Effect of Laparoscopic Sleeve Gastrectomy on Type 2 Diabetes Mellitus Obese Patients

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Background: Type 2 diabetes mellitus represents high proportion of diabetics which is mainly due to obesity and insulin resistance. Obesity is asscoiated with many co-morbidities like type 2 DM, cardiovascular (CV) complications, hypertension and dyslipidymia. Laparoscopic sleeve gastrectomy (LSG) was used as the first stage in a multistage procedure in obese patients with at least two severe co-morbidities. Two years after sleeve gastrectomy, more than 50% of those patients showed resolution of their co morbidities. Bariatric surgery has emerged as a highly effective management for morbid obesity and many related co-morbidities, including type 2 diabetes mellitus (T2DM). However, it has recently been approved that LSG is more than a gastric restrictive operation. It has been suggested that the changes in ghrelin and peptide YY after LSG may help to explain the weight loss results. So the aim of this study was to evaluate the effect of laparoscopic sleeve gastrectomy (LSG) on obese patients with type 2 DM.

Methods: This study was conducted on 30 obese patients suffering from T2DM (9 males and 21 females) who underwent laparoscopic sleeve gastrectomy at the Ain Shams University Hospital (El-Demerdash) and Ain Shams Specialized Hospital. Follow up of the patients was done for a period of 6 months to investigate their HbA1c changes and diabetic status.

Results: Our results showed significant reduction in the mean level of HbA1c ($p<0.001$) at 6 months follow-up post-surgery, with 16.7% (5 patients) completely cured from T2DM while 40% (12 patients) became pre-diabetic and 43.3% (13 patients) remained diabetic.

Conclusion: Most patients with type 2 DM experience resolution or improvement in diabetic status after LSG. LSG might play an important role as a metabolic therapy for patients with type 2 DM.

Key words: Obesity- type 2 diabetes mellitus- Laparoscopic sleeve gastrectomy.

Introduction

Type 2 diabetes mellitus and obesity are assumed to be two major public health problems worldwide nowadays. Vascular complications are thought to be the leading cause of disability in diabetics. The high cardiovascular (CV) risk that diabetes induces is better explained by approaching not only hyperglycemia but also the usual coexisting risk factors.[1]

Better glucose control with lowering hemoglobin A1c (HbA1c) value to 6.5% yielded a 10% relative reduction in major macrovascular and microvascular events. However, in another study, an intensive glucose control in patients with poorly controlled T2DM had no significant effect on the number of major CV events, deaths, or microvascular complications.[1]

Remission of type 2 DM can be achieved by surgical procedures in the majority of morbidly obese patients.[1]

Bariatric surgery is starting to be effective and long-lasting treatment for morbid obesity and many related conditions, including type 2 diabetes mellitus (T2DM) and the metabolic syndrome (MS).[2]

LSG is a surgical procedure, by which a laparoscopic vertical gastrectomy is done, that excises the fundus and the lateral 80% of the gastric body leaving a tubular-like stomach with an intact pylorus.[1]

Since its introduction, the procedure has gained acceptance due to its simplicity, good results in weight lost, and less complication.[1]

The aim of this operation is to remove a part of the stomach in order to provide long-lasting control of obesity, to decrease caloric intake, to accelerate gastric emptying, and to decrease the circulating levels of ghrelin Hormone.[1]

This surgery is associated with increase in insulin sensitivity and ß cell function which could be related to decrease ghrelin levels postoperatively and these results have been compared to non-resection restrictive procedures like adjustable gastric banding. Therefore, it is assumed that the final effect of procedures involving gastric

transection decreases the serum ghrelin levels and improves insulin sensitivity.[3]

The other characteristic of the operation is to correct the defective amplification of the late-phase plasma insulin response to glucose by (glucose-dependent insulinotropic polypeptide) (GIP). Both characteristics were addressed in a recent publication of the hormonal changes before and after LSG.[1]

Also, data collected have shown that Sleeve Gastrectomy (GS) is associated with a high rate of resolution of T2DM and other obesity related co-morbidities such as hypertension, hyperlipidemia, and sleep apnea.[4]

Aim of the work

To determine the effect of LSG on blood glucose level in type 2 diabetic obese Egyptian patients.

