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Study of serum lipid profile and insulin resistance in morbid obese subjects before and after Sleeve gastrectomy

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Abstract
Introduction: The prevalence of obesity and type 2 diabetes mellitus is increasing quickly and is a major challenge to health care systems in the world. Bariatric surgery, which has been used widely for the treatment of morbidly obese patients, results not only in weight loss but also in a dramatic improvement in glucose metabolism. However, there is evidence that the improvement in glucose metabolism is present immediately after surgery before any significant weight loss occurs. This evidence, therefore, supports the role of other weight loss-independent mechanisms in mediating the anti-diabetic effect of bariatric surgery. To better understand the beneficial effects of bariatric surgery it is designed a study in which Obese and morbidly obese cases with non-diabetes or uncomplicated type-2 diabetes receiving bariatric surgery have to follow. The aim was to evaluate the role of caloric restriction and weight loss on glucose and lipid metabolism after Sleeve gastrectomy (Bariatric Surgery).
Materials and methods: Obese and morbidly obese cases with non-diabetes or uncomplicated type 2 diabetes receiving Sleeve Gastrectomy. The protocol includes two phases. The first phase lasts about 9 weeks & the second phase lasts 12 weeks and subjects are seen on an out-patient basis. Glucose and lipid metabolism were assessed before beginning caloric restriction (visit 1), and again after 9 weeks (visit 2) and 12 weeks (visit 3). The improvement in glucose metabolism was evaluated by changes in fasting blood glucose, fasting insulin, and dose of Anti-diabetic medications. The improvement in lipid metabolism was evaluated by changes in lipid parameters. Potential mechanisms mediating the improved glucose metabolism, which were evaluated in the current study, include changes of the insulin sensitivity or Resistance. Changes in insulin Resistance were evaluated by changes in fasting plasma insulin, fasting plasma glucose and estimated by HOMA-IR method.
Observations and Results: Fifty cases were included in the study (19 women, 31 men; age between 20 to 40 years; duration of diabetes <10 years). There was a significant improvement in glucose metabolism after the 9wks and the 12wks of Sleeve Gastrectomy. A significant improvement in lipid metabolism was also present at visit 2 (total cholesterol decreased significantly from 174.58 mg/dl to 166.12 mg/dl and triglyceride decreased from 167.92 mg/dl to 143.92 mg/dl and LDL-cholesterol decreased significantly from 107.42mg/dl to 95.04 mg/dl and HDL-cholesterol increased from 38.46 mg/dl to 42.30 mg/dl). The improvement in glucose metabolism after caloric restriction in the study is accompanied by an improved enhanced insulin resistance or insulin sensitivity. Enhanced HOMA-IR(Insulin resistance) was decreased at visit 2 from11.08 to 9.32 and at visit 3 from 11.08 to 5.43.
Conclusion: Caloric restriction and weight loss due to Sleeve gastrectomy leads to an improvement in glucose and lipid metabolism. Properly controlled studies with larger cohorts are necessary to elucidate the beneficial effects of bariatric surgery.

Keywords: obesity, Sleeve gastrectomy, insulin sensitivity, insulin resistance

Introduction
Obesity has emerged as one of the most serious public health problem and concern in the 21st century. The consequences of this chronic disorder are serious and complicated. Bariatric surgery (Sleeve gastrectomy) has been shown to eliminate co-morbid conditions associated with obesity like diabetes mellitus and hypertension. Currently Sleeve gasterctomy is considered to be the only successful, long-term therapy and intervention for weight loss in morbid obese subjects to lead normal healthy life.

Aims and Objectives
- The aim of this study is to evaluate changes in serum lipid parameters like total cholesterol (TC), triglycerides (TG), LDL-c and HDL-c and fasting serum glucose, serum insulin, and insulin resistance in morbid obese patients before and 6,9 and 12 weeks after Sleeve gastrectomy by different analytical and assessment methods.
- The main objective of this study is to observe the early biochemical changes within 3 months after Sleeve gastrectomy and to propose a biochemical follow-up protocol in morbid obese subjects.

