medications and measurable change in glycemic control as seen by changes in Blood sugar, HbA1c, insulin & Homeostatic model assessment of insulin resistance (HOMA-IR) levels

Material and methods: All the patients with BMI > 32.5 kg/ m2 with type 2 diabetes mellitus undergoing Laparoscopic Sleeve Gastrectomy were included in the study. The period of the study was from Oct. 2017 to Mar. 2019. Blood sugar (fasting and postprandial) and insulin levels were checked before the surgery, 3 months, and 6 months after the surgery. We also recorded BMI and HOMA-IR levels.

Statistical analysis: Statistical analysis was carried out using SPSS 21.0.

Results: Out of 51 patients, 18 were males and 33 were females. The mean age of the patients was 42.26 ± 10.3 years. The mean BMI was 41.74 ± 4.28 kg/m2. 68.63% (35) stopped the medication and 31.37% (16) continued the medication after the surgery. The insulin, blood sugar levels (fasting and postprandial), HbA1c, BMI and HOMA-IR values decreased after the surgery.

Conclusion: LSG results in an improvement in glycemic control and achieving remission in most of the diabetic patients

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INTRODUCTION:

Our present armamentarium for combating obesity and its associated metabolic disorders can be divided into three categories: behavioural, medical, and surgical. Dietary modifications have the greatest impact on maintaining a healthy weight when it is used as part of a multimodal regimen. There is no effective medical monotherapy for treating obesity. The modern practice of bariatric surgery is the product of more than a half-century of surgical evolution and innovation, with over 300, 000 procedures performed annually, and is now the second most common abdominal operation [2,3]. Surgical intervention has been repeatedly shown to deliver the most significant and sustained weight loss [1]. As one would expect, the procedures themselves have evolved over the past 15 years. Originally begun as the first stage of the BPD/DS operation, laparoscopic sleeve gastrectomy (LSG) became a standalone operation in the early 2000s and has since gained rapid popularity [4]. Baltasar et al. proposed LSG could be employed as a primary bariatric procedure [5]. It is technically much simpler than either the RYGB or the BPD/DS. Many studies have revealed benefits following LSG, although its long-term efficacy both as a bariatric and a metabolic procedure is yet to be established. Pories et al. and others have shown that bariatric surgery is very effective in the control of diabetes, which is seen much before actual weight loss, suggesting the involvement of another mechanism like alteration in levels of gastrointestinal hormones [6,7]. This study was carried out to have a comprehensive picture of the effects on various parameters following LSG in obese populations with T2DM in the Indian scenario. Insulin resistance before and after the procedure is one of the ways of knowing glycemic control. There are different methods of measuring insulin resistance. The Hyper-Insulinemic Euglycemic Clamp (HIEC) technique is the reference standard for the measurement of insulin resistance. However, it is time-consuming, costlier, and cumbersome [8]. One of the most commonly used measures of insulin resistance is the statistically derived 'Homeostatic model assessment of insulin resistance (HOMA-IR)' formula. This is a surrogate marker of insulin resistance which has been validated and shown to have a good correlation with HIEC. The HOMA-IR formula uses only the fasting glucose and insulin values to calculate insulin resistance [9,10]. HOMA-IR = Fasting Insulin (micro IU/ml) x fasting glucose (mg/dl)/ 405. The normal value of HOMA-IR is less than 1.6 and a value more than 2.6 is taken as abnormally high.

AIM:

The effect of Laparoscopic Sleeve Gastrectomy (LSG) on the usage of medications and measurable change in glycemic control as seen by changes in Blood sugar, HbA1c, Insulin & Homeostatic model assessment of Insulin resistance (HOMA-IR) levels.

MATERIALS & METHODS: All the patients with BMI > 32.5 kg/ m2 with type 2 diabetes mellitus undergoing Laparoscopic Sleeve Gastrectomy were included in the study.

