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Mini-Gastric Bypass versus Sleeve Gastrectomy in Treatment of Type IIDiabetes Mellitus; a Randomized Comparative Study

Abdelshafy Mostafa Abdelshafy [1], Ali HelmyElshewy [2], Emad Mohammed Salah[3], Osama Abdelaziz Mohammed[4]

[1]Assistant Lecturer of General Surgery, Faculty of medicine, Zagazig University, Egypt, senior_med2010@yahoo.com

[2] Professor of General and GIT Surgery, Faculty of medicine, Zagazig University, Egypt, dr_ali_elshewy@yahoo.com

[3]Professor of General and GIT Surgery, Faculty of medicine, Zagazig University, Egypt, e_salah66@hotmail.com

[4]Assistant Professor of General and GIT Surgery, Faculty of medicine, Zagazig University, Egypt, Osamaeltih75@gmail.com

Corresponding author: Abdelshafy Mostafa Abdelshafy

Abstract

Introduction Although, the primary goal of bariatric surgery is body weight control, other various beneficial effects have been confirmed especially the improvement in type 2 diabetes mellitus and associated comorbidities after surgery.

Patients and Methods:

A prospective study to compare the effect of sleeve gastrectomy and minigastric bypass on obese patients with type II DM, divided into 2 groups, each containing 22 patients.

Results:

The follow-up was 12 months for both groups. Duration of surgery was different in both groups with Mean ± SD 89.5 ± 15 in SG group and 105 ± 11.1 in MBG. There was 2 cases had intraoperative bleeding that managed immediately intraoperative. Leak test was done and 2 patients were positive in MGB and intraoperative repair was done One case of leakage was detected after SG and managed nonsurgically with percutaneous drainage for intraabdominal collection and Mega stent insertion. Both surgical procedures achieved T2DM remission. Both FPG and HbA1c at 1 year are significantly lower in diabetic patients treated by MGB when compared to SG patients (SG from 201 ± 17.8 to 98.8 ± 12.7, MGB from 214.2 ± 27.6 to 83.9 ± 6.3 for FPG); (SG from 7.6 ± 0.71 to 5.5 ± 0.41 ,MGB from 7.9 ± 0.53 to 5.3 ± 0.38 for HbA1c).

Conclusion:

MGB and SG achieved T2DM remission, but MGB provided a better performance than SG at 1 year.

Keywords:

Morbid obesity, type II DM. Sleeve gastrectomy, mini-gastric bypass, bariatric surgery

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Introduction

Type II diabetes mellitus is characterized by hyperglycemia, insulin resistance, and relative impairment in insulin secretion. It is a common disorder with a prevalence that rises markedly with increasing degrees of obesity.[1]

Bariatric surgery describes surgical procedures in morbidly obese patients. Although, the primary goal of these procedures is body weight control, other various beneficial effects have been confirmed especially the improvement in type 2 diabetes mellitus and associated comorbidities after surgery. These findings has led to the rise of a new concept in surgery named diabetes or metabolic surgery.[2]

The aim of this study is to test the effect of MGB and SG on T2DM in patients with BMI more than 35. This is achieved by strict follow up of the patients and obtaining various laboratory and clinical data that can detect the patient's response to surgery regarding their diabetic state.

Patients and Methods

In this study data had been collected and analyzed to compare the effect of sleeve gastrectomy and minigastric bypass on obese patients with type II DM. The hospital Ethical Committee to authorized the study.

Our study involved 44 patients included both male and females with age ranging from 30 to 60 years. All patients had type II DM with BMI more than 35 Kg/ m2.

We excluded from this study any patient with type I DM or those who are unfit for surgery. Also Patients above 60 years or below 30 years old were excluded. Patient with BMI under 35 Kg/ m2 or over 60 Kg/ m2 were not involved as well.

All patients were asked to sign an informed consent after meeting the surgeon and explaining all the possible benefits and risks of the two procedures and stressing on the importance of regular follow up visits.

Recruited patients were divided randomly into two nearly equal groups; sleeve gastrectomy group and minigastric bypass group. Each group included 22 patients. Randomization was done in the operating room at the time of induction of anesthesia using sealed envelope technique. The envelope was drawn by a staff member not otherwise involved in the study.

