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BIOLIFE RESEARCH ARTICLE

The Role of Mini Gastric Bypass in the Control of Type 2 Diabetes Mellitus

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ABSTRACT

Background: Diabetes mellitus (DM) is one of the most common non-communicable diseases worldwide. The present prospective study was conducted to define the efficacy of mini gastric bypass (MGB) in controlling Type 2 diabetes mellitus (T2DM).
Subjects and Methods: From February 2014 to February 2015, 30 consecutive adult patients with T2DM underwent MGB at the Department of Surgery, Faculty of Medicine, University of Alexandria, Egypt. Twenty-six patients (86.7%) were female and 4 (13.3%) were male. The mean age was 40.70 ± 8.57 years and the mean body mass index (BMI) was 49.76 ± 6.61. Data collected included disease duration, family history, medications used, remission, and biochemical indicators, including fasting plasma glucose (FPG), glycosylated hemoglobin (HbA1c). Remission of T2DM was defined as HbA1c <6.0 % without medication.
Results: Complete remission of T2DM was achieved in 26 patients (86.7%) ($p<0.001$). The MGB procedure achieved significant improvement in glucose metabolism as compared to preoperative baseline values, reflected by a significant drop of FPG from 238.20 ± 55.57 to 106.03 ± 49.22 ($p<0.001$) and significant reduction of HbA1c from 7.86 ± 0.77 to 5.50 ± 0.85 ($p<0.001$). In addition, there was a significant improvement of comorbidities including hypertension, dyslipidemia and osteoarthritis.
Conclusions : Based on the data presented, it may be concluded that (1) The MGB is an effective procedure for T2DM remission with return of HbA1c to normal within 6 months of the operation and (2) there is significant reduction of BMI and (3) significant amelioration of co-morbidities including hypertension and dyslipidemia.

Key words: Minigastric bypass, Type 2 diabetes, obesity, remission, hypertension, dyslipidemia.

INTRODUCTION

Diabetes mellitus (DM) is one of the most common non-communicable diseases. In the Middle East and North Africa Region, 1 in 10 adults have diabetes; the region has the highest prevalence of diabetes, 10.9%. It is one of the most challenging health problems of the 21st century being the fourth leading cause of death in most high-income countries, and there is substantial evidence that it is epidemic in many economically developing and newly industrialized countries.(1)

The global prevalence of Type 2 DM (T2DM) is rising dramatically, driven by an 'obesogenic' environment that favors increasing sedentary behavior and easier access to attractive calorie-dense foods acting on susceptible genotypes.

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The most recent global predictions by the International Diabetes Federation (IDF) suggest that there are 285 million people with diabetes currently (1).

Tight glycemic control minimizes microvascular complications; however, macrovascular complications and cardiovascular mortality remain difficult to address even with intensive glucose-lowering therapy. Furthermore, despite substantial advances in pharmacotherapy and disease management, a large number of patients remain inadequately controlled, and complete remission of hyperglycemia and the associated metabolic alterations is rare (2).

Bariatric surgery has so far shown high efficacy in achieving T2DM long-term remission and durable weight loss, leading the IDF and the American Diabetes Association (ADA) to suggest bariatric surgery as an effective treatment modality in obese patients with T2DM.(3)

Different laparoscopic bariatric procedures have been investigated to treat T2DM obese patients, with excellent results in terms of weight loss and glycemic control reported for both the biliopancreatic diversion with or without the duodenal switch (BPD/BPD-DS) and the Roux-en-Y gastric bypass (RYGBP).(4) Conversely, restrictive procedures such as the sleeve gastrectomy (SG) and the laparoscopic adjustable gastric banding (LAGB), although effective on weight loss, seem to provide different results on T2DM remission.(5) The mini gastric bypass (MGB) or one anastomosis gastric bypass (OAGB) originated by Rutledge(6)in 1997, is an emerging technique consisting in a simplified version of the classic RYGBP. When described, MGB/OAGB raised severe criticism, reprised in a more recent debate, but despite such skeptical position, different authors have reported excellent results in terms of weight loss and resolution of obesity-related comorbidities, including T2DM.(7)

The present prospective clinical study was conducted to evaluate the role of MGB in the control of T2DM as defined by the ADA (8)

PATIENTSS AND METHODS

Study population

The study was carried out on 30 consecutive adult patients with uncontrolled T2DM (on diet, exercise and proper oral therapy) admitted to the Head, Neck and Endocrine (HNE) Unit, Department of Surgery, Faculty of Medicine, Alexandria Main University Hospital.

