The Egyptian Journal of Hospital Medicine (April 2020) Vol. 79, Page 400-405

Outcome of Single Anastomosis Gastric Bypass in 100 Obese Diabetic Patients, A Prospective Study

Hussein Ali Mostafa Abd Al-Motalib[1], Osama Yassin Mostafa Taha[2], Abdel Aal Ali Sleem[3], Ahmed Mostafa Maghraby Mohamed*[1]

[1]Department of General and Laparoscopic Surgery, Faculty of medicine, Aswan University,
[2]Department of Plastic and Bariatric surgery, Faculty of Medicine, Assiut University,
[3]Department of General surgery, Faculty of Medicine, Sohag University

***Corresponding author:** Ahmed Mostafa Maghraby Mohamed,
Tel: (+20)1064600048, **Email:** ahmedmmahraby@yahoo.com

ABSTRACT

Background: Type 2 diabetes mellitus ((T2DM) is one of the most challenging health problems of the twenty-first century. A further 318 million adults are estimated to have impaired glucose tolerance, which puts them at high risk of developing the disease. (T2DM remission has been reported to varying degrees after all current bariatric operations. **Objective:** The aim of this study was to evaluate if laparoscopic mini gastric bypass (MGB) operation is effective for treatment of (T2DM associated with morbid obesity.

Material and methods: This prospective study included a total of 100 patients with morbid obesity submitted to Laparoscopic MGB from March 2018 to January 2019. This comprises the initial part of our series, and data was analyzed after all patients completed a follow up of 1 year. This study was conducted in the Bariatric Surgery Unit, at Assuit university hospital and Osama Taha group clinic. Demographic and clinical data were prospectively collected from the preoperative evaluations. **Results:** Diabetic patients showed significant decrease in random blood sugar (RBS) and HA1c in 1 year follow up after surgery. The mean RBS preoperative was 294.40±57.13 while after 1 year follow up was 182.38±4.71 and significant decrease in HA1C from mean 8.24±1.91 to 5.61±1.20 1 year after surgery. Remission was achieved in 92% with (86.0%) of patients have complete remission, and (6.0%) of patients have partial remission. In this study The DM complete remission rates for those with disease duration < 2years, 2-5 years and > 5 years were 93.02%, 66.67% and 25% respectively.

Conclusion: It could be concluded that one-Anastomosis Gastric Bypass (OAGB) can be an excellent alternative to Roux-en-Y Gastric Bypass (RYGB) for the treatment of diabetes and obesity. Pre-operative medications and duration of disease may be used to predict postoperative diabetes remission.

Keywords: Anastomosis, Gastric bypass, Obese diabetic patients

INTRODUCTION

T2DM is one of the most challenging health problems of the twenty-first century. It is estimated that there are now 415 million adults aged 20–79 with diabetes worldwide, including 193 million who are undiagnosed. A further 318 million adults are estimated to have impaired glucose tolerance, which puts them at high risk of developing the disease **(1)**.

Furthermore, T2DM is the leading cause of kidney failure, non-traumatic lower limb amputations, coronary heart disease, stroke, and visual impairments among adults **(2)**.

Studies have shown that BMI is a powerful predictor of T2DM. Visceral fat is an important source of inflammatory cytokines such as tumor necrosis factor alpha (TNF-α), transforming growth factor β (TGF-β), interleukin-6 (IL6), resistin, and plasminogen activator inhibitor type 1 (PAI-1) that can directly affect insulin-mediated glucose uptake (insulin resistance). On the other hand, there is a reduction of secretion of other factors such as adiponectin that reduce insulin resistance. This imbalance leads to a pro-inflammatory state which is related to an increased risk of cardiovascular complications **(1)**. Metabolic surgery involves any intervention that alters the food passage through the GI tract, resulting in improved T2DM control. Such a result does not solely depend on weight loss. In some cases, the effects can be observed days after bariatric operations, before substantial weight loss, precluding a direct antidiabetic effect. The term (bariatric(is gradually being replaced by (metabolic(, because the operations previously recommended for morbid obesity (defined as BMI >40 kg/m2 or >35 kg/m^2 with co-morbidities) have demonstrated excellent results in T2DM remission. In 2011, the IDF released its position statement that bariatric surgery is an accepted option for T2DM patients with BMI >35 and may be an alternative therapy for patients with BMI < 35 who do not respond to standard medical therapy. Metabolic surgery includes conventional bariatric operations (RYGB, biliopancreatic diversion [BPD] with or without duodenal switch, sleeve gastrectomy, and MGB) and new procedures (ileal interposition) designed to have metabolic effects irrespective of massive weight loss **(3)**.