Materials and Methods
50 morbid obese patients of both the genders (from Metabolic & Bariatric Surgery department, SAIMS hospital) will be

included in this study. Age ranging between 20-40 yrs will be enrolled in this prospective study who agreed to undergo bariatric surgery willingly. Body mass index (BMI), waist circumference, total cholesterol (TC), high-density lipoprotein cholesterol (HDL-c), low density lipoprotein cholesterol (LDL-c), triglycerides (TG), fasting glucose, fasting insulin and insulin sensitivity will be measured before and 6,9 and 12 weeks after Sleeve Gastrectomy.

1. After taking written consent from the subjects, venous blood will be collected in Vacutainer, allowed to clot and then immediately taken to the biochemistry lab, where the samples will be centrifuged for 10 minutes, then Serum will be separated and analyzed for the following tests on HITACHI-902 and ELECSYS-2010 analyzer by Enzymatic methods: -
2. Serum Insulin Level- By Electrochemiluminescence Immunoassay Method.
3. Fasting & Postprandial Blood Glucose - By GOD-POD Method.
4. Serum Total Cholesterol- CHOD -POD Method.
5. HDL –C- By Direct Method.
6. LDL –C & VLDL-C -by Chol Method.
7. Triglycerides – By GPO – PAP Method.
8. Insulin Sensitivity-By HOMA-IR (FBG X FI/405)

Study protocol

All the Patients will undergo a clinical assessment including; medical history, physical examination and co-morbidity evaluation by a multidisciplinary consulting team. In addition, for all patients, anthropometric measurements and blood sampling for biochemical assays will be performed before and 6, 9 &12 weeks after SLEEVE GASTRECTOMY. Each subject will be given written informed consent to participate in this study, which is approved by the ethical committee of SAIMS & P.G. institution, INDORE.

Sample Size

Morbidly Obese patients, BMI>35kg/m2 as study group (50). This controlled cross-sectional study group subdivided into 4 groups of patients.

1. Group I - Morbid obese subjects selected before SLEEVE GASTRECTOMY as control group for serum analysis will be compared with the same groups post-surgery at 3 different time points.
2. Group II - Morbid obese subjects 6 weeks after SEEVE GASTRECTOMY.
3. Group III - Morbid obese subjects 9 weeks after SEEVE GASTRECTOMY.
4. Group IV - Morbid obese subjects 12 weeks after Sleeve Gastrectomy.

Inclusion Criteria

A group of 50 morbid obese patients of both the gender [age, 20-40yr), body mass index (BMI) >35kg/m2 matched for age and sex, will be included.

Exclusion Criteria

Exclusion criteria for patients with history of diabetes mellitus, hypo- or hyperthyroidism, Cushing syndrome, a history of convulsions, liver and kidney disease, ischemic heart disease, Rheumatoid arthritis, pregnancy, use of hormonal contraception, lipid-lowering drugs (statins, fibrates) and antidiabetic medications (e.g. metformin, thiazolidinediones, insulin) and patients who had undergone bariatric surgery.

Observation and Results

Table 1: Distribution of patients according to diabetes status

	Frequency	Percent
DM	22	44.0
Non-DM	28	56.0
Total	50	100.0

Table 2: Distribution of patients according to Age

	Frequency	Percent
20-30	13	26.0
31-40	36	72.0
41-50	1	2.0
Total	50	100.0

Table 3: Distribution of patients according to Gender

	Frequency	Percent
Female	19	38.0
Male	31	62.0
Total	50	100.0

Distribution according to DM & NON-DM

Table 4: Comparison of Total cholesterol – Pre-surgical, 9 weeks follow-up and 12 weeks follow-up

DM (less than 10 Y)		Pre-Surg-TCho	9wks-T.Cho	12wks-T.Cho
DM	N	22	22	22
	Mean	159.64	160.91	168.00
	Std. Deviation	40.621	30.808	25.766
Non-DM	N	28	28	28
	Mean	186.32	170.21	174.57
	Std. Deviation	36.607	41.981	23.742
Total	N	50	50	50
	Mean	174.58	166.12	171.68
	Std. Deviation	40.307	37.412	24.617

