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Efficacy of SADI-S vs MGB on Type 2 Diabetes Mellitus in Morbidly Obese Patients: Comparative Analytical Study

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ABSTRACT

Background: Body mass index (BMI) greater than 40 kg/m^2 is known as morbid obesity which is considered to be a complicated health status now day. Now a day bariatric surgery represents golden approach for long term management of morbid obesity not only for weight reduction but also for control of associated metabolic complication especially diabetes mellitus type 2. SADI-S is associated with superior outcomes in the treatment of type 2 diabetes mellitus (DM) compared to other surgical choices.
Methods: This study was done between June 2017, and June 2020. The study population included 50 obese patients complaining from diabetes type. 50% of the patients underwent Mini Gastric Bypass, and the other half underwent SADI-S.
Results: the study group mean age was 38.12 (±8.44) years. Thirty-four patients (68%) were females and 16 (32%) were males. The BMI ranged between 40 -58 kg /m^2 with a mean of 49.36 (±7.44) kg/m^2. Both groups achieved a statistically significant reduction in weight and BMI, and glycemic levels (HbA1C), but the MGB had a significant favorable effect over the SADI-S as regards the lipid profile.
Conclusion: Both SADIS and MGB are highly effective in controlling Type 2 diabetes, other metabolic syndrome manifestations.
Key words: bariatric surgery, redo surgery, metabolic surgery, minigastric by pass, failed VBG

Abbreviations:
BMI - Body mass index,
DM - diabetes mellitus,
T2DM - diabetes type two

INTRODUCTION

Body mass index (BMI) greater than 40 kg/m^2 considered to be the most scientific explanation for morbid obesity nowadays. In the last decade, the mean BMI in the population of age 20 years or older has been increasing at a rate of 0.4 kg/m^2 (1). Obesity is a complex disease which is associated with major metabolic complication's such as diabetes type two (T2DM), hypertension, obstructive sleep apnea, heart disease (2).

Diabetes mellitus (DM) defined as hyperglycemia state secondary to decrease insulin secretion or defect in its action on the receptor or post-receptor level (3).

Now a day bariatric surgery rise as an effective way not only for weight reduction, but also for the treatment of associated co-morbidity in morbid

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obese patients. Complete diabetes remission was noticed by bariatric surgeon in many patients who did weight loss gastric bypass surgery (4).

In 1977 Dr Robert Rutledge from published his first research on MGB. Decrease size of the stomach (refashioning into small narrow tube) followed by connecting this tube to loop of small intestine about 180 to 250 cm from the start of the intestine (ligament of Treitz) is defined as MGB (5).

Aiming to simplify, to decrease the potential complication rate, and to maintain or even to improve, if possible, the out-comes of bilio-pancreatic diversion principles, single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) delivered as a new bariatric operation (6).

This prospective study aimed to compare efficacy of SADI-S vs MGB in the treatment of type 2 Diabetes mellitus in morbid obese patients.

METHODS

Our study was carried out between June 2017 – June 2020 in the bariatric unit at general surgery department in Ain shams university medical hospitals. 50 morbid obese patients with diabetes type 2 were enrolled in this study. Half of patients under went SADI-S and half of them under went MGB. Written informed consents were obtained and the study acquired ethical review committee approval.

Patients enrolled in this study aged between 18-60 years with BMI > 40 kg/m^2, with history of diabetes type 2 not more than 5 years. Patients were excluded if they had endocrine abnormalities (e.g. hypothyroidism, Cushing syndrome), previous bariatric or major abdominal surgery, significant ventral hernia, or contraindication to insufflation as those with severe cardiovascular or restrictive respiratory diseases.

Preoperatively full clinical assessment was done for all patients including full medical history with special focus on previous attempts for lose weight in the last two years, detailed dietary history, and associated comorbidities, full clinical examination including BMI measurement and abdominal examination, and laboratory investigations that included a complete blood picture, liver (SGOT/ SGPT/Serum Albumin) and kidney (Urea/Creatinine) function tests, full lipid profile (LDL /HDL/Triglyceride/Cholesterol), hemoglobin A1C, besides the routine preoperative investigations. High protein diet was instructed for all patients and to perform regular exercises one week before the operation, while the day before the operation they were instructed to only take clear fluids.