Operative technique:

Patients will be allocated into two groups randomly:Group A will undergo MGB and Group Bwill undergo SG. Comparison ofpreoperative, intraoperative and postoperative outcome of each group

Operational Design:

Informed consent regarding the study will be taken from every patient.

Data collection:

a) Before operation

Full medical and surgical history was taken from patients. Fitness for surgery was assessed. Thourough general clinical examination and preoperative laboratory investigations was done. Also BMI calculation and measuring of Hb A1c and blood glucose levels.

A) During operation:

Each group allocated for definite procedure with assessment of operative time and intraoperative complications such as bleeding, injuries and anaesthetic complications.

B) After operation:

We monitored length of hospital stay, blood sugar monitoring every 6 hours & medications given till discharge.Early post-operativecomplication e.g infection, bleeding and leakage were assessed. Follow up for one year with serial measurement of blood sugar and Hb A1c.

Surgical procedures

The operative technique was standardized for all patients. DVT prophylaxis precautions were done pre- and post-operative in the form of: receiving 20mg low molecular weight heparin (LMWH) (Clexan) once daily, 12 hours pre-operative and 12 hours post-operative then once daily till discharge of the patient and wearing above knee elastic stockings during and after the surgery till complete ambulation and discharge of the patient. One gram of third generation cephalosporinwas administered intravenously at induction of anesthesia before trocars insertion. All patients had general anesthesia.

Sleeve gastrectomy

Patient Preparation

The patient is placed in lithotomy position and the operating table is put in a 30 degree reverse Trendelenburg position. In this position the patient is almost sitting with legs wide apart. Both upper limbs are put in abduction position for easier access. The operating field is prepared with betadine or any appropriate solution. The patient is covered with surgical drapes surrounding the operative field.

Surgical Team Position

The surgeon is positioned between the patient's lower limbs with the first assistant on the left side of the patient and the second assistant on the patient's right side.

Trocar Placement

The pneumoperitoneum is achieved with a 12 mm optical trocar, or with any other technique the surgeon is familiar with. When the intrabdominal pressure reaches 14 mmHg, four more work trocars are placed under direct view. Figure (1) shows ports design.

Identify the pylorus The first step is to identify the pylorus by visualizing the prepyloric vein of Mayo and palpating with laparoscopic instruments. The pylorus is a crucial landmark because gastric transection typically begins 2 to 6 cm from the pylorus. Some surgeons transect the stomach close to the pylorus (eg, 2 cm), while others begin the gastric transection further away from the pylorus (eg, 6 cm) to preserve the entire gastric antrum to ensure proper gastric emptying postoperatively.

Mobilize greater curvature — Once the site of future gastric transection is identified, the greater curvature of the stomach is devascularized using an advanced vessel-sealing device. This process is continued proximally onto the posterior fundus until the left crus of the diaphragmatic hiatus is clearly identified. All the short gastric vessels should be divided along the way. A complete mobilization of the greater curvature ensures that a sizable portion of the posterior fundus is not left behind during gastric transection. Although the merit of such mobilization was once debated, it has been accepted by the majority of experts .

Assess hiatus — At this point, most surgeons would assess the hiatus for hernias. Any large hiatal hernia should be repaired using standard laparoscopic techniques. The blood supply to the lesser curvature (ie, left gastric artery) must be preserved since it will become the sole blood supply to the sleeve after gastric transection .

Insert bougie — A bougie is then inserted transorally by the anesthesiologist, advanced under direct vision to the pylorus, and positioned against the lesser curvature

Transect stomach — The gastric transection is then performed using sequential applications of 60 mm linear staplers beginning at a point 2 to 6 cm proximal to the pylorus. As the gastric transection proceeds, the height of the staples may need to be adjusted according to the thickness of the tissue.While transecting the stomach,we must avoid twisting the staple line along the longitudinal axis and avoid narrowing the sleeve, particularly at the level of the incisura angularis. A twisted or narrowed sleeve can cause distal obstruction, which is responsible for the majority of the occurrences and persistence of staple line leaks in the proximal sleeve. Figure (2)

Constant symmetric lateral traction during the transection provided by the assistant is paramount to avoiding corkscrewing, twisting, or narrowing of the sleeve . When performing the last stapler firing, it is important to avoid stapling too close to the gastroesophageal junction, which may result in ischemia and postoperative leak .