The period of the study was from Oct. 2017 to Mar. 2019. To exclude any upper GI pathology, all patients underwent UGI endoscopy and USG abdomen. All had their endocrine, psychological, and other relevant consultations done based on comorbidities. Standard 5 port technique was used in all. The greater omentum was dissected (from 5 cm proximal to pylorus up to left diaphragmatic crus) using a harmonic scalpel close to the stomach wall and medially to the gastroepiploic vessels. Subsequently, a 36 Fr bougie passed through the oral route was placed along the lesser curvature of the stomach and directed into the duodenum. The sequential staplers were fired along the bougie and continued till the angle of His.

Bleeding from the staple line was controlled using a hemostatic suture/clip. In each case, a leak test was performed using methylene blue at the end of the procedure. The patients were discharged home on the 4th postoperative day after performing an oral contrast study to rule out leaks or strictures. Low-calorie liquids and semi-solids were advised for the initial two weeks, followed by a gradual change over to solids. Fasting (FBS), postprandial blood sugar (PPBS), HbA1c, and Insulin levels were

checked before the operation, 3 months and 6 months after the operation. We also recorded BMI and HOMA-IR levels and their trends were recorded. Statistical Analysis was made to see overall changes in blood glucose, insulin, BMI, and HOMA-IR (insulin resistance) levels before and after surgery.

STATISTICAL ANALYSIS:

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean ± SD. The normality of data was tested by the Kolmogorov-Smirnov test. If the normality was rejected, then a nonparametric test was used. Quantitative variables were compared using paired t-test/Wilcoxon signed rank test (when the data sets were not normally distributed) between pre and post. A p-value of <0.05 was considered statistically significant and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

RESULTS:

We had 51 patients, out of which 18 were males and 33 were females. The mean age of the patients was 42.26 ± 10.3 years. Table 1 shows the values, mean, and SD of FBS, PPBS, HbA1c, BMI, HOMA-IR, and insulin before surgery, 3 and 6 months after surgery. Overall, a statistically significant difference was found between the pre-op and the post-op values of FBS, PPBS, insulin, HbA1c, BMI, and HOMA-IR, both 3 and 6 months after the surgery [Table 1]. In this study, 68.63% (35) stopped the medication and 31.37% (16) continued the medication after the surgery. After 3 and 6 months of surgery, the patients were reviewed for diabetic medication based on blood sugar, HbA1c, and insulin levels. The diabetic treatment for all the patients was revised. Most of the patients, i.e. 68.63% (35) stopped the medication and advised lifestyle changes, and the remaining 31.37% (16) continued with the medication and were either shifted from insulin injection to oral hypoglycemic agents or continued with a combination of oral hypoglycemic agents with a reduced dosage of insulin. Compared to the medicine-continued group, the medicine-discontinued group had a lower mean age distribution (39.83 ± 10.1 vs. 47.56 ± 8.88, p =0.01). At 3 and 6 months postoperatively, as compared to medicine continued group, medicine discontinued group had significantly lower BMI, FBS, PPBS, HbA1c, serum insulin, and HOMA-IR, and the difference was significant at all the times intervals (with $p < 0.001$). [Table 2]

DISCUSSION:

Because of its efficacy coupled with its relative technical simplicity, the LSG is becoming the predominant bariatric procedure. As it is still a relatively new procedure, it continues to be evaluated by the medical community as more long-term information presents itself. Most of the studies have shown clinical improvement in diabetic status following LSG. A recent systemic review of all the available literature has suggested that centres performing LSG should continue to collect and report their outcome data [11]. Our study has shown that there is a definite improvement in the clinical status of diabetes, as seen by the resolution of diabetes and discontinuation of medications in most of the patients. This fact has now been reported by many authors. Mechanisms beyond weight loss have been implicated in DM resolution following LSG. The changes in the level of intestinal hormones may also possibly play a role in better glycemic control after a bariatric procedure [12]. Individuals with higher BMI tend to have increased insulin resistance [13,14]. Our study also reflected a trend of rising insulin resistance with an increase in BMI. HOMA-IR is a robust surrogate method for quick assessment of insulin resistance in clinical settings [16]. Insulin resistance is the better predictor of metabolic syndrome [15]. Other authors also have shown improvement in values of HOMA-IR (16.5 versus 6.6) as early as 2 weeks following bariatric surgery, with a substantial decrease in the requirement of medication (from 2.2 to <1) within 2 weeks after surgery [17]. In our study also similar results were noted that there was a significant reduction in the blood glucose, HbA1c, Insulin levels, and HOMA-IR index at 3 and 6 months after LSG, and it was seen that 68.63% (35) stopped the medication and went to diabetic remission whereas 31.37% (16) continued medication even after the