For patients whom underwent SADI-S, the greater curvature of the stomach was devascularized followed by sleeveing of the stomach over a 40 French oral bougie, with linear stapler about 5 cm proximal to the pylorus (regular sleeve). The dissection of the greater curvature was then prolonged through the duodenum followed by division of the duodenum preserving all the vascularization to the lesser curvature especially supraduodenal artery. The ileocecal junction was identified, and 350 cm of the ilium was measured upwards regardless the total length of the intestine, the selected loop was lifted up in an antecolic fashion to the duodenal stump end to side duodeno-ileal-anastomosis was done (*figures 1, 2*).

For patients whom underwent MGB after pneumoperitoneum was achieved as previously, dissection of phreno-gastic ligament was performed followed by creation of a window at the level of incisura to enter lesser sac. A gastric tube was then created starting just below incisura using three 60 mm linear stapler. Anterior gastrostomy was done in the new pouch. 180-250 cm loop of jejunum was measured from the ligament of treitz regardless the total length of the intestine and then an antecolic-antegastric gastro-jejunostomy was done. The residual stoma is closed manually (*figures 3, 4*).

Postoperatively, patients received nothing by mouth; gastrografin study was performed on the third postoperative day. Postoperative anticoagulation, proton pump inhibitors, and antibiotics were administered to all patients. Patients were usually discharged on the fourth postoperative day and they were instructed to follow five stages of diet each for one week under supervision of the nutritionists (clear fluids, protein rich fluids, smashed diet, low-calorie soft food, and then low-fat low-sugar food).

The follow up period was carried out on an outpatient clinic: weekly for one month postoperatively, then at 6 weeks, 3 months, 6 months, and 1 year postoperatively. Each visit, the patient was followed up by BMI, HbA1c, blood pressure, and lipid profile.

Statistical analysis

The comparison between groups regarding qualitative data were done by using Chi-square test while comparison between two group with quantitative data and parametric distribution were done by using Independent t-test. P-value was considered significant at the level of < 0.05; the sample size was calculated using a two-sided two-sample t-test.