After the stomach is transected, an intraoperative leak test can be performed.

Extract specimen — The resected portion of the stomach is extracted through the periumbilical trocar site. The enlarged trocar site is then closed, completing the procedure .

Gastric bypass (GBP)

Patient's position, port design, surgeons layout, DVT prophylaxis and antibiotic regimen were similar to those for SG.

Pneumoperitoneum Trocar Placement

The pneumoperitoneum is performed by means of a direct puncture with a Veress needle in the left upper quadrant, near the costal margin at the level of the midclavicular line (Palmer's point). The initial pressure is set at 15 mmHg, and maintained till the expected pressure (about 15 mmHg) is reached. The surgery initiates by the placement of the 10 mm permanent trocars for introduction of 30 degrees optics/camera placed at the mesogastrium between 12-15 cm below the xiphoid process and 3 cm to the left of the midline, considered as number 1 trocar. The trocar number 2, of 5 mm, is placed near the xiphoid process for the use of liver retractor which is usually a stick/probe held by the 2nd assistant. The number 3, disposable of 12 mm, is used by the surgeon's left hand, placed on the right side of the patient in an intermediate position between the previous two, 3-5 cm lateral to the midline. The number 4, also permanent of 5 mm, is placed along the left costal margin in the anterior axillary line to the 1st assistant. The last trocar, number 5, disposable of 12 mm, is placed adjacent to the left costal margin in the hemi-clavicular line to surgeon's right hand manipulation. The pneumoperitoneum is maintained by trocar number 5 .

Surgical Technique

The operation begins with the dissection of the esophagogastric angle and the opening of the left gastrophrenic ligament with a harmonic scalpel, so as to expose the lateral aspect of the left diaphragmatic crus. Then, the ressection of the fat pad of the esophagogastric junction (Belsey's fat) is performed. Then, the surgeon proceeds the ligation of the distal lesser sac, next to the insertion of the Latarjet nerve, using a harmonic scalpel until the exposure of the posterior gastric wall. The gastric pouch must be lengthy and narrow, measuring around 15-18 cm, with a 50-150 ml reservoir capacity. The pouch is created using 01 unit of 45mm blue cartridges to perform the horizontal section and 02 to 03 units to perform the vertical section. The stapling lines of the pouch and excluded stomach are then reinforced with a 3-0 polydioxanone continuous suture.Figure (3)

The Treitz ligament is then identified and the small bowel is counted until 200 cm from the Treitz angle, determining the exclusion of part of the stomach, duodenum, and proximal jejunum from the food pathway. This segment is then attached to the pouch and a vertical or slightly oblique omega-loop, isoperistaltic, antecolic, and side-

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to-side 25mm-gastrojejunostomy is performed using a 45mm white cartridge; the orifice for the cartridge insertion is closed by means of a continuous suture with 3-0 polydioxanone reinforced with separate stitches of 3-0 polyester. Figure (4) shows Side-to-side gastrojejunostomy using 45mmendo-GIA stapler. The Petersen's defect is closed by means of a continuous suture with 3.0 silk 9 . The placement of a silicone ring around the gastric pouch is randomly opted following the study protocol for evalution of the effects of the ring.

❖ Post-operative care:

Post-operativecare included close monitoring of the vital signs, urine output , drains, intravenous fluids, intravenous antibiotic, analgesic, PPI, subcutaneous LMWH and encourages early ambulation of the patient.

The patient was discharged if haemodynamically stable, pain free and in the absence of post-operative complication with instructions to receive liquid diet for the first week, followed by soft diet for another 3 weeks. Subsequently, a long-term solid diet (hypo-caloric, protein-enriched) was maintained. Daily oral supplements of vitamins and monthly administration of the intramuscular vitamin B12 were given to all patients for long term.

