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Comparative study between Single Anastmosis Duodeno-ileal Bypass and one anastomosis-gastric bypass as regard remission of type-2 DM after application of DIAREM Scoring System

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ABSTRACT

Background: Accumulating evidence obviously supports the superiority of weight loss surgery over non-surgical treatments for management of morbidly obese patients in terms of outcomes as sustained weight loss, improved quality of life and prevention, reduction, or resolution of co-morbidities (e.g., Type 2 Diabetes Mellitus, dyslipidemia), as well as reduced overall mortality. *Objective:* To compare Type 2 DM remission as well as the metabolic effects of 2 types of bariatric surgery; Single Anastomosis Duodeno-ileal Bypass-Sleeve (SADI-S) and One Anastomosis-Gastric bypass (OAGB), in the first year postoperative follow up in relation to DiaRem Scoring system. *Methodology:* This is a prospective randomized clinical trial study conducted in Ain-Shams University Hospitals bariatric surgery unit. The study started in March 2018 and ended in July 2020 - 2 years and 4 months - over 40 patients with minimal follow-up of 16 months. The 40 patients were divided equally into 2 groups (Group A: underwent O.A.G.B., Group B: underwent S.A.D.I-S). *Results:* Our study found that resolution of DM in SADIS patients initially occurred in 75% after 12 months increased to 80% after 15 months. However, in MGB patients it was 60% after 12 months and reached 65% after 15 months. Remission rates of SADIS patients under oral therapy is about 100% while MGB patients it was 92.3%, whereas patients under insulin therapy the number markedly goes down with shift to oral therapy or marked decrease in insulin requirements to control D.M. *Conclusion:* No statistical significant difference between both groups as regard remission of DM The main determinant noticed during the study influencing remission is the duration of DM and preoperative C-peptide level-in addition to HBA1C level. We recommend OAGB as a metabolic surgery for patients with early onset DM type II with BMI ranging from 30-40. The study needs to be repeated over larger sample size and longer duration to determine the long term effects of metabolic surgery.

Keywords: Single anastomosis duodeno-ileal bypass-sleeve, one anastomosis-gastric bypass

1. INTRODUCTION

Obesity is a pandemic health problem in both developed and developing countries and the costs of care continue to grow in parallel with the prevalence of the disease. This morbid condition leads to a high incidence of complications and a decrease in life expectancy, especially among younger adults (Fontaine et al., 2013). In comparison to medical therapy of obesity, Bariatric surgery provides the only long term sustainable decrease in both excess weight and obesity related comorbidities (Sjostrom et al., 2007).

Several conventional and novel methods of bariatric surgery - termed metabolic surgeries - induce long-term remission of type 2 diabetes mellitus (T2DM) and dramatically improve other metabolic abnormalities, such as hyperlipidemia and hypertension, independent of the patients' weight. Metabolic effects of bariatric surgery are related to endocrine changes that result from surgical manipulation of the gastrointestinal tract (Rubino et al., 2010; Kosta et al. 2019; Sayadishahraki et al. 2020). Laparoscopic mini gastric bypass (LMGBP), described by Rutledge, has a lower operative morbidity with equivalent efficacy compared to laparoscopic Roux-en-Y gastric bypass (RY-GBP), in terms of resolution of the metabolic syndrome, loss of excess weight (EWL) and improvement of the quality of life (Lee et al., 2005).

Single anastomosis duodeno–ileal bypass with sleeve gastrectomy (SADI-S) includes sleeve gastrectomy followed by an end-to-side duodeno-ileal diversion. SADI-S offers excellent weight loss and metabolic results (Sánchez-Pernaute et al., 2010). Clinicians must consider metabolic surgery for patients with T2DM when life style modification and medical treatment fail with the potential complete remission of the disease (Rubino et al., 2010).

Whilst considered cost-effective and safe, the availability of the operation is unable to meet the demand due to the rapidly rising prevalence of obesity (Warren et al., 2015). Furthermore, although metabolic surgery may result in improvement in obesity co-morbidities, not all patients with diabetes undergo remission. In the context of a health service with limited resources, the patients those will respond to metabolic surgery by remission of DM must be predicted prior to the surgery. Current predictive scores include the DiaRem score (Still et al., 2014).

Various mechanisms have been proposed for predicting Type 2 DM remission Durable Type 2 DM remission has been associated with early diabetes stage and significant percent excess body weight loss (%EWL), While, failure to achieve long-term remission has been associated with inadequate weight loss beside use of insulin and high percent of glycated haemoglobin (Still et al., 2014).