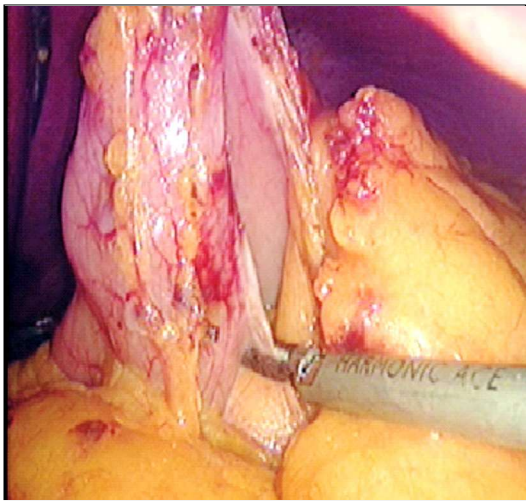

Figure 1 - Rertroduoduenal dessection in SADI-S

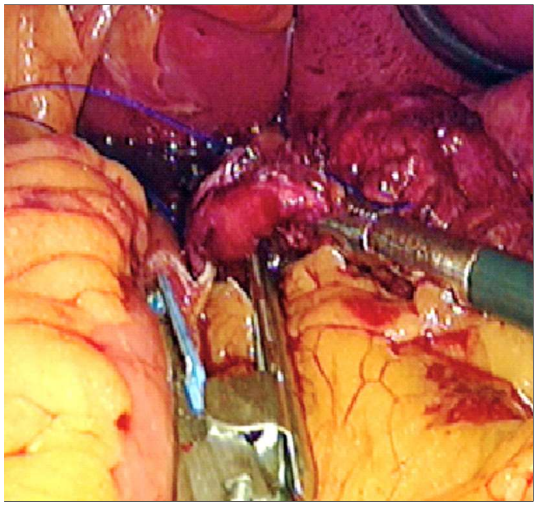

Figure 2 - Side toside anastomosis in SADI-S

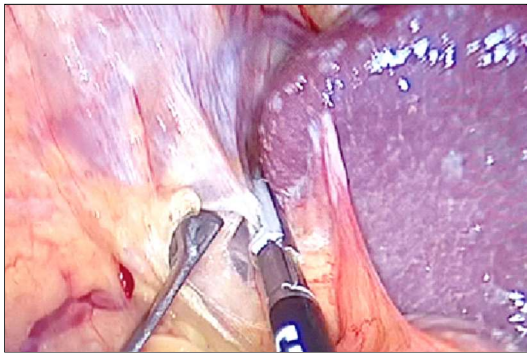

Figure 3 - Phreno gastic dessection

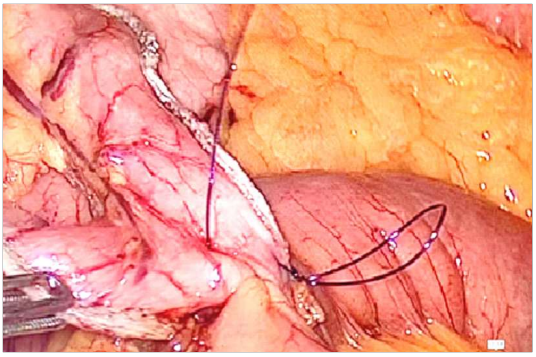

Figure 4 - Gastro jejenal anastmosis

RESULTS

Fifty patients were involved in this study with age ranged between 25 -55 years with a mean (SD) of 38.12 (±8.44) years. The BMI ranged between 40-58 kg/m^2 with a mean (SD) of 49.36 (±7.44) kg/m^2. Thirty-four of patients (68%) were females and 16 (32%) were males. No statistically significant differences were found between both groups as regards demographic characteristics or baseline medical parameters. There was no statistically significant differences were found between both groups as regard operative time and intra or postoperative complications .No morbidity or mortality in both groups

Family history for DM was positive in 30 patients (60%) and negative in 20 patients (40%). Twelve patients (24%) were on insulin while 38 patients (76%) on oral hypoglycemic medications. Twenty-three patients (46%) on anti-hypertensive medications and 10 (20%) were on anti-hyperlipidemia medications. The preoperative HbA1C ranged between 8.5-13% with a mean (SD) of 11.12 (±1.44) %.

Both groups achieved a statistically significant reduction in almost all measured parameters when comparing preoperative measurements to postoperative 3 months, 6 months, and 12 months postoperatively. *Table 1* demonstrates change in parameters over time in the SADI-S group while *table 2* demonstrates the change in the MGB group. A statistically significant reduction was detected postoperatively in both groups regarding HbA1C levels, FBS, number of patients on insulin, number of patients with hypertension, total triglycerides measured, serum cholesterol levels, LDL and HDL levels. No statistically significant difference was detected in serum ferritin levels in both groups between preoperative measurements and postoperative ones.

DISCUSSION

Diabetes has been considered one of the most dangerous global public health threats in the new decad, (7) and bariatric surgery has been involuting as golden key to control such a threat (4). In this work, we

Table 1 - The extent of the difference regarding different measured variables at preoperative and 3, 6 and 12 months postoperative in the SADI-S group (n=25)