Figure (1): Ports design

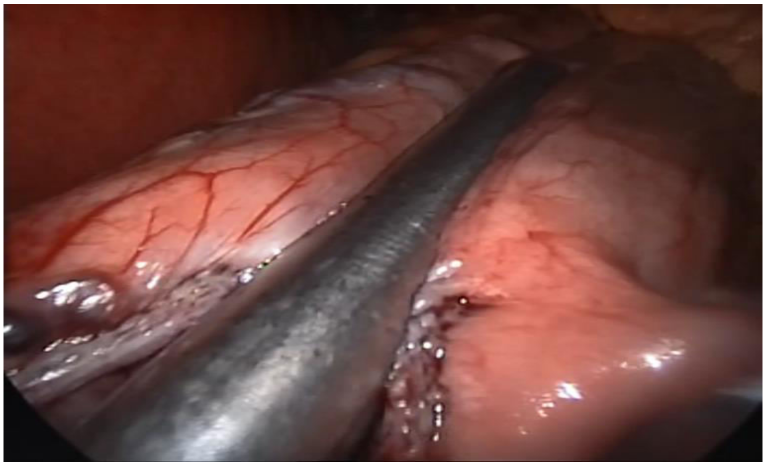

Figure (2):The stomach was stapler-divided upwards parallel to the lesser curvature after insertion of the bougie.

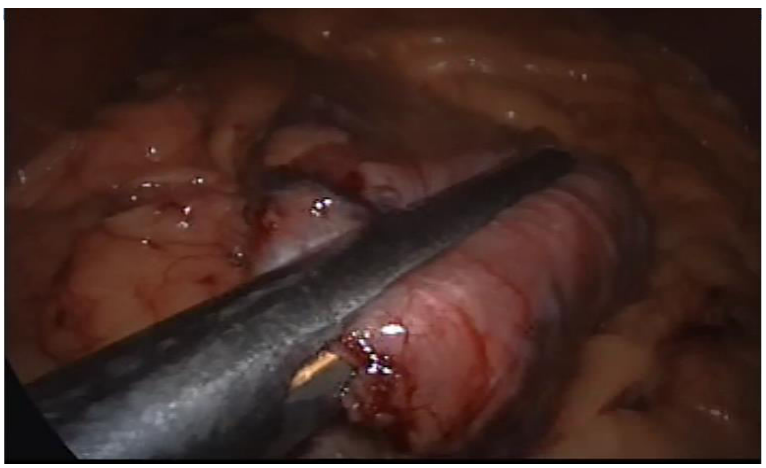

Figure (3): Creation of lesser-curvature gastric pouch using a stapler at a right-

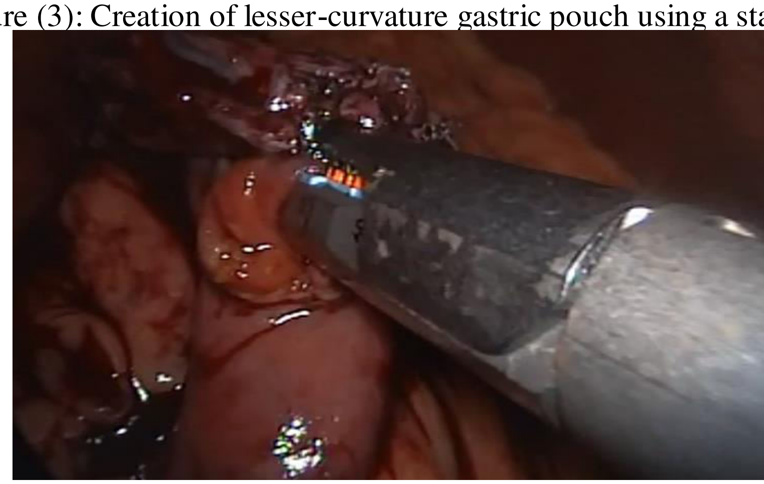

Figure (4): Side-to-side gastrojejunostomy using 45mmendo-GIA stapler.