Patients and methods

- **Patients:**

This prospective study was conducted on thirty obese Egyptian patients with type 2 diabetes mellitus that underwent LSG at the Ain Shams University Hospital (El-Demerdash) and Ain Shams Specialized Hospital. All the patients met the inclusion/exclusion criteria followed the by the National Institute of Health (NIH) Bariatric guidelines.[5]

Inclusion criteria: were type 2 diabetic obese patients aged more than 18 years old, BMI ≥ 35 kg/m2 with duration of diabetes > 1 year, glycated hemoglobin (HbA1c) ≥ 6.5%, receiving either oral hypoglycemic drugs (0HG) or insulin or OHG +insulin.

Exclusion criteria: were type 1 diabetic patients, glycated hemoglobin (HbA1c) < 6.5%, age <18 years, BMI < 35 kg/m2, endocrine obesity, a history of medical problems such as mental impairment, drug or alcohol addiction and patients who had previous bariatric surgeries.

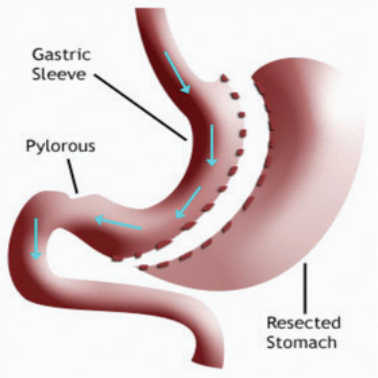
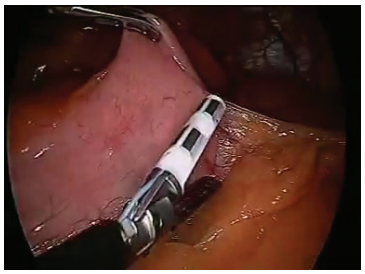


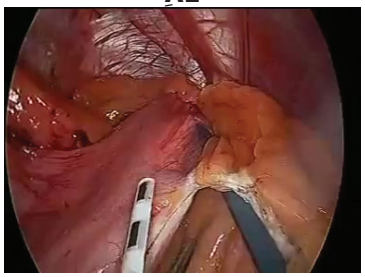
Fig 1: Diagram show Sleeve gastrectomy procedure.[7]

- **Methods:**

1. **Preoperative evaluation:** The preoperative evaluation included discussing in detail the risks, benefits and long-term consequences of the procedures during the initial encounter with the surgeon, internist and dietician. All patients were examined by a medical team consisting of an internist, a bariatric surgeon, a psychiatrist, and a dietician. All patients were subjected to the following: Full history taking, clinical examination, calculation of body mass index (BMI),[6] and laboratory investigations including: complete blood picture, liver function tests, renal functions tests, hepatitis markers (HBsAg and HCVAb), glycated hemoglobin (HbA1c) and fasting blood sugar on day of operation. Written informed consent was obtained from all patients before being assigned to surgery.
2. **Operative technique:** Surgical technique LSG was performed according to the technique described by Gagner[7] - Division of the gastric greater curvature vascular supply, starting at 6-8 cm from the pylorus and proceeding upwards until the angle of His, was carried out with Harmonic Scalpel, (Ethicon). The LSG was created using a linear stapler Endo GIA, with two sequential 60-mm green load firings for the antrum, followed by two or three sequential 60- mm blue loads for the remaining gastric corpus and fundus. The stapler was applied alongside a 36 Fr calibrating bougie strictly positioned against the lesser curve, to obtain a 120-150 ml gastric pouch. The resected stomach was extracted by enlargement of the 15-mm port-site. Abdominal drainage was left in place.