Inclusion criteria were (1) Glycated hemoglobin (HbA1c) ≥ 6.5%, (2) fasting plasma glucose (FPG) ≥126 mg/dL, (3) a random plasma glucose ≥ 200 mg/dL in a patient with classic symptoms of hyperglycemia, and (4) age: 29-60 years.

Exclusion criteria included (1) previous bariatric surgery, (2) patients with controlled T2DM on diet, exercise and oral therapy, (3) patients with eating disorders, (4) patients not suitable for general anesthesia, (5) patients with acute severe systemic infection, endocrinal disorders and peptic ulcer disease, and (6) patients with abnormal free T_4, TSH, morning cortisol and prolactin serum levels

Data collected

In addition to demographics and body mass index (BMI), the following data were recorded *preoperatively and at 3 and 6 months postoperatively*; levels of fasting plasma glucose (FPG), HbA1c, glucagon-like peptide-1 (GPL-1), cholesterol, and triglycerides, in addition to blood pressure, duration of DM, intake of insulin, oral antidiabetic agents, antihypertensive drugs, and lipid-lowering drugs. Post-operative morbidity and mortality were also documented.

Definitions

Hypertension was defined as a systolic blood pressure of ≥140 mmHg and/or diastolic blood pressure of ≥90 mmHg, or chronically taking antihypertensive drugs. *Dyslipidemia* was defined as a serum triglyceride concentration ≥100 mg/dl, and *hypercholesterolemia* as a serum total cholesterol ≥200 mg/dl.(9, 10)

Diabetes was considered remitted when serum glucose values were <110 mg/dl and HbA1c ≤6 %, on free diet and with no antidiabetic medical therapy, *controlled* when, under the same conditions, HbA1c was ≤7.0 %, and *improved* when preoperative HbA1c was steadily reduced by at least 1 % with less antidiabetic therapy.(11)

Surgical technique

Under general anesthesia, MGB procedure was performed, by the same surgical team, according to Rutledge technique. Briefly, the procedure involves making a long narrow tube of the stomach along its right border at the lesser curvature by creating a window at the craw-foot to enter the lesser sac through which a 45 mm Endo-GIA is passed horizontally and then vertically to the axis of stomach and fired. This creates a gastric tube reaching to the angle of His, under a 36-Fr nasogastric bougie guidance. Short gastric vessels are not divided at the lesser curvature and a lateral gastroenterostomy (GJ) is performed at 200 cm distal to the ligament of Treitz (Figure 1). It is considered a simple procedure that can be easily reversed or revised.(12)

Statistical Analysis (13, 14)

Data were analyzed using the SPSS software package version 20.0 (Prentice Hall, Chicago, IL). Qualitative data were described using number and percent. Quantitative data were described using range (minimum and maximum), mean, standard deviation and median. The McNemar-Bowker test was used to analyze the significance between the different stages, the paired student t-test to compare the normally quantitative values between two periods, the analysis of variance (ANOVA) test to compare between more than two periods or stages, and post-Hoc test for pairwise comparisons. Wilcoxon signed ranks test was also used for abnormally quantitative values to compare between

two periods. Significance of the obtained results was judged at the 5% level.

RESULTS

The BMI of the 30 patients with T2DM included in this study was 49.76 ± 6.61. Twenty-six (86.7%) patients were female and four (13.3%) were male. Their ages ranged between 29-50 years with a mean of 40.70 ± 8.57 years. The mean duration of DM was 2.49 ± 2.75 years.

Before surgery, 26 (86.7%) patients were on oral hypoglycemic medications, 2 (6.7%) on insulin, and the remaining two patients on both. In addition, 18 patients (60%) were on anti-hypertensive medications and 11 (36.7%) on lipid-lowering agents.