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Statistical analysis

Collected data entered and analyzed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0) software for analysis. According to the type of data qualitative represent as number and percentage, quantitative continues group represent by mean ± SD and range.

RESULTS

In our study we had 44 patients divided into 2 groups (SG and MBG) and there was no statistically significant difference between SG and MBG groups as regard age and sex as shown in **(Table 1).**

Duration of surgery was different in both groups with ***Mean ± SD*** **89.5± 15** in SG group and **105 ± 11.1** in MBG , so there was statistically significant increase in operative duration as shown in **(Table 2)**. **(Table 2)** also showed that there was no statistically significant difference between SG and MBG groups as regard intra-operative bleeding, blood transfusion, cardiac arrest and leak test.

Postoperative BMI started to decrease in both groups and there was no statistically significant difference between SG and MBG groups as regard BMI 1 M, BMI 3 M, BMI 6 M and BMI 12 M as shown in **(Table 3).**

(Table 4) showed dramatic improvement in HbA1c in both groups with no statistically significant difference between SG and MBG groups as regard HbA1c 3 M and HbA1c 6 M but that there was statistically significant difference as regard HbA1c 12 M. It should be noticed that MGB provided a better performance than SG at 1 year.

Table 1: Some demographic data among the studied groups:

Variable	Group I (SG) N=22		Group II (MBG) N=22		t-test	P-value
Age (years): • ***Mean ± SD*** • ***Range***	45.4 ± 5.4 39-55		44.5 ± 4.6 36-53		-.58	0.559
Variable	**N**	**%**	**N**	**%**	**χ 2**	**P-value**
Sex:					----	1
• ***Male***	10	45.5	10	45.5		
• ***Female***	12	54.5	12	54.5		

Data is shown as number (percentage) or mean ± standard deviation. S: Significant
Chi-square (χ 2) and t- tests were used.Bold values are statistically significant at $p<0.05$.

Table 2: Intra-operative data among the studied groups:

Variable	Group I (SG) N=22	Group II (MBG) N=22	t-test	P-value

Duration of Surgery (min): • *Mean ± SD* • *Range*	89.5 ± 15 39-55		105 ± 11.1 36-50		-3.9	**0.000*** **(HS)**
Variable	**N**	**%**	**N**	**%**	**χ 2**	**P-value**
Bleeding: • *Yes* • *No*	2 20	9.1 90.9	4 18	18.2 81.8	0.77	0.664
Blood transfusion: • *Yes* • *No*	2 20	9.1 90.9	4 18	18.2 81.8	0.77	0.664
Cardiac arrest: • *No*	22	100	22	100	------	------
Leak test: • *Yes* • *No*	0 22	0 100	2 20	9.1 90.9	2.1	0.488

HS: Highly Significant

Table 3: Follow-up BMI among the studied groups:

Variable	Group I (SG) N=22	Group II (MBG) N=22	t-test	P-value
BMI 1 M: • ***Mean ± SD*** • ***Range***	40.8 ± 3.9 36.47	41.2 ± 4.99 35-49	-0.271	0.788
BMI 3 M: • ***Mean ± SD*** • ***Range***	36.4 ± 3.8 31-42	36.5 ± 4.9 30-44	-0.07	0.945
BMI 6 M: • ***Mean ± SD*** • ***Range***	32.7 ± 3.3 28-38	32.8 ± 4.5 27-40	-0.8	0.940
BMI 12 M: • ***Mean ± SD*** • ***Range***	29.2 ± 3 26-35	29.4 ± 3.9 25-36	-0.17	0.865
Pre-operative BMI: • ***Mean ± SD***	43.6 ± 3.7	44.2 ± 4.99	-0.41	0.684

• ***Range***	39-50	38-52		
P#1=0.000*		**P#2=0.000***		

P#1, repeated measure Anova among SG group.
P#2, repeated measure Anova among MBG group.