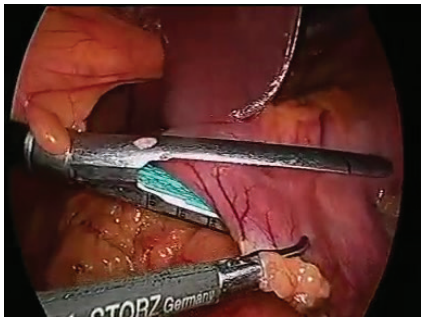


A1

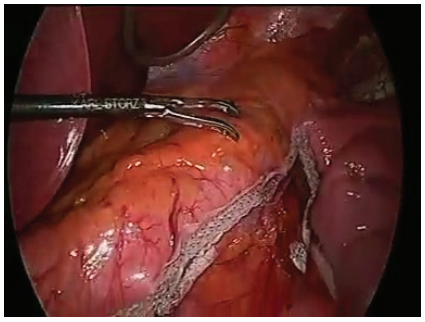


A2

Figs: 2A1,A2 The division of the gastric greater curvature vascular supply, starting at 6-8 cm from the pylorus.



B1



B2

Figs: 3B1,B2 The LSG is created using a linear stapler (Endo GIA).

3. **Postoperative care:** All patients were monitored in the recovery room and were transferred to the wards or to the intensive care unit. Early postoperative ambulation was strongly encouraged with patients getting out of bed the evening of the surgery and walking by the first postoperative day. A clear liquid diet was started on first postoperative day, and was advanced to pureed food 2 weeks later, and to solid food by the fourth postoperative week. Patients were advised to take daily multivitamins and supplemental minerals, as well as proton pomp inhibitor (PPI) prophylaxis for 6 months. Follow-up appointments with the internist, surgeon and the dietitian were scheduled at second week, 3, and 6 months postoperatively, with six months follow up of (HbA1c) after laparoscopic sleeve gastrectomy with assessment at 0, 3, 6 months interval. Patients were grouped to non-diabetic (HbA1c<5.7%), pre- diabetic (HbA1c 5.7%-6.4%), and diabetics (HbA1c≥6.5%) at 6 month of follow up.

Statistical analysis:

The collected data was revised, coded, tabulated and introduced to a PC using Statistical package for Social Science (SPSS 19.0.1 for windows; SPSS Inc, Chicago, IL, 2001). Quantitative data was presented as Mean and Standard deviation (±SD) while number and percentage was used to present qualitative data. Fisher exact test was used to analyze qualitative data. Repeated measure ANOVA was used to analyze quantitative data measured more than two times for one group, with Bonferroni post hoc test for pair wise comparisons. Friedman test was used to analyze quantitative data measured more than two times for one group. ANOVA was used to analyze quantitative data measured between more than two groups. P Value<0.05 will be considered statistically significant.

Results

1-Descriptive data:

Patients' descriptive data are described in **Table 1**. This study was conducted on 21 Females (70%) and 9 males (30%), their mean age was 33.6±10.51years, range (18-58). The mean pre-operative weight was 137.87±21.28 Kg (range 101- 166 Kg). The mean pre-operative body mass index was 44.91±5.49 Kg/m² (range 36-55 Kg/m²) as shown in **Table 2**. Regarding pre-operative hypoglycemic medications, 20 patients (66.7%) were on OHG, 6 patients (20%) on insulin and 4 patients (13.3%) on both OHG + insulin as shown in **Table 2 and Figure 4**.

The mean pre-operative fasting blood sugar (FBS) on the day of surgery was 197.53±35.2 mg/dl, range (120-283 mg/dl), with mean HbA1c 7.95±0.88 %, range (6.55-10.2%). At 3 months follow-up, there was decline in the mean of HbA1c; it reached 7.27±0.77%, range (5.8-9.14%). At 6 months follow-up, much more decline occurred in the mean of HbA1c; it reached 6.47 ± 0.75 %, range (5.16-8.6%) as shown in **Table 3**.