Table-1. Intra-operative and post-operative complications

Complications	N	%
Early	**5**	**16.7**
Leakage	*2*	6.67
Bleeding	*2*	6.67
Seroma	*1*	3.33
Late	**5**	**16.7**
Dyspepsia/ Gastritis	*2*	3.33
Cholelithiasis	*1*	3.33
Bile reflux	*1*	6.67
Diarrhea	*1*	3.33

The mean operation time was 114.63 ± 23.73 minutes (range 80-180 minutes). Intra- and post-operative complications are listed in Table 1. As may be seen, the most important complications were gastric leakage and bleeding, which occurred in two patients (6.67%) each. The first patient with leakage presented on the first post-operative day with severe abdominal pain associated with fever and tachycardia after which diagnostic laparoscopy was performed and revealed dehiscence at the GJ. Repair was done laparoscopically using interrupted Vicryl 2/0 stitches. The second patient, presented on the 9th day postoperatively with acute abdomen, sepsis, fever, leukocytosis and discharging intestinal content from the trocar site. Ultrasonography (US) was performed and showed a moderate free intraabdominal collection. A mini-laparotomy was performed for exploration and revealed dehiscence of the staple line at the excluded stomach. Repair was performed using Vicryl 2/0. Both patients had an ultimate favorable outcome.

Regarding bleeding, one patient had intraoperative bleeding caused by stapler misfiring that resulted in bleeding from both edges of the unstapled transected stomach. The gastric wall was successfully repaired and bleeding controlled by interrupted Vicryl sutures. The other patient presented with hematemesis and melena in the first 3 post-operative days resulting from staple-line intraluminal bleeding. Blood transfusion was not required, and bleeding stopped spontaneously with conservative measures.

The MGB procedure achieved significant improvement in glucose metabolism as compared to the pre-operative values. The mean level of FBG dropped significantly from 238.20 ± 55.57 mg/dL preoperatively to 106.03 ± 49.22 mg/dL post-operatively ($p<0.001$), and HbA1c from 7.86 ± 0.77 to 5.50 ± 0.85 ($p<0.001$). Also recorded was a significant increase in postprandial GLP-1 reaching a mean of 9.86 ± 0.84 pmol/L as compared to 2.21 ± 0.50pmol/l pmol/L pre-operatively ($p<0.001$) as shown in Table 2.

As may be seen in Table 3, a complete remission of T2DM was achieved in 26 patients (89.7 %) and partial improvement in one (3.3%), within the first 6 months.

Table-2. Comparison between pre and post-operative clinical and biochemical parameters

Parameters	Perioperative (n = 30)	Postoperative (n = 29)	p
Clinical			
Weight	131.67 ± 15.90	95.79 ± 12.12	< 0.001*
BMI	49.76 ± 6.61	36.29 ± 4.93	< 0.001*
% EWL	73.46 ± 15.67	49.86 ± 7.35	< 0.001*
EBMIL	-	56.86 ± 10.34	-
HTN	18 (60.0%)	4 (13.8%)	< 0.001*
Biochemical			
FPG	238.20 ± 55.57	106.03 ± 49.22	< 0.001*
HbA1c	7.86 ± 0.77	5.50 ± 0.85	< 0.001*
Oral antidiabetic	28 (93.3%)	2 (6.7%)	< 0.001*
Insulin	2 (6.7%)	1 (3.3%)	0.574
TG	108.57 ± 16.95	98.97 ± 7.51	0.004*
Cholesterol	197.97 ± 34.64	162.97 ± 31.42	< 0.001*
GLP-1	2.21 ± 0.50	9.86 ± 0.84	< 0.001*

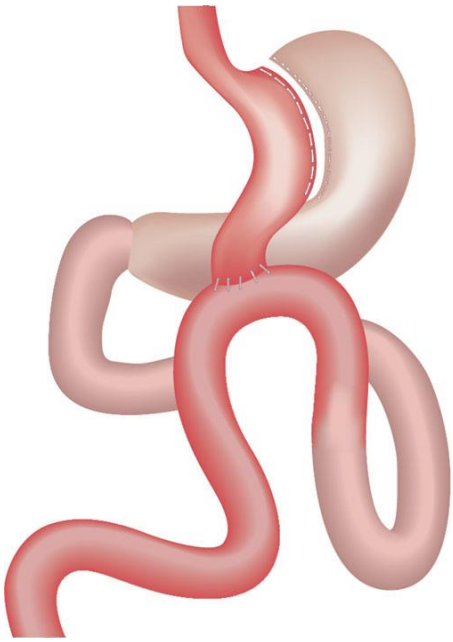
BMI: body mass index, EWL: excess weight loss, EBMIL: excess body mass index loss,
HTN: hypertension, FPG: fasting blood glucose, TG: triglycerides, GLP: Glucagon-like peptide
*: Statistically significant at $p \leq 0.05$