Table 4: Follow-up HbA1c among the studied groups:

Variable	Group I (SG) N=22	Group II (MBG) N=22	t-test	P-value
HbA1c 3 M: • ***Mean ± SD*** • ***Range***	6.7 ±0.41 6-7	6.8 ±0.40 6-7	-0.44	0.657
HbA1c 6 M: • ***Mean ± SD*** • ***Range***	6.3 ±0.34 5.9-6.9	6.2 ±0.28 5.6-6.7	1.7	0.091
HbA1c 12M: • ***Mean ± SD*** • ***Range***	5.5 ±0.41 4-6	5.3 ±0.38 4-5	2.8	**0.007* (HS)**
Pre-operative HbA1c 12M: • ***Mean ± SD*** • ***Range***	7.6 ±0.71 6.4-8.7	7.9 ±0.53 6.9-8.8	-1.7	0.091
P#1=0.000*		**P#2=0.000***		

P#1, repeated measure Anova among SG group.
P#2, repeated measure Anova among MBG group.

Discussion

Obesity is a worldwide problem that is estimated to reach 50% in some countries. Diabesity is a term that has been proposed by Ethan Sims in 1973 which means the presence of both type 2 diabetes and obesity and it’s considered the pandemic of the 21st century. The International Diabetes Federation (IDF) has announced that by the year 2035 more than 600 million of the world population will be obese, and that more than 90% of them will be affected by type 2 diabetes [3]

The increase in body weight leads to increased risk of development of T2DM. For population with BMI between 25 and 30 kg/m2, the risk of type 2 diabetes rises by 2 to 8 folds, and this risk is significantly raised more than 10 to 40 folds when BMI is between 30 and 35 kg/m2 and the risk is more than 40 folds for BMI greater than 40 kg/m2 [(4)]

In our study, A total of 44 subjects who underwent sleeve gastrectomy or mini-gastric bypass for obesity and diabetes were screened for the inclusion in this study (20 males and 24 females; mean age: **45.4 ± 5.4**years for SG and **44.5 ± 4.6** for MGB group) so, there was no statistically significant difference between SG and MBG groups as regard age and sex.

In our study BMI was **43.6 ± 3.7** for SG and **44.2 ± 4.99** kg/m2 for MGB.

All patients were diagnosed with type 2 diabetes and none of them had type I DM.The mean glycemia value was **201 ± 17.8** for SG / **214.2 ± 27.6** for MGB.The mean HbA1c level was **7.6 ± 0.71** for SG / **7.9 ± 0.53** for MGB.

Major and minor complication rate reported after bariatric surgery is also low (10.3%). In our study, 2 cases had intraoperative bleeding that managed immediately intraoperative. Leak test was done and 2 patients were positive in MGB and intraoperative repair was done .

There was no statistically significant difference between SG and MBG groups as regard post-operative need for ICU, thromboembolism, bleeding, vomiting, fever.

One case of leakage was detected after SG. It was intermediate type II leak. Patient presented on 6th day postoperative with sudden abdominal pain, accompanied with fever and tachycardia. Computed tomography (CT) of the abdomen with IV and PO water soluble contrast was done and showed the presence of small abdominal collection, extravasation of contrast into the abdominal cavity through minute perforation.

As the patient was stable, we managed this case nonsurgically with percutaneous drainage for intraabdominal collection and Mega stent insertion endoscopically and left for 6 weeks then removed.

The main purpose of this study was to compare SG and MGBP in the treatment of T2DM patients .

In our study, Both surgical procedures achieved T2DM remission if compared to baseline values. Both FPG and HbA1c at 1 year are significantly lower in diabetic patients treated by MGB when compared to SG patients (SG from **201 ± 17.8 to 98.8 ± 12.7**, MGB from **214.2 ± 27.6 to 83.9 ± 6.3** for FPG); (SG from **7.6 ± 0.71 to 5.5 ± 0.41** ,MGB from **7.9 ± 0.53 to 5.3 ± 0.38** for HbA1c).