Reversal of T2DM occurs due to mechanisms such as the increase in insulin sensitivity associated with an improvement in β-cell function, as a consequence of increase of GLP-1 production.

Received: 4/1 /2020
Accepted:13 /2 /2020

Remission of T2DM is observed in the first post-operative days after the operation [4].

The MGB and OAGB have been documented to be dependable bariatric operations in large series [5]. They have shown superiority in resolution of co-morbidities, in comparative studies to the RYGB and SG [6]. Furthermore, the MGB and OAGB have resulted in resolution of T2DM in 85–95% of diabetics followed >5 years, requiring no medication [7], which is superior to more complex operations. Following MGB with the rapid passage of food contents into lower bowel, significant rapid elevation in levels of GLP-1 has been found [8,9] compared to the other operations. **Lee *et al.*** [10] found that MGB and SG can rapidly augment the incretin effect, which persists up to 5 years. However, they demonstrated that MGB had a significantly better incretin effect than SG at longer follow-up. The improvement of the incretin effect is explained by the increase of GLP-1 serum levels. GLP-1 is an intestinal hormone that exerts profound effects in the regulation of glycemia, stimulating glucose-dependent insulin secretion, proinsulin gene expression, cell proliferative and anti-apoptotic pathways, as well as inhibiting glucagon release, gastric emptying, and food intake.

The aim of this study was to evaluate if laparoscopic mini gastric bypass operation is effective for treatment of (T2DM associated with morbid obesity.

MATERIAL AND METHODS

This prospective study included a total of 100 patients with morbid obesity submitted to Laparoscopic MGB from March 2018 to January 2019. This comprises the initial part of our series, and data was analyzed after all patients completed a follow up of 1 year. This study was conducted in the Bariatric Surgery Unit, at Assuit university hospital and Osama Taha group clinic.

Ethical approval.

Written informed consent of all the subjects was obtained. **Approval of the ethical committee was obtained.**

Inclusion criteria were according to criteria by the National Institutes of Health Development Panel (body mass index (BMI) > 40 kg/m^2 or BMI >35 kg/m^2 with severe related comorbidity) [11]**,** age after puberty to 55 years, patients applicable for 1 year follow up.

Exclusion criteria included chronic obstructive airway, bronchial asthma, obesity due to syndromes or monogenetic disease and GERD and patients not applicable for 1 year follow up.

Preoperative evaluation included history, physical examination, measurement of blood pressure, weight, height, BMI, and waist circumference. Laboratory investigations included complete blood count (CBC), prothrombin concentration, random blood sugar, liver function and renal function tests, thyroid function tests, lipid profile, glycated hemoglobin (HbA1c), and serology for hepatitis and HIV. Preoperative low molecular-weight heparin was used only for high-risk patients to guard against DVT. Radiological modality included: abdominal US, echocardiography for cardiac disease patients.

Operative Technique:

A five-port technique was applied as described by **Rutledge** [12], one 10-mm trocar for the camera, two 12-mm trocars as operating ports, and two5-mm trocars for retraction of the liver with paddle retractor and mobilization of the small bowel (SB) and stomach. A long and narrow gastric tube calibrated with a 36-French bougie was created, begin by one horizontal gastrointestinal anastomosing (GIA) stapler loaded with cartridges (4.8 mm staples) at the level of the crow's foot a three to four vertical 60-mm GIA upward to the angle of His. In the majority of patients, there was no need for reinforcement of the staple lines with continuous sutures. Then, antecolic end-to side gastrojejunostomy using a posterior 30-mm roticulator Endo-GIA stapler and an anterior hand sutures at a distance 150–300 cm distal to the ligament of Treitz based on BMI of the patient was performed. We carried out this technique with the intent to make the gastric pouch longer and narrower.

Therefore, stapling had to be vertical, perpendicular to the incision in the pouch, and above the posterior surface of the stomach so that the afferent loop comes from the back and is higher than the efferent loop. Also, we used a hanging suture between the gastric pouch and the afferent loop to be higher than the efferent one. Intraoperative methylene blue test for leak was performed in all patients. No nasogastric tube but intraperitoneal abdominal drain was inserted in the majority of cases.

Every patient that underwent a bariatric operation in this study had a DVD recorded video from the laparoscopic camera. The time obtained from the camera recording was added to the patient file under the title of duration of surgery. So, the operative time in our study was the knife time that was recorded in the DVD video.

Postoperative Follow up of, assessment of weight loss, RBS and HA1C at 3,6,12 months

Statistical analysis

Statistical analysis was calculated using a paired t test for continuous data carried out by using the SPSS version 15.0 for windows statistical package (SPSS Inc., Chicago, IL, USA). Results are reported in the form of mean ± SD or as percentages when appropriate; statistical significance was generally set at p values <0.05.