The DiaRem score was created using a Cox regression model, and four preoperative clinical variables were identified in the final scoring model: insulin use, age, HbA1c, and type of antidiabetic drugs used. On the basis of the DiaRem score (ranging from 0 to 22); patients were classified into five groups (Ali et al., 2014).

Aim of the work

The aim of this prospective study is to compare Type 2 DM remission as well as the metabolic effects of 2 types of bariatric surgery; Single Anastomosis Duodeno-ileal Bypass-Sleeve (SADI-S) and One Anastomosis-Gastric bypass (OAGB), in the first year postoperative follow up in relation to DiaRem Scoring system.

2. METHODOLOGY

This is a prospective randomized clinical trial study conducted in Ain-Shams University Hospitals bariatric surgery unit over 40 patients with minimal follow-up of 16 months (March 2018 to July 2020).

2 groups of patients;

Group A: composed of 20 patients that undergone OAGB.

Group B: composed of 20 patients that undergone SADI-S.

All patients who will accept to participate will sign an informed consent.

Inclusion criteria: Adult male or female patients fit for surgery, age (18-60 years). Patients who have BMI (30-40). Type 2 DM. Acceptable level of C-Peptide (< 2).

Exclusion criteria: Are generally unfit for operation. Old age patients more than 60 years. Patients with history of psychiatric illness. Patient refusal. Type 1 DM and C-peptide >2.

All patients will be subjected to the following:

Preoperative assessment: Full clinical history; personal history, present history, past history especially history of any endocrine disorder. Full clinical examination; BMI, vital signs, body examination. Routine preoperative investigations. Preoperative co-morbid factors such as hypertension, Diabetes mellitus or electrolyte disturbance will be controlled when possible before surgery.

Data collection: Data will be collected from medical files, and follow up of patients at bariatric surgery clinic post operative .

Outcome measures: The results of the 2 types of bariatric surgeries will be compared as regards the following endpoints: Pre-operative DiaRem Score. Remission of metabolic disorders such as diabetes, hypertension, lipid profile over a time scale (3, 6, 9, 12, 15) months either complete remission or decrease in medical treatment dose.

Steps of study

All patients were subjected to preoperative assessment which included

History taking: Personal history. History of obesity and weight loss trials. Detailed dietary history and eating habits. History of previous operations especially gastrointestinal surgery. Other systems review (cardio- vascular system, respiratory, liver diseases). Associated comorbidities e.g. endocrine disorder. Psychological status, Medications history.

Examination:

A- General: Full general examination was done, focusing on: BMI and body circumferences measurement. Vital data. Complexion (pallor, jaundice). Cardiovascular fitness. Respiratory fitness.

B- Local: Full abdominal examination focused on: Scars of previous operations (mainly in the upper abdomen). Abdominal wall hernias.

Investigations:

Laboratory:

General pre-operative investigations for all the patients include: Complete blood picture, Coagulation profile, Liver function tests, Arterial blood gases, Kidney function tests, Lipid profile, Thyroid profile, Haemoglobin A1C. Patient was described as diabetic if fasting blood sugar was 126 mg/dl or above or two hours postprandial blood sugar was 200 mg/dl or above or random blood sugar was 200 mg/dl or above. Serum electrolytes including calcium. VitaminB12 and Vitamin D.

Cardio-respiratory investigations:

All patients had ECG, Pulmonary function tests while some had echocardiography for cardiac troubles.

Radiological:

All patients had preoperative chest X-ray and pelvi-abdominal ultrasound. CT volumtery and upper GI endoscopy if indicated. Preoperative co-morbid factors such as hypertension or electrolyte disturbance were corrected as much as possible. All cases were operated by consultant surgeon and according to the standardized technique. Surgeries were done by the same surgical team throughout the study. As part of their preparation, SADI-S and MGB operations were described in details to the candidates for surgery and the surgical procedure was reviewed with them with the possibility of conversion to open surgery and all the possible intraoperative, early and late postoperative complications.

Procedure:

Preoperative medications:

Two grams of third generation cephalosporin. Proton pump inhibitor. Anti-emetic.

Surgical Technique Steps of SADI-S operation:

Surgery was performed under general anesthesia. The patients were placed in supine position with the table in reverse Trendelenburg position with legs spread. Ryle tube was inserted.