Variable	Pre-operative	Post-operative (3 months)	Post-operative (6 months)	Post-operative (12 months)	F/x2#	p-value
DM						
HbA1c						
Mean±SD	10.92±1.19	8.8±0.91	7.86±0.93	6.06±0.87	16.485	<0.001**
Range	9-13	7-11	6-10	5-8		
FBS						
Mean±SD	176.8±15.47	138.4±10.28	128.8±13.33	101±21.41	14.348	<0.001**
Range	150-210	120-160	100-150	70-140		
Treatment						
Insulin	12(48.0%)	3 (12.0%)	0 (0%)	0 (0%)	61.451	<0.001**
Oral	13 (52.0%)	8 (32.0%)	16 (64.0%)	2 (8.0%)		
Stopped	0 (0.0%)	14 (56%)	9 (36.0%)	23 (92%)		
HTN	12 (48.0%)	9 (36.0%)	4 (16.0%)	3 (12.0%)	10.714	0.013*
TG						
Mean±SD	193.4±32.01	157.6±20.47	145.92±23.67	120.4±13.61	11.225	<0.001**
Range	140-300	120-200	90-190	95-145		
Cholesterol						
Mean±SD	232±18.93	215.2±14.75	200±13.54	185.6±9.61	10.942	<0.001**
Range	190-260	180-240	170-230	160-200		
LDL						
Mean±SD	166.4±12.21	156.4±12.21	132.8±13.08	114.4±8.21	17.882	<0.001**
Range	140-190	130-180	100-150	100-130		
HDL						
Mean±SD	47±4.83	49.76±4.47	53.2±4.50	56±11.08	3.706	0.005*
Range	41-57	44-59	47-62	6-64		
Serum ferritin						
Mean±SD	85.2 ± 26.57	82.8±32.73	71.32±35.22	77.6±35.94	0.548	0.586

p-value < 0.001 HS**

Table 2 - The extent of the difference regarding different measured variables at preoperative and 3, 6 and 12 months postoperative in the MGB group (n=25)

Variable	Pre-operative	Post-operative (3 months)	Post-operative (6 months)	Post-operative (12 months)	F/x2#	p-value
DM						
HbA1c						
Mean±SD	11.36±1.15	8.6±1	7.9±1.37	6.02±0.96	17.823	<0.001**
Range	9-13	7-10	6-11	5-8		
FBS						
Mean±SD	182±17.80	139.96±13.51	127.2±17.20	93.84±27.54	13.442	<0.001**
Range	150-210	120-170	100-160	9-150		
Treatment						
Insulin	8 (32.0%)	5 (20%)	0 (0.0%)	0 (0%)	48.985	<0.001**
Oral	17 (68.0%)	15 (60%)	8 (32.0%)	5 (20.0%)		
Stopped	0 (0.0%)	5 (20%)	17 (68.0%)	20 (80.0%)		
HTN	11 (44.0%)	11 (44.0%)	5 (20.0%)	4 (16.0%)	7.994	0.046*
TG						
Mean±SD	216.8±35.91	176±18.71	166.6±17.72	132.8±17.68	10.897	<0.001**
Range	120-280	150-230	140-220	100-160		
Cholesterol						
Mean±SD	226.4±17.29	205.6±15.83	189.2 ±11.15	165.6±10.03	14.812	<0.001**
Range	200-260	170-240	160-210	150-180		
LDL						
Mean±SD	168±13.84	154±14.14	131.2±13.01	112.8±7.37	18.737	<0.001**
Range	140-190	130-180	110-160	100-120		
HDL						
Mean±SD	47.52±6.04	50.76±4.62	54.88±4.35	59±2.89	8.557	<0.001**
Range	41-65	44-62	50-65	55-64		
Serum ferritin						
Mean±SD	82.16	79.6±32.59	61.16±37.01	66.44±38.22	1.32	0.193

p-value < 0.001 HS**; *p-value < 0.05 S*

Table 3 - Comparison between both groups according to postoperative parameters at final follow up (12 months)