30 T2DM patients who underwent LSG were enrolled in this study; on follow up at 3 months, 4 patients (13.3%) became pre-diabetic and 26 patients (86.7%) remained diabetic. At 6 months follow up, more improvement occurred, 5 patients (16.7%) became non- diabetic, 12 patients (40%) became pre-diabetic and 13 patients (43.3%) remained diabetic as shown in **Table 4**.

2-Comparitive data:

Comparison between the mean values of HbA1c at 0, 3, 6 months follow-up among patients who underwent LSG; revealed a highly significant reduction (p=0.0001) in the mean value of HbA1c at 3 months and at 6 months as shown in **Table 5 and Fig. 5**.

Follow up of diabetic status of patients for 6 months after LSG revealed a highly significant reduction in the number of diabetic patients (HbA1c≥6.5%) reaching 43.3 % (p=0.001) as shown in **Table 6**.

In terms of treatment based outcomes, patients who were on OHG (pre-operative) showed better reduction in the mean of value of HbA1c (6.39±0.77%) than those on insulin (6.59±0.82%) and OHG+insulin (6.74±0.63%) at the 6 months

follow up as shown in **Table 7 and Figure 6**.

Moreover, better reduction in the number of diabetic patients who were on OHG (35 %) than those on insulin (66.7 %) and OHG+insulin (50%) at the 6 months follow up was noted. However, these differences lacked statistical significance with p=0.643, 0.695 respectively as shown in **Table 7**.

Table 1: Studied Patients` descriptive data

No	Age	Gender	Weight .in kgs	BMI	Type of anti diabetic treatment	FBS on surg. day	HbA1c 0 Month	HbA1c 3 Months	HbA1c 6 Months
1	55y	Female	130kgs	42	OHG	220mg/dl	7%	6.5%	5.6%
2	35y	Female	140kgs	46	INSULIN	181mg/dl	8.26%	5.8%	5.16%
3	58y	Female	120kgs	41.5	OHG	120mg/dl	7.4%	6.8%	5.8%
4	40y	Female	101kgs	37	OHG	171mg/dl	7.3%	7.1%	6.4%
5	37y	Female	109kgs	36.8	OHG	162mg/dl	8.2%	7.3%	6.7%
6	37y	Female	124kgs	41.75	OHG	200mg/dl	7.8%	7.12%	6.4%
7	44y	Female	162kgs	52	OHG+insulin	190mg/dl	7.7%	7.2%	6.15%
8	21y	Female	164kgs	51	OHG	202mg/dl	7.4%	7.16%	6.2%
9	38y	Female	107kgs	37.5	OHG	183mg/dl	7.8%	7.22%	6.3%
10	43y	Female	128kgs	43	OHG	203mg/dl	7.6%	7.4%	6.8%
11	23y	Female	128kgs	44.2	OHG	160mg/dl	9%	8.23%	7.6%
12	30y	Male	160kgs	49	INSULIN	196mg/dl	7.4%	7.1%	7%
13	26y	Male	150kgs	48.2	INSULIN	154mg/dl	8.7%	8%	7.2%
14	18y	Female	133kg	43	OHG	240mg/dl	7.3%	6.44%	5.3%
15	30y	Male	154kgs	47.8	INSULIN	220mg/dl	8%	7.6%	6.5%
16	27y	Female	160kgs	49.5	OHG	207mg/dl	7.4%	7%	6.5%
17	22y	Female	131kgs	41	INSULIN	193mg/dl	9.4%	8.1%	7.40%
18	36y	Male	140kgs	45	OHG	223mg/dl	8.55%	7.8%	6.7%
19	28y	Male	165kgs	52.3	OHG	194mg/dl	7.6%	7.1%	6.2%
20	43y	Female	108kgs	38	OHG	176mg/dl	7.2%	6.9%	6.4%
21	39y	Female	166kgs	55	OHG	283mg/dl	10.2%	9.14%	8.6%
22	23y	Female	105kgs	36	OHG+insulin	172mg/dl	7.2%	7%	6.4%
23	46y	Male	148kgs	47	OHG	186mg/dl	7.4%	7.1%	6.2%
24	32y	Female	155kgs	49	OHG	258mg/dl	9%	8.25%	6.8%
25	28y	Male	157kgs	49.5	OHG	222mg/dl	7.23%	6.9%	6.4%
26	45y	Female	122kgs	41	OHG	132mg/dl	7.2%	6.4%	5.5%
27	24y	Female	166kgs	54	INSULIN	202mg/dl	8.3%	7.16%	6.3%
28	40y	Male	145kgs	44.75	OHG+insulin	244mg/dl	9.9%	8.2%	7.6%
29	21y	Male	151kgs	47.5	OHG+insulin	232mg/dl	8.5%	7.88%	6.8%
30	19y	Female	107kgs	37	OHG	200mg/dl	6.55%	6.1%	5.3%