Creating Pneumoperitoneum & Ports placement:

Closed method using Veress needle at Palmer's point was used for establishing the pneumoperitoneum. In patients where the Veress cannot be inserted safely or has failed, optical entry using a zero-degree telescope is used for insertion of the first port. The open Hasson technique was also used in some cases. The intrabdominal pressure is maintained between 15 and 20 mm. The optical 10 mm port is placed 2–3 finger breadths above the umbilicus in the left paramedian line. A 12 mm left-subcostal port is placed for the surgeon's right hand, and a 12 mm right paramedian port is used for the linear stapler and the surgeon's left hand. A 5 mm port in the left mid axillary line for the assistant. A 5 mm incision in the sub- xiphoid region for hook liver retractor to elevate the left lobe of liver.

Mobilization of the stomach and the duodenal dissection:

The dissection is commenced approximately 4–5 cm distal to the pylorus by having the assistant grasp the antrum and retracting it laterally, which linearizes the first portion of duodenum. Using harmonic scalpel, the peritoneum overlying the inferior and superior portions of the duodenum is freed avoiding injury to the right gastric vessels and the supra-duodenal artery (preserving all the vascularization to the lesser curvature). The mobilization is performed until the point where the duodenum fuses posteriorly with the pancreas. The retro-duodenal dissection is performed bluntly with judicious bipolar cauterization of vessels creating a small window between the duodenum and pancreatic head wide enough to admit a linear stapler cartridge avoiding injury to the gastroduodenal artery as it passes behind the duodenal bulb. Doudenal transection: The duodenum is divided 2-4cm from the pylorus with a 60mm blue linear stapler (EndoGIA) "ETHICON J&J".

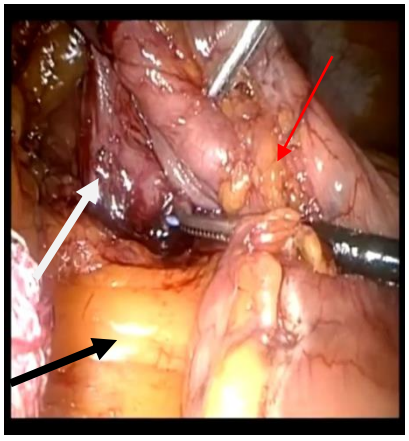

Figure (1): SADIS: Posterior blunt dissection between the duodenum and the pancreas creating a window for the stapler avoiding damage of gastroduodenal artery.(white arrow :1st part of duodenum, Black arrow : pancreas, Red thin arrow : pylorus)

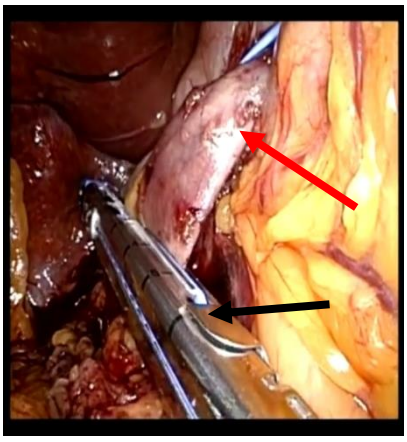

Figure (2): SADIS: Duodenal Transection A) Endo-GIA stapler is applied 3 mm from the pylorus (Black arrow). B) Duodenum divided (red arrow).

Choosing & measurement of ileal loop:

The ileo-cecal junction is identified. Two hundred and fifty centimeters are measured proximally along the ileum. Doudeno-ileal anastomosis: The selected loop is lifted cranially in an antecolic fashion to the duodenal stump and an isoperistaltic end-to- side duodeno-ileal anastomosis is completed using either semimechanically with a 30-mm linear stapler or hand sewn with sequential running sutures of a 3/0 PDS or Vicryl TM.

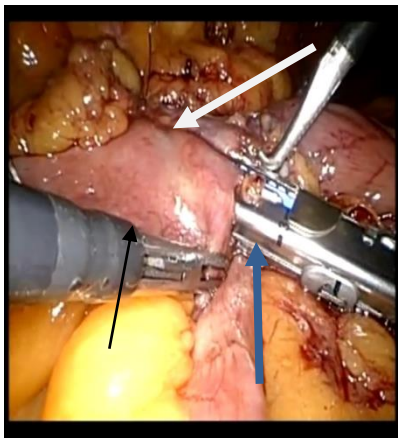

Figure (1): SADIS: end-to-side duodeno-ileal anastomosis using 30mm linear stapler.