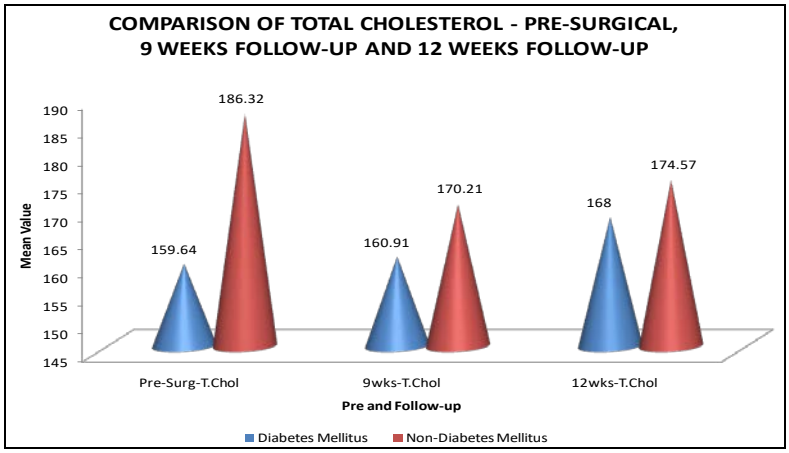

Fig 1: Comparison of total cholesterol- pre surgical. 9 weeks of follow-up and 12 weeks follow-up

Table 5: Comparison of Triglycerides – Pre-surgical, 9 weeks follow-up and 12 weeks follow-up

DM (less than 10 Y)		Pre-Surg-TG	9wks-TG	12wks-TG
DM	N	22	22	22
	Mean	155.64	144.32	164.55
	Std. Deviation	68.175	74.758	68.763
Non-DM	N	28	28	28
	Mean	177.57	143.61	143.93
	Std. Deviation	83.717	85.409	58.947
Total	N	50	50	50
	Mean	167.92	143.92	153.00
	Std. Deviation	77.296	80.093	63.624

Table 6: Comparison of HDL Cholesterol – Pre-surgical, 9 weeks follow-up and 12 weeks follow-up

DM (less than 10 Y)		Pre-Surg-HDL	9wks-HDL	12wks-HDL
DM	N	22	22	22
	Mean	38.77	42.650000	44.782500
	Std. Deviation	6.661	7.3275572	7.6939351
Non-DM	N	28	28	28
	Mean	38.21	42.035714	44.137500
	Std. Deviation	7.223	7.9455189	8.3427948
Total	N	50	50	50
	Mean	38.46	42.306000	44.421300
	Std. Deviation	6.917	7.6087332	7.9891698

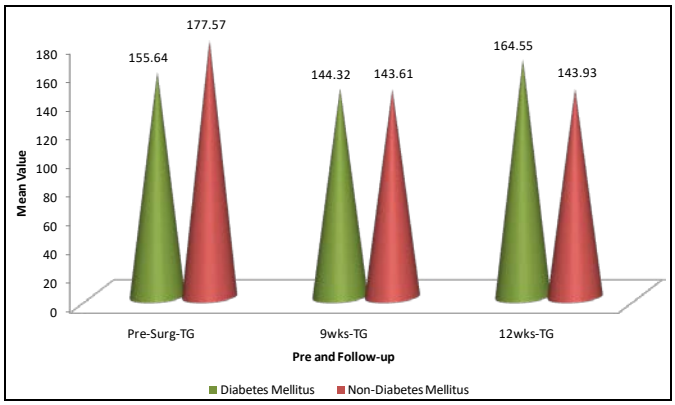

Fig 2: Comparison of triglycerides- pre-surgical, 9 weeks follow up and 12 weeks follow up.

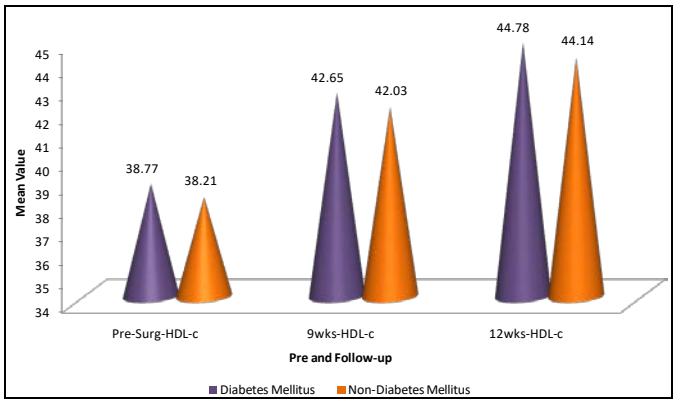

Fig 3: Comparison of HDL cholesterol – pre surgical, 9 weeks follow-up and 12 weeks follow-up.