RESULTS

In This study, the mean value of age was 38.25± 7.83 years with (15.0%) of patients were male vs. (85.0%) female ,mean value of weight 124.55±23.50 kg with height 163.48 ±7.86 cm, also EBW mean value was 67.91±19.93 Kg, the BMI was 46.69±6.99 kg/m^2 and mean value of WC was 127.20±12.78 cm. (table 1)

Table (1): Pre-operative demographic data of 100 morbidly obese patients submitted to Laparoscope Mini-gastric Bypass. Presented by (mean±SD)

Item	Descriptive (n=100(
Age (years)	38.25±7.83
Sex:	
Male	15(15.0%)
Female	85(85.0%)
3-Weight (kg)	124.55±23.50
4-Height (cm)	163.48±7.86
5-EBW (kg)	67.91±19.93
6-BMI (kg/m^2)	46.69±6.99
7-WC (cm)	127.20±12.78

In this study, the mean value of Pre-operative Random blood glucose and HbA1c of 100 morbidly obese patients was 294.40 and 8.24 respectively. (table 2)

Table (2): Diabetes mellitus evaluation after MGB in 100 morbidly obese patients in follow-up at 1year by(mean±SD)

Item	Descriptive (n=100)
1-RBS (mg/dl)	294.40±57.13
2-HbA1C (%)	8.24±1.91

Regarding mean value of BMI Mean value of body mass index preoperative was 46.69 kg/m^2, after 3 months decrease to 39.70 kg/m^2 with significance different (P<0.05) comparing with preoperative. After 6 months decrease to 34.67 kg/m^2 with moderate significance different (P<0.001) comparing with preoperative. After 12 months was 28.16 kg/m^2 with highly significance different (P<0.000) comparing with preoperative. (table 3)

Table (3): BMI evaluation after MGB in 100 morbidly obese patients in follow-up at 1year by (mean±SD)

Item	preoperative	After 3months	After 6 months	After 12months
-BMI (kg/m^2)	46.69±6.99	39.70±5.90* **P<0.03**	34.67±4.92** **P<0.001**	28.16±2.80*** **P<0.000**

*n.s:P>0.05 *:P<0.05 **:P<0.001 ***:P<0.000*

Each p-value was calculated by paired T-test we compare each value with just before follow-up.

In this study, RBS & HbA1C decrease after 3 months to 218.63±44.26 and 6.27±1.26 respectively with significance difference (P<0.05). After 6 months follow up decrease than preoperative to 201.94±3.67 and 5.94±1.04. respectively with moderate significance different (P<0.001). As regard about 12 months follow up decrease than preoperative to 182.38±4.71 and 5.61±1.20 respectively with highly significance difference (P<0.000). (table 4)

Table (4): Diabetes mellitus evaluation after MGB in 100 morbidly obese patients in follow-up at 1year by (mean±SD)

Item	preoperative	After 3months	After 6 months	After 12months
1-RBS	294.40±57.13	218.63±44.26* **P<0.02**	201.94±3.67** **P<0.001**	182.38±4.71*** **P<0.000**
2-HbA1C	8.24±1.91	6.27±1.26* **P<0.02**	5.94±1.04** **P<0.001**	5.61±1.20*** **P<0.000**

*n.s:P>0.05 *:P<0.05 **:P<0.001 ***:P<0.000*

Each p-value was calculated by paired T-test we compare each value with just before follow-up

There were (86.0%) of patients have complete remission, also there were (6.0%) of patients have partial remission and there are (8%) of patients have improved disease. (table 5).

Table (5): Effect of MGB on diabetes mellitus

Effect	No. of patients	Percent
Complete remission	86	86%
Partial remission	6	6%
Improved disease	8	8%
No improvement	0	0

It was found that diabetic patient with less than 2 years duration 93.02 %, in diabetic patients with 2-5 years duration 66.67% showed complete remission,16.67% showed partial remission and 16.67% showed only improvement while in patients with more than 5 years duration only 25% showed complete remission ,12.5% showed partial remission and 62.5% shoed only improvement. (table 6)

Table (6): Effect of MGB on diabetes mellitus according to disease duration effect.