Leak test:

The anastomosis and staple line are tested for leaks with methylene blue instillation through the nasogastric tube and a suction drain is left behind (Black arrow: Ileum loop; side, white arrow: 1st part of duodenum; end, Blue arrow: Endo-GIA stapler)

Steps of MGB operation:

Surgery was performed under general anesthesia. The patients were placed in supine position with the table in reverse Trendelenburg position with legs spread. Nasogastric tube was inserted. Creating Pneumoperitoneum & Ports placement: After Veress needle insufflation in the left hypochondrium, the first 10-mm trocar for the camera was placed in the midpoint between the xiphoid and the umbilicus at mid line. The second trocar (5 mm) was placed in the left hypochondrium at anterior axillary line; the third trocar (12 mm) was inserted in the left hypochondrium, symmetrical to the previous one. The fourth trocar (12 mm) was placed in the right quadrant at anterior clavicular line on the same level of the camera. A 5 mm incision in the sub-xiphoid region for hook liver retractor to elevate the left lobe of liver. Creation of the gastric pouch: The stomach is divided at the junction of the body and the antrum at the level of the crow's foot with 45-mm Endo- GIA stapler to get the longest possible gastric pouch. A lesser curvature-based tube of stomach is constructed with a 60-mm linear stapler "ETHICON J&J" using green or blue cartridges around an orogastric tube of 36 Fr size.

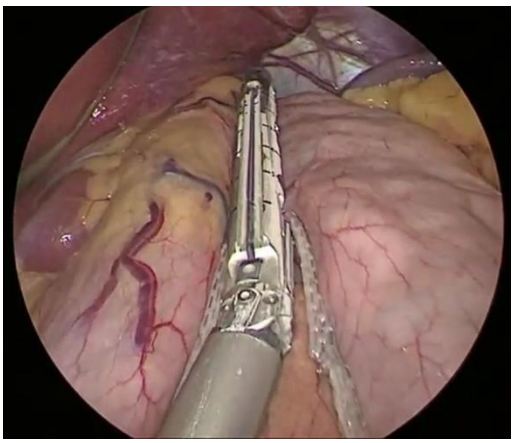

Figure (2): MGB: Creation of the gastric pouch along lesser curvature of the stomach.

Choosing & Measurement of jejunal loop:
A graded grasper is used to measure about 180 cm of jejunum from the ligament of Treitz.

Creation of gastrojejunostomy:
The jejunal loop brought up antecolic and anastomosed to the stomach tube with 45mm Endo-GIA stapler. Antireflux stitch between biliary limb and gastric pouch was made to decrease biliary reflux. The common stapling defect was closed over nasogastric tube with two layers of No 2-0 absorbable Vicryl TM suture in a running fashion.

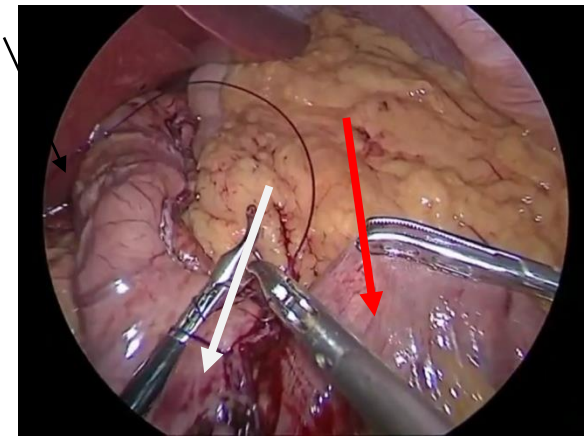

Figure (3): MGB: Closure of the stapling defect of the gastrojejunostomy "White arrow" (Black arrow: gastric pouch, Red arrow; jejunal loop).

Leak test:
The anastomosis was then tested with methylene blue injected through the nasogastric tube. A tube drain was left in the vicinity of the gastrojejunostomy under the left lobe of the liver. All patients were given a standard regimen of multivitamins, including vitamin B12, iron supplementation and calcium. A 6 month course of proton pump inhibitors (omeprazole 40 mg) was prescribed to all patients. All patients were encouraged to follow exercise program.

Postoperative follow up:
The follow up period of one year was carried out on an outpatient basis: Weekly visit for one month after discharge from the hospital, Monthly till the end of the third month then every three months till the end of the first follow-up year. In each visit patient had: Full clinical assessment, Measurement of the anthropometric measures, Required investigations as indicated and according to study plan follow up.