Table 7: Comparison of LDL Cholesterol – Pre-surgical, 9 weeks follow-up and 12 weeks follow-up.

DM (less than 10 Y)		Pre-Surg-LDL	9wks-LDL	12wks-LDL
DM	N	22	22	22
	Mean	96.82	90.00	91.36
	Std. Deviation	33.138	28.724	26.451
Non-DM	N	28	28	28
	Mean	115.75	99.00	101.71
	Std. Deviation	30.999	31.191	20.743
Total	N	50	50	50
	Mean	107.42	95.04	97.16
	Std. Deviation	33.019	30.167	23.746

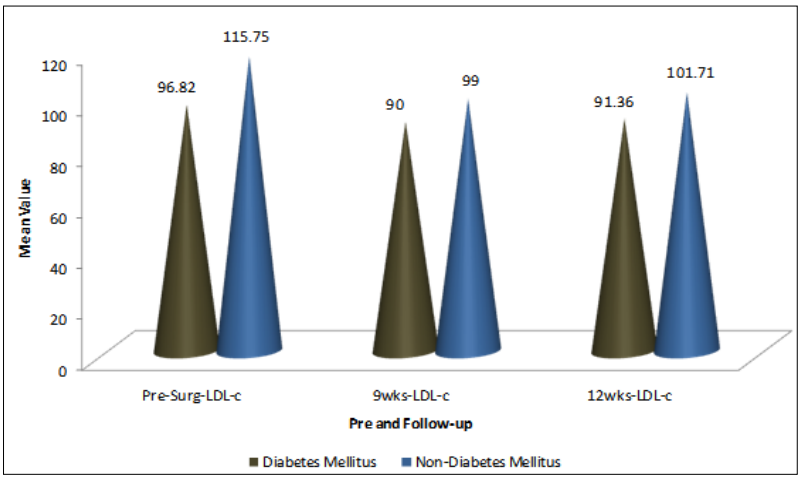

Fig 4: Comparison of LDL cholesterol – pre surgical, 9 weeks follow-up and 12 weeks follow up

Table 8: Comparison of Serum FBS – Pre-surgical, 9 weeks follow-up and 12 weeks follow-up.

DM (less than 10 Y)		Pre-Surg-S.FBS	9wks-S.FBS	12wks-S.FBS
DM	N	22	22	22
	Mean	208.23	192.50	157.64
	Std. Deviation	57.155	53.280	42.775
Non-DM	N	28	28	28
	Mean	137.79	130.18	119.14
	Std. Deviation	33.749	28.618	21.438
Total	N	50	50	50
	Mean	168.78	157.60	136.08
	Std. Deviation	57.229	51.424	37.549

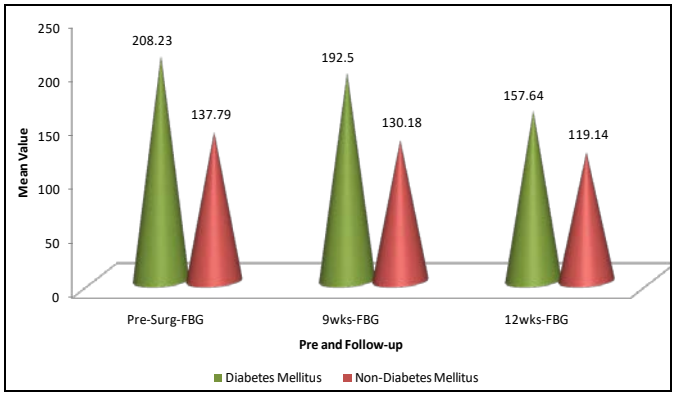

Fig 5: Comparison of fasting blood glucose – pre surgical, 9 weeks follow-up and 12 weeks follow-up

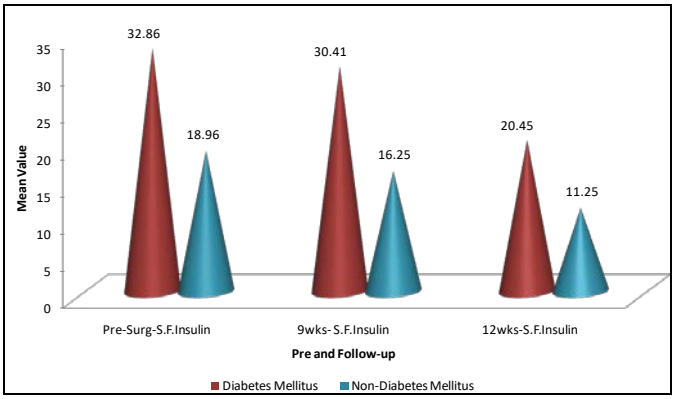

Fig 6: Comparison of serum fasting insulin pre surgical 9 weeks follow up and 12 weeks follow up.