Parameter	SADI-S (N=25)	MGB (N=25)	p-value
Anthropometric measurements			
Wt.			
Mean±SD	79.8±13.97	78.04±13.18	0.649
Range	50-105	60-110	
DM			
HbA1c			
Mean±SD	6.06±0.87	6.02±0.96	0.878
Range	5-8	5-8	
FBS			
Mean±SD	101±21.41	93.84±27.54	0.310
Range	70-140	9-150	
TTT			
Insulin	0 (0%)	0 (0%)	
Oral	2 (8.0%)	5 (20.0%)	0.221
Stopped	23 (92.0%)	25 (80%)	
HTN	3 (12.0%)	4 (16.0%)	0.684
Lipid Profile			
TG			
Mean±SD	120.4±13.61	132.8±17.68	0.008*
Range	95-145	100-160	
Cholesterol			
Mean±SD	185.6±9.61	165.6±10.03	<0.001**
Range	160-200	150-180	
LDL			
Mean±SD	114.4±8.21	112.8±7.37	0.472
Range	100-130	100-120	
HDL			
Mean±SD	56±11.08	59±2.89	0.197
Range	6-64	55-64	
Serum ferritin			
Mean±SD	77.6±35.94	66.44±38.22	0.293
Range	10-150	6-120	

p-value < 0.05 S*; p-value < 0.001 HS**; p-value > 0.05 NS

are trying to evaluate the effectiveness of SADI-S and MGB in control of type 2 DM and other metabolic parameters in morbid obese patients.

In our study when we compare both groups at the final follow up of 12 months (*table 3*), there was no statistically significant difference could be detected as regards absolute weight reduction (p = 0.649), HBA1c and FBS levels (p = 0.878 and 0.310, respectively), proportion of patients that stopped DM treatment (p = 0.221), those with hypertension (p = 0.684), LDL, HDL, and serum ferritin levels (p = 0.472, 0.197, and 0.293, respectively). A statistically significant difference in favor of the MGB group was found regarding total triglyceride levels (p = 0.008) and serum cholesterol levels (p < 0.001).

In study done by Rutledge and Walsh (8) on 2,410 patients who underwent laparoscopic MGB they demonstrated the long-term safety of the procedure in 2005. Since then, the popularity of the procedure has been rising among bariatric surgeons, with further demonstration of favorable effect on metabolic risk factors (9). In another study done by Buchwald et al (10) they conducted a systematic review and meta-analysis on bariatric surgery in 2004 and reported a significant decrease in levels of total cholesterol, LDL cholesterol, and triglycerides after bariatric procedures in 70 % of patients. DM was completely resolved in 76.8% of the patients, while hypertension resolved in 61.7% of the patients.

In 2013, Pernaute et al (11) reported a mean excess weight loss of 95% after 12 months postoperative in a case series of 100 patients with morbid obesity or metabolic disease who were managed with (SADI-S), while in 2015, the same group published a case series of 97 obese patients with type 2 diabetes managed with SADI-S, and reported an excess weight loss of 73% at 6 months, 91% at the first year, and 92% in the second postoperative year (6). In another work, the same group also reported that overall diabetes remission rate to be 77% at 2 years and 52% at 5 years postoperative, denoting possible cumulative long-term effects, whereas Zaveri et al. reported that the remission rate

over 4-year follow-up post SADI-S is 81% (12).

In our study, we can stat that multiple factors were associated with better T2DM remission including younger age, male gender, cases on oral hypoglycemic medication, central distribution of body fat, negative family history of D.M, and high preoperative C-peptide level. We found that a shorter duration of T2D.M (<5 years) and better preoperative diabetic control (HBAlc < 8.5%) to be the most independent significant predictors for diabetes resolution and other significant predictors were dependent on them.in study done by Lee et al., they reported that the surgical technique (LGB, LMGB, and LSG), waist circumference, and C-peptide levels to be the most significant predictors for the remission of T2DM in obese patients while Milone et al, reported HBAlc to be a negative predictor of diabetes remission (9).

A limitation to our work is the relatively small sample size, and the non-randomized design of our study. Another limitation is the relatively short follow up period of 1 year with the possibility of missing long-term cumulative benefit of the surgery.

CONCLUSION

In conclusion, we can say that both SADI-S and MGB are both highly effective and safe with high similarity in the post-operative outcome for the management diabetic in morbid obese patients. However, long term follow up period and more number of patients are needed to confirm these results.

Conflicts of interest and source of funding

None declared.

Ethical approval

For performing this study ethical approval was obtained.

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