Table 2: Personal and medical data of the studied patients underwent Laparoscopic Sleeve Gastrectomy (LSG)

		Mean	SD ±	Minimum	Maximum
Age		33.60	10.51	18.00	58.00
Weight		137.87	21.28	101.00	166.00
BMI		44.91	5.49	36.00	55.00
		N	%		
Gender	Male	9	30.0%		
	Female	21	70.0%		
Pre-operative hypoglycemic medications	OHG	20	66.7%		
	Insulin	6	20.0%		
	OHG+Insulin	4	13.3%		

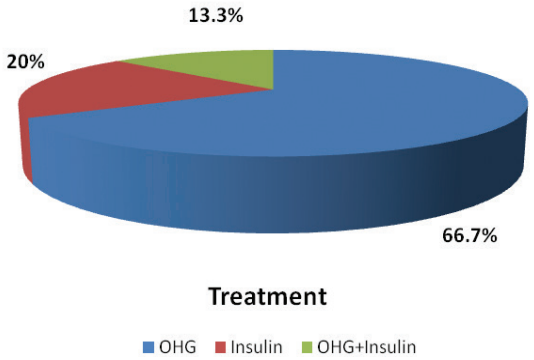


Fig 4: Description of the pre-operative hypoglycemic treatment of the studied patients underwent LSG.

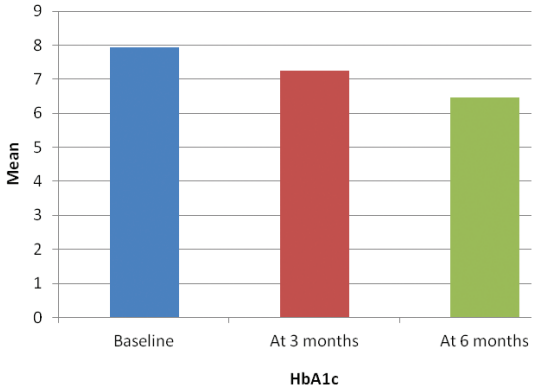


Fig 5: Comparison between mean values of HbA1c at 0, 3, and 6 months follow up postoperative.

Table 3: Description of FBS (preoperative) and HbA1c changes at 0, 3, and 6 months follow up among patients underwent LSG

	Mean	SD±	Minimum	Maximum
FBS on surgey day	197.53	35.20	120.00	283.00
HbA1c 0 month	7.95	0.88	6.55	10.20
HbA1c 3 months	7.27	0.71	5.80	9.14
HbA1c 6 months	6.47	0.75	5.16	8.60

Table 4: Description of diabetic status at 0, 3, and 6 months follow up among patients underwent LSG

		N	%
HbA1c 0 month	Non Diabetics (% HbA1c < 5.7)	0	0.0%
	Pre Diabetic (% HbA1c 5.7 – 6.4)	0	0.0%
	Diabetic (% HbA1c ≥ 6.5)	30	100.0%
HbA1c 3 months	Non Diabetics (% HbA1c < 5.7)	0	0.0%
	Pre Diabetic (% HbA1c 5.7 – 6.4)	4	13.3%
	Diabetic (% HbA1c ≥ 6.5)	26	86.7%
HbA1c 6 months	Non Diabetics (% HbA1c < 5.7)	5	16.7%
	Pre Diabetic (% HbA1c 5.7 – 6.4)	12	40.0%
	Diabetic (% HbA1c ≥ 6.5)	13	43.3%