Table 9: Comparison of Serum F. Insulin – Pre-surgical, 9 weeks follow-up and 12 weeks follow-up.

DM (less than 10 Y)		Pre-Surg-S.F.Insulin	9wks-S.F.Insulin	12wks-S.F.Insulin
DM	N	22	22	22
	Mean	32.86	30.41	20.45
	Std. Deviation	8.725	8.433	5.869
Non-DM	N	28	28	28
	Mean	18.96	16.25	11.25
	Std. Deviation	6.642	6.456	4.805
Total	N	50	50	50
	Mean	25.08	22.48	15.30
	Std. Deviation	10.271	10.191	6.985

Table 10: Comparison of Resistance – Pre-surgical, 9 weeks follow-up and 12 weeks follow-up.

DM (less than 10 Y)		Pre-Surg-Resistance	9wks-Resistance	12wks-Resistance
DM	N	22	22	22
	Mean	16.686548	14.262386	8.042185
	Std. Deviation	5.5971329	4.8212641	3.9438176
Non-DM	N	28	28	28
	Mean	6.691214	5.439335	3.380368
	Std. Deviation	3.2454390	2.7325453	1.5229149
Total	N	50	50	50
	Mean	11.089161	9.321478	5.431567
	Std. Deviation	6.6595395	5.8007839	3.6616960

- Fifty cases were included in the study (19 women, 31 men; age between 20 to 40 years; duration of diabetes <10 years). Most of the subjects had good glycaemic control.
- There was a significant improvement in glucose metabolism after the 9wks and the 12wks of Sleeve Gastrectomy. This improved glucose metabolism is evident from a significant decrease in fasting blood glucose at visit 2 (9wks) (decreased from 168.78 mg/dl to 157.60 mg/dl, $p < .01$), and from the combined decrease in fasting blood glucose, at visit 3(12wks) (fasting blood glucose deceased from 168.78 mg/dl to 136.08 mg/dl, $p < .001$);
- A significant improvement in lipid metabolism was also present at visit 2 (total cholesterol decreased significantly from 174.58 mg/dl to 166.12 mg/dl and triglyceride decreased from 167.92 mg/dl to 143.92 mg/dl and LDL-cholesterol decreased significantly from 107.42mg/dl to 95.04 mg/dl and HDL-cholesterol increased from 38.46 mg/dl to 42.30 mg/dl).
- The improvement in glucose metabolism after caloric restriction in the study is accompanied by an improved enhanced insulin resistance or insulin sensitivity. Enhanced HOMA-IR(Insulin resistance) was decrease at visit 2 from11.08 to 9.32 and at visit 3 from 11.08 to 5.43, and evident from the significant improvement in fasting plasma insulin (decreased from 25.08 μU/ml to 22.48 μU/ml, $p < .05$) at visit 2 and from 25.08 μU/ml to 15.30 μU/ml at visit 3)

Conclusion

- In this study it is evaluated that mechanisms of glucose metabolism is improved, in obese and morbid obese with uncomplicated type 2 diabetic and non-diabetic cases after sleeve Gastrectomy.
- Caloric restriction and weight loss due to Sleeve gastrectomy leads to an improvement in glucose and lipid metabolism.
- Improved glucose metabolism after Sleeve gastrectomy may be mediated by an improvement in the insulin Resistance.
- Improved lipid metabolism after Sleeve gastrectomy leads to increase in HDL-C and decease in LDL-C which will reduce risk of cardiovascular disease.
- Improvement in glucose metabolism after Sleeve gastrectomy may be at least partly explained by caloric restriction and weight loss, not specific for the type of intervention.
- Properly controlled studies with larger cohorts are necessary to elucidate the beneficial effects of bariatric surgery.

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