Starting from the first month post-operatively and through 6 months, there was a statistically significant decrease of BMI ($p<0.05$). The mean patients' percentage of excess weight loss (EWL%) significantly increased from 11.35 ± 2.29 at one month post-operatively to 49.86 ± 7.35 at 6 months ($p<0.05$). Moreover, there was an obvious amelioration of obesity-related comorbidities. Post-operatively, 14 patients (86.3%, 14/18) stopped their anti-hypertensive medications and 10 (90%, 10/11) ceased using lipid-lowering agents after the significant reduction of their cholesterol and triglycerides serum levels.

Table-3. Remission of T2DM at 6 months post-operatively (n=29)

HbA1c	N (%)
- Complete remission (<6%)	26 (89.7%)
- Partial remission (6% – 6.5%)	1 (3.4%)
- Improved (6.5% - <7%)	1 (3.4%)
- No improvement (≥7%)	1 (3.4%)

Figure-1. The mini-gastric bypass. Stomach at lesser curvature divided below crow's foot, and then divided vertically against a 36-Fr bougie. Gastrojejunostomy performed 200 cm distal to Treitz' ligament.[12]



No mortality was encountered in the peri-operative period; however, one patient (3.3%) passed away after 13 weeks due to myocardial infarction.

DISCUSSION

The primary risk factor for T2DM diabetes is obesity, approximately 90 % of all patients, diabetes is either overweight or obese. The National Health and Nutrition Examination Survey III (1988–1994) data demonstrated that the risk for chemical diabetes is approximately 50%with a BMI greater than or equal to 30 kg/m2 and over 90 % with a BMI of 40 kg/m2 or more.(7)

The present study clearly demonstrated that MGB can be used to treat T2DM patients. At 6 months post-operatively, there was a significant drop in both FPG and HbA1c levels with complete remission of diabetes in 90% of patients (26/29). Similarly, several authors reported that complete remission was achieved in 85% of patients at 5 years post-operatively (15), in 90% at 3 years (5), and in 100% at two years.(16) The longer duration taken for their complete remission is attributed to the nature of the study population as most patients (26/30) in the present study had controlled T2DM in contrast to their diabetic patients the majority of whom had uncontrolled DM.

The results of the current study regarding EWL% (49.86%) matches that of Kular and colleagues (2014) from the Indian subcontinent who studied 1054 patients with T2DM and reported an EWL% of 48% at 6 months post-operatively that reached 85% at 6 years.(15)

The GLP-1 showed significantly higher levels at six months postoperatively, which is the cause of postprandial stimulation of beta cells after gastric bypass.(17, 18) These findings were similar to those of other studies assessing outcomes after MGB for non-obese T2DM patients.(19, 20) This postulates the lower intestinal hypothesis, which claims that the intestinal shortcuts created by bariatric surgery, expedite delivery of ingested nutrients and increase GLP-1 release.

The overall complication rate in the present study (6.67%) were similar to that reported by other authors.(21) When compared with other gastric bypass methods, especially RNY, the MGB showed better control of diabetes with fewer complications.(17, 21, 22)

Based on the data presented, it may be concluded that (1) MGB is an effective surgical procedure in controlling T2DM with complete remission reaching nearly 90% within 6 months, (2) there is a significant increase in postprandial serum GLP-1 after MGB, (3) there is a significant reduction of mean BMI, and increase of % EWL and % BMIL, and (4) there is an obvious amelioration of associated comorbidities including hypertension, dyslipidemia and osteoarthritis within 6 months after MGP.

In view of the admittedly small population size and short follow-up period (6 months), a further study with a larger population and longer follow-up (5 years) is being currently conducted to evaluate the results of MGB on different groups of patients categorized according to their BMI, age and duration of diabetes in an attempt at refining the indications and highlighting the merits of the procedure.

Conflict of Interests

Authors declare that there is no conflict of interests regarding the publication of this paper.

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