Table 5: Comparison between mean values of HbA1c at 0, 3, and 6 months follow up among patients underwent LSG

	Mean	SD±	P	Sig	post hoc test
HbA1c 0 month (pre-operative)	7.94%	0.88%	0.0001	HS	HbA1c 0M Vs HbA1c 3M (HS)
HbA1c 3 months	7.26%	0.71%			HbA1c 0M Vs HbA1c 6M (HS)
HbA1c 6 months	6.47%	0.74%			HbA1c 3M Vs HbA1c 6M (HS)

HS=highly significant

Table 6: Comparison between preoperative, 3 months and 6 months post-operative diabetic status among patients underwent LSG

		month 0 (pre-operative)		3 month		month 6		P	.Sig
		N	%	N	%	N	%		
HbA1c	Non Diabetics (HbA1c < 5.7%)	0	0.0%	0	0.0%	5	16.7%	0.001	HS
	Pre Diabetic (HbA1c 5.7 6.4%)	0	0.0%	4	13.3%	12	40.0%		
	Diabetic (HbA1c ≥ 6.5%)	30	100.0%	26	86.7%	13	43.3%		

HS = highly significant

Table 7: Comparison between patients with different treatment regimen as regard mean level of HBA1c and diabetic status at 6 months follow up after LSG

		Treatment						P	.Sig
		OHG		Insulin		OHG+Insulin			
		Mean	SD±	Mean	SD±	Mean	SD±		
HbA1c 6M		6.39	0.77	6.59	0.82	6.74	0.63	*0.643	NS
		N	%	N	%	N	%		
HbA1c 6M	Non Diabetics (% HbA1c < 5.7)	4	20.0%	1	16.7%	0	0%.		
	Pre Diabetic (% HbA1c 5.7-6.4)	9	45.0%	1	16.7%	2	50.0%	**0.695	NS
	Diabetic (% HbA1c ≥ 6.5)	7	35.0%	4	66.7%	2	50.0%		

NS = none significant

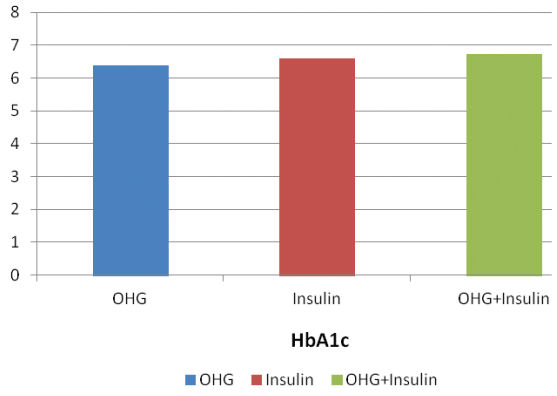


Fig 6: Comparison between patients with different treatment regimen as regard mean level of HBA1c at 6 months follow up after surgery.

Discussion

T2DM is considered to be a highly prevalent chronic disease with limited major treatments. Bariatric surgery is suggested as an alternative treatment for T2DM that has possibilities to induce remission of the disease. In 2011, the International Diabetes Federation (IDF) stated that bariatric surgery could be used in obese patients with a BMI >40 kg/m^2 and that it might bring benefit to obese T2DM patients with a relatively low BMI (BMI 30~35 kg/m^2), who do not respond to the usual medical therapies.[8]

However, the effects of bariatric surgery for non-obese T2DM patients have not been established. Although past studies predominantly focused on the role of bariatric surgery in patients with BMI<35kg/m^2, patients with BMI<30kg/m^2 were occasionally included in many studies.[9]

The results of this study points to the fact that LSG can play a remarkable role in managing T2DM obese patients. Our study revealed a highly significant reduction in the mean value of HbA1c at 3 and 6 months after surgery (P<0.001). These findings are comparable to those of Wei-Jee Lei et al. who showed that out of 20 diabetic patients type 2 who underwent LSG; median reduction in HbA1c was from 10.1 % to 7.1%.[10]

The fact that 56.7 % (n=17) of our patients showed either complete remission (5/30 patients completely cured from T2DM) or improvement (12/30patients became pre-diabetic) of the disease 6 months after LSG; is keeping with the concept that LSG could be a potential option for the management of T2DM in obese patients.