DM duration	*Complete remission 'n=86(*	*Partial remission (n=6(*	*Improved disease (n=8(*
• ***<2yrs.n=86***	*80/86(93.02%)*	*4/86(4.65%)*	*2/86(2.32%)*
• ***2-5yrs. n=6***	*4/6(66.67%)*	*1/6(16.67%)*	*1/6(16.67%)*
• ***>5yrs.n=8***	*2/8(25%)*	*1/8(12.5%)*	*5/8(62.5%)*

In this study, Remission of diabetes achievement at 1-year follow-up was significantly higher in patients who were receiving oral hypoglycemic drugs before surgery than in those who were receiving an injection treatment ($p < 0.01$). Remission was 94.20 % in patient who receiving oral drugs as following: 93.75% (30/32) in patients who were receiving a single oral hypoglycemic drug preoperatively. In patients treated with a bitherapy, the remission rate was 96.77% (30/31) and 83.3% (5/6) in patients who were on three oral hypoglycemic drugs. Diabetic patients who were discovered accidentally during the preoperative assessments showed 100% (10/10) complete diabetic remission. Patients who received preoperative insulin injection to control DM showed 52.83% (11/21) remission rate. (table 7)

Table (7): Diabetes remission rates according to pre-operative management of DM.

Pre-op. treatment of DM	No. of DM remission	Percent of DM remission	p-value
No drugs (n=10(	**10**	**100%**	
oral drug (n=69(	**65**	**94.20%**	**P=0.483n.s**
• Single oral drugs (n=32(	30	93.75%	**p^a<0.01***
• Two oral drugs (n=31(	30	96.77%	
• Three oral drugs (n=6(	5	83.3%	
Injection (n=21(	**11**	**52.38%**	

*n.s:P>0.05 *:P<0.05 **:P<0.001 ***:P<0.000*
P-value calculated by Chi-square test P^a: comparison between oral drug & injection drug

DISCUSSION

The positive impact of metabolic surgery such as RYGB or biliopancreatic diversion (BPD) on metabolic syndrome and glycemic control has been reported in obese patients [(13)].

The mechanism of this glycemic control was thought to be weight loss independent because it occurs immediately even before any weight loss occurs [(14)]. T2DM remission after gastric bypass surgery can be a result of several possible mechanisms: increased secretion of glucagon-like peptide 1 (GLP-1) and PYY hormones, decreased ghrelin hormone production and decrease in insulin resistance through weight loss are among the strongest hypotheses [(15)].

Early exposure to nutrients in the ileum stimulates L-cells to secrete GLP-1, which has anti-diabetogenic and strong insulinotropic effect. During hyperglycaemia, GLP-1 improves insulin sensitivity, decreases glucagon secretion, increases insulin secretion, delays gastric emptying and reduces appetite [(16)].

Although RYGB is approved as a gold standard treatment for (T2DM in obese and non-obese patients, approaching it laparoscopically still remains a challenge and still requires a long learning period with high complication rates particularly when performed by less experienced surgeons [(17)].

In this study the average weight of patient was 124.55±23.51 kg with significant reduction after 1

year follow up to 75.69±10.49 kg and significant reduction in BMI from 46.69±6.99 (kg/m2) to 28.16±2.80 (kg/m2) after 1 year follow up. Also, excess weight loss after 1 year were significant about 72.26±5.18 kg.

These results were in agreement with **Ansar *et al.*** [18] study in which the average weight of patient were 126.04± 23.02 kg with significant reduction after 1 year follow up to 79.62± (15.52) kg and significant reduction in BMI from 46.62 (6.43)to 29.49 (4.7) after 1 year follow up also excess weight loss after 1 year were significant about 81.63 (18.61) also different lines of evidence that have also reported a significant post-OAGB-MGB excess weight loss after 1 year or more (80–93%).

Carbajo *et al.* [19] study showed that One year after surgery, BMI after SG was 28.9 ± 2.1 Kg/m^2, after RYGB 28.7 ± 2 Kg/m^2 and after OAGB 25 ± 1.6Kg/m2 ($p < 0.001$), with EBMIL of 81.7 ± 6.3, 81.2 ± 5.9 and 100.4 ± 6.7%, respectively ($p < 0.001$). Pairwise analysis revealed that BMI after OAGB was significantly lower than after RYGB and SG ($p < 0.001$, respectively), while there were no significant differences between RYGB and SG ($p = 0.864$). Similarly, EBMIL after OAGB was significantly lower than after RYGB and SG ($p < 0.001$, respectively).