surgery. Hence, we state that our study reinforces the role of LSG as a standalone bariatric surgery procedure for diabetic patients and those with metabolic syndrome as brought out by some of the recent studies. [18,19,20]

LIMITATIONS:
Because of the short duration of the study, the effects of LSG on various parameters like resolution or improvement in diabetes or decrease in drug dosage could not be generalized to the population. Secondly, our study focused mainly on Insulin levels and their association with obesity; other hormones regulating obesity were not considered.

CONCLUSION:
Obesity has reached epidemic levels in India and worldwide. LSG as single therapy has shown excellent results in the treatment of morbid obesity for regulation of metabolic derangement, especially glycemic control. Diabetic parameters like Blood glucose levels, Insulin levels, and HOMA-IR index showed significant improvement after 6 months of surgery.

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Authors' information
The patient received all information about their clinical condition taking their surgical treatment into account the latest knowledge in literature.

Ethics approval and consent to participate
The patient has been approved for treatment at our centre and written consent for publication of this research has been taken. Ethical clearance was taken for the study

Competing interests - Nil

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Table 1 Glycemic parameters at various time intervals

N=51	Mean +/- SD		
	Pre-op	Post-op 3 month	Post-op 6 Month
FBS	139.12 ± 37.89	105.12 ± 18.46	89.08 ± 11.85
p- value	-	<.0001	<.0001
PPBS	187.31 ± 45.8	140.67 ± 21.38	121.92 ± 16.89
p- value	-	<.0001	<.0001
HbA1c	7.26 ± 1.15	6.21 ± 0.52	5.7 ± 0.37
p- value	-	<.0001	<.0001
Serum Insulin	19.54 ± 4.64	13.38 ± 3.31	9.01 ± 3.16
p- value	-	<.0001	<.0001
BMI	41.74 ± 4.28	35.06 ± 3.51	31.25 ± 3.77
p-value	-	<.0001	<.0001
HOMA-IR	6.94 ± 3.61	3.72 ± 1.69	2.02 ± 0.92
p- value	-	<.0001	<.0001

Table 2 Comparison of various glycemic parameters between medicine continued/discontinued at 03 and 06 months postop

3 months	Mean +/- SD			6 months	Mean +/- SD		
	Medicine continued (n=16)	Medicine discontinued (n=35)	P value		Medicine continued (n=16)	Medicine discontinued (n=35)	P value
BMI	36.96 ± 4.01	34.2 ± 2.92	0.008	BMI	33.54 ± 4.36	30.2 ± 2.99	0.002
FBS	117.88 ± 24	99.29 ± 11.64	0.0005	FBS	97.88 ± 15.29	85.06 ± 7.1	0.0001
PPBS	154.25 ± 26.86	134.46 ± 15.07	0.001	PPBS	133.5 ± 19.9	116.63 ± 2.37	0.001
HbA1c	6.61 ± 0.65	6.02 ± 0.33	0.0007	HbA1c	6.09 ± 0.22	5.52 ± 0.26	<.0001
Serum Insulin	15.34 ± 4.21	12.48 ± 2.38	0.003	Serum Insulin	12.35 ± 2.97	7.48 ± 1.78	<.0001
HOMA-IR	4.62 ± 2.01	3.31 ± 1.37	0.009	HOMA-IR	3.01 ± 0.98	1.58 ± 0.42	<.0001