It should be noticed that MGB provided a better performance than SG at 1 year.If we, in fact , consider patients who underwent MGB ,we have a remission rate from

T2DM of 18/22 patients **(81.8 %)** for those controlled at 1 year, while patients who underwent SG have a remission rate of 14/22 **(63.6%).**

Our results are similar to other studies, in a double-blind randomized trial included 60 participants done by Lee and Lin , comparing the efficacy of diabetic control and the role of duodenal exclusion in mildly obese diabetic patients undergoing SG and MGB, followed-up for 5 years, it was founded that SG and MGB have the weight loss but MGB decreases HbA1c better than SG [(5)]

In a comparison of mini-gastric bypass with sleeve gastrectomy in mainly super-obese patients, Plamper et al.2017 , noticed that MGB cases weight loss greater than SG cases after one year[(6)]

A retrospective review done by Alkhalifah et al.2018 , of 15-year experience of MGB comparing it with other bariatric procedures, data showed that MGB had great weight loss than RYGBP and SG from 2 to 6 years. Also, it was noticed that SG had similar high efficacy in diabetes remission rate compared to MGB and RYGBP[(7)]

In a retrospective study done by Musella et al.2016 , to define the efficacy of both mini gastric bypass and sleeve gastrectomy in T2DM remission in morbidly obese patients, baseline values for HbA1c and FBG were not related to BMI reduction for both operations[(8)]

We noticed that improvement of diabetic control occurred in the early post-operative period especially in the MGB cases and this demonstrated that diabetic remission post bariatric surgery is not only due to weight reduction but other mechanisms are present, however great weight loss is associated with better diabetic control.

While some authoritative series claims, in fact, the importance of BMI decrease in reaching a significant and long-lasting T2DM remission, on the other hand, if we observe large numbers of meta-analysis, this issue seems to lose relevance especially when moderately obese diabetic patients are considered [(9)]

This debatable issue has been validated by Mingrone as well, who recorded T2DM remission occurring before significant weight loss [(10)]

Our finding seems to confirm those hypotheses that diabetes remission may be independent from weight loss and reinforces the concept that the type of surgery may play a more relevant role. If we, in fact, consider, for both MGB and SG, the changes of FPG and HbA1c in relation to BMI decrease, we did not find any significant correlation between BMI decrease and diabetes remission.

The underlying mechanism for the superiority of MGB than SG on diabetes remission is intriguing. The most wellknown important mechanism is a rapid decrease of insulin resistance after bariatric surgery. The effect of the bariatric surgery-induced insulin resistance decrease has been evaluated in a large number of studies [11]

One possible mechanism is the bypass of the hormonally active foregut. This theory was investigated by designing a study comparing the duodenal exclusion MGB surgery with a control group of SG without duodenal bypass. This study demonstrated a better glycemic control with MGB than SG but did not observe a significant role of duodenal exclusion. No dramatic improvement in the glycemic control was found by adding duodenal exclusion to the SG in this study. The possible duodenal factor related to diabetes remission remained unknown, but an eliminated post-meal response of cholecystokinin in the MGB subjects comparing with the SG subjects in our previous report was found [8]

Another possible mechanisms involved is the rapid recovery of the incretin effect after bariatric surgery. A reduced or absent incretin effect has been demonstrated in patients with type 2 diabetes and is considered a consequence rather than a cause of diabetes [12]

In a study by Musella et al., 2016, they found that MGB and SG can rapidly augment the blunt incretin effect, and this effect persists up to 5 years. They found also that MGB had a significantly better incretin effect than SG at longer follow-up. The improvement of the incretin effect can be explained by the increase of incretin, glucagon-like-peptide-1 (GLP-1) [8]

The SG and MGB groups had the same amount of insulin secretion, but the MGB group had a higher early peak of insulin secretion. This early insulin response effect may contribute to the improved incretin effect found[11]

Limitations of the study:

short term follow up and small sample size are drawbacks , so we recommend a long term follow up and a bigger sample size .

Conclusion

According to our results at 1 year, both MGB and SG, in patients presenting a BMI >35 kg/ m2 , provide significant weight loss and T2DM remission. Both procedures result in amelioration of hyperglycemia and reduction of HbA1c levels and this effect starts immediately after surgery and continues for the first year of follow up.

Overall, there is a potential superiority of the mini-gastric bypass over the sleeve gastrectomy in obtaining diabetes remission.

Conflict of interest: No conflicts of interest

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