In most recent studies **Salvi *et al.*** [20] study, The most important finding was that OAGB/MGB perform excellently in terms of weight loss in the short to intermediate term with an average %EBWL of 79% at 6 years of follow-up, the excellent weight loss in the OAGB group in this series is consistent with the reports by **Kular *et al.*** [21] **and Carbajo *et al.*** [19] who report weight loss and maintenance in the 70%+ range in their 5-year follow-up studies The weight loss after the OAGB in this study is similar to that reported by **Magouliotis *et al.*** [22] who, in a comparative study of the OAGB/MGB with RYGB ,found the percentage excess weight loss at 1, 2, and 5 years postoperatively was greater for the OAGB group. This better weight loss is also collaborated by another previous report comparing OAGB/MGB vs. RYGB where it was found that OAGB/MGB is associated with more weight loss and better resolution of co-morbid conditions. The %TWL was 34.4 in OAGB/MGB whereas was it was 25.9 in RYGB.

In this study all 100 patient have type 2 DM patients showed significant decrease in random blood sugar and HA1c in 1 year follow up after surgery the mean RBS preoperative was 294.40±57.13 while after 1 year follow up was 182.38±4.71 and significant decrease in HA1C from mean 8.24±1.91 to 5.61±1.20 1 year after surgery. Remission was achieved in 92% with (86.0%) of patients have complete remission, and (6.0%) of patients have partial remission.

This was in agreement with **Carbajo *et al.*** [19]**,** that found that, referring to the remission of comorbidities, OAGB obtains significantly greater long-term resolution of (T2DM, HT, and DL, than RYGB and SG. On the other hand, RYGB and SG do not show significant differences in (T2DM and HT remission, though the rates tend to be slightly better after RYGB. This confirms the actual evidence of non-superiority of RYGB over SG in (T2DM and HT remission, but a clear superiority of OAGB over the other 2 techniques.

One year after surgery, the remission rate of T2DM after SG was 86.9%, after RYGB 89.8% and after OAGB 94.2% (p=0.305). 2 years after surgery, the remission rate of DM after SG was 85.2%, after RYGB 91.5% and after OAGB 95.7% (p=0.046). 5 years after surgery, the remission rate of DM after SG was 82%, after RYGB 86.4% and after OAGB 95.7% (p=0.027) [19]**.**

Also, **Hussain and EL-Hasani** [24] study showed that (T2DM remission (ADA definition) was achieved in 83% of the patients for the first year.

(T2DM remission after gastric bypass surgery can be a result of several possible mechanisms: increased secretion of glucagon-like peptide 1 (GLP-1) and PYY hormones, decreased ghrelin hormone production and decrease in insulin resistance through weight loss are among the strongest hypotheses [15]**.** Early exposure to nutrients in the ileum stimulates L-cells to secrete GLP-1, which has anti-diabetogenic and strong insulinotropic effect. During hyperglycaemia, GLP-1 improves insulin sensitivity, decreases glucagon secretion, increases insulin secretion, delays gastric emptying and reduces appetite [16]**.**

In this study The DM complete remission rates for those with disease duration< 2years, 2-5 years and > 5 years were 93.02%, 66.67% and 25% respectively , partial remission rates for those with disease duration< 2years, 2-5 years and > 5 years were 4.65%, 16.67% and 12.5% respectively while DM improvement rates for those with disease duration< 2years, 2-5 years and > 5 years were 2.32% 16.67% and 62.5% respectively.

This was in agreement with **Lee *et al.*** [10] study in which The (T2DM remission rates for those with disease duration< 2 years, 2-5 years and > 5 years were (98.5%), (39.3%) and (37.3%), respectively.

Remission of diabetes achievement at 1-year follow-up in the current series was significantly higher in patients who were receiving oral hypoglycemic drugs before surgery than in those who were receiving an injection treatment ($p < 0.01$). remission was 93.75% (30/32) in patients who were receiving a single oral hypoglycemic drug preoperatively. In patients treated with a bi-therapy, the remission rate was 96.77% (30/31) and 83.3% (5/6) in patients who were on three oral hypoglycemic drugs. Diabetic patients who were discovered accidentally during the preoperative assessments showed 100% (10/10)

complete diabetic remission. Patients who received preoperative insulin injection to control DM showed 52.83% (11/21) remission rate.

This was in agreement with **Taha *et al.* [25],** study in which Remission was 92.2% (142/154) in patients who were receiving a single oral hypoglycemic drug preoperatively and 95.2% in patients treated with a bi-therapy (139/146) and 72.4% (21/29) in patients who were on three oral hypoglycemic drugs. Diabetic patients who were discovered accidentally during the preoperative assessments showed 100% (43/43) complete diabetic remission. Patients who received preoperative insulin injection to control DM showed 52% (52/100) remission rate .remission was significantly higher in patients who were receiving oral hypoglycemic drugs before surgery than in those who were receiving an injection treatment.

CONCLUSION

It could be concluded that OAGB can be an excellent alternative to RYGB for the treatment of diabetes and obesity. Pre-operative medications and duration of disease may be used to predict postoperative diabetes remission

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