Our results were in agreement with those of Guo et al. who conducted a study that included 34 obese patients with T2DM and BMI less than 40 kg/m^2 who underwent LSG. The clinical data and 3-year follow-up outcomes regarding remission of diabetes was retrospectively analyzed. It showed the complete remission rate of diabetes at 6, 9, 12, 24 and 36 months was 33.3% (8/24), 50.0% (12/24), 54.2% (13/24), 45.8% (11/24) and 50.0% (12/24), respectively. That study confirms the efficacy of LSG in the treatment of T2DM patients with a BMI less than 40 kg/m^2.[11] In addition, Abbatini et al. showed 80.9% resolution of T2DM after LSG over a 3-year follow up.[12]

With regard to the effect of LSG on T2DM obese patients, in another review that analyzed 27 studies and 673 patients, it was stated that diabetes resolved in 66.2% of the patients, improved in 26.9% of the patients, and was unchanged in 13.1% of patients. The mean decrease in HbA1c levels after an LSG was −1.7%.[13]

Although the mechanisms underlying T2DM remission following LSG is not fully determined, some studies have reported favorable changes in insulin sensitivity. Improvement in insulin sensitivity could be attributed to decreased body weight, decreased calorie intake and reduction in inflammatory mediators.[12,14] Some believe that hormonal regulation plays a key role. Recent studies have shown that LSG is associated with a marked reduction of ghrelin secretion, which is produced by the gastric fundus and is involved in mealtime hunger regulation. Moreover, ghrelin is known to exert several diabetogenic effects (increase in growth hormone, cortisol, and epinephrine). Therefore its suppression could contribute to improved glucose homeostasis.[15] Interestingly, Peterli et al. measured higher GLP-1 levels following LSG.[15]

Undoubtedly, bariatric surgery is now becoming a viable treatment option for T2DM in obese patients, with recent large studies showing its superiority over traditional medical therapy.[16] However, there is still a lack of large scale studies observing LSG in particular when it comes to diabetes resolution. This is due to the fact that Roux enY gastric bypass (RYGB) remains the gold standard bariatric procedure, with a T2DM remission rate reaching as high as 60%.[17] However, recent evidence has been emerging showing no significant difference between LSG and RYGB in treating T2DM, with both procedures showing comparable results in diabetes control.[15] Another prospective study conducted by Vidal et al. on the changes in glucose homeostasis in 35 severely obese T2DM subjects undergoing laparoscopic SG (LSG) and 50 subjects undergoing laparoscopic Roux-en-Y gastric bypass (LRYGBP); showed at 4-months after surgery, T2DM had resolved respectively in 51.4% and 62.0% of the LSG and LRYGBP operated subjects (P=0.332). That proved that LSG and LRYGBP result in a similar rate of type 2 DM resolution at 4-months after surgery.[18]

The current study revealed insignificant difference in HbA1c reduction and T2DM resolution among patients with different treatment regimens. This suggests that LSG might prove to treat the disease regardless of the severity.

Our study has few limitations; first, number of studied patients was relatively small. Second, short term follow up for 6 months only. Third, other co-morbidities like hypertension and hypercholesterolemia were not evaluated.

In conclusion, LSG seems to be a restrictive procedure, but it also appears to induce significant changes in glucose homeostasis regardless of the pre- operative type of hypoglycemic medications.

These data confirm LSG contribution to improve and induce remission in Type 2 DM obese patients regardless of the severity of the disease.

Conflicts of interest
No conflicts of interests

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