Statistical Analysis:
The data will be collected tabulated and statistically analyzed. Description of quantitative variable will be done as mean and standard deviation, and qualitative data as frequency. Chi square test will be used to compare the groups as regard qualitative variable. Student t-test will be used to compare two groups as regard quantitative variable in parametric data. The results will be considered significant (S) with $P < 0.05$ & highly significant (HS) with $P < 0.01$. $P \geq 0.05$ will be considered non-significant (NS). Analysis of data will be done using IBM SPSS software (statistical program for social science version 21.

3. RESULTS

This study included 40 type II Diabetic patients divided into 2 groups; Group (A) of 20 patients who underwent OAGB and group (B) of 20 patients who underwent SADI-S. Group (A) OAGB patients included 8 males (40% of patients) and 12 females (60%) with mean age of 35.9 ± 7.5 years while Group (B) SADI-S patients included 6 males (30%) and 14 females (70%) with mean age of 36.6 ± 8.36 years. Group (A) patients had mean preoperative body mass index (BMI) of 37.2 ± 1.94 Kg/m2, and the mean preoperative weight of 100.2 ± 11.3 Kg. Group (B) had a mean preoperative body mass index (BMI) of 36.7 ± 2.27 kg/m2 and mean preoperative weight of 105.9 ± 13.7 kg.

Table (1): Mean, SD and Range of Age, Height, Weight and BMI in each study group.

		Group A	Group B	Test value•	P-value	Sig.
		No. = 20	No. = 20			
Age	Mean±SD	35.90 ± 7.50	36.60 ± 8.36	-0.279	0.782	NS
	Range	25 – 55	23 – 51			
Height	Mean±SD	1.64 ± 0.07	1.70 ± 0.09	-2.166	0.037	S
	Range	1.5 – 1.75	1.5 – 1.85			
Weight	Mean±SD	100.20 ± 11.30	105.90 ± 13.17	-1.470	0.150	NS
	Range	79 – 121	79 – 128			
BMI (Approx.)	Mean±SD	37.20 ± 1.94	36.70 ± 2.27	0.749	0.459	NS
	Range	34 – 40	33 – 40			

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
•: Independent t- test

Co-morbidities of patients included diabetes (100%) in both groups, with 13 patients (65%) of group (A) on oral hypoglycaemics and 7 patients (35%) on insulin therapy with mean preoperative HbA1c of 7.98 ± 1.38 %. Meanwhile 9 patients (45%) of group B were on oral hypoglycaemics and the other 11 patients (55%) on insulin therapy with mean preoperative HbA1c of 7.78 ± 1.07 %.

Table (2): HBA1C and type of treatment in each study group.

		Group A	Group B	Test value	P-value	Sig.
		No. = 20	No. = 20			
HBA1C	Mean±SD	7.98 ± 1.38	7.78 ± 1.07	0.513•	0.611	NS
	Range	6 – 11	6.2 – 10			
Treatment	Oral	13 (65.0%)	9 (45.0%)	1.616*	0.204	NS
	Insulin	7 (35.0%)	11 (55.0%)			

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
*:Chi-square test; •: Independent t-test

Table (3): DiaRem score distribution among each study group

		Group A	Group B	Test value	P-value	Sig.
		No. = 20	No. = 20			
DIAREM score	Median(IQR)	9 (7 - 13)	12 (8 - 15)	-1.388‡	0.165	NS
	Range	0 – 17	3 – 16			
Distribution	Score (0-2)	1 (5.0%)	0 (0.0%)	2.835*	0.418	NS
	Score (3-7)	8 (40.0%)	5 (25.0%)			
	Score(8-12)	6 (30.0%)	6 (30.0%)			
	Score(13-16)	5 (25.0%)	9 (45.0%)			

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
*:Chi-square test; ‡: Mann Whitney test

Table (4): Percentage of remission "recovery" in each study group

		Group A	Group B	Test value	P-value	Sig.
		No. = 20	No. = 20			
Recovered	No recover	7 (35.0%)	4 (20.0%)	1.129*	0.288	NS
	Recover	13 (65.0%)	16 (80.0%)			
Time till recover(months)	Mean±SD	8.77 ± 3.96	7.69 ± 3.94	0.733•	0.470	NS
	Range	3 – 15	3 – 15			

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
*:Chi-square test; •: Independent t-test

Table (5): Mean time of recovery of each group in each strata

Remission	Time to Recovery				Test value•	P-value	Sig.
	Group A		Group B				
	Recover/total	Mean±SD	Recover/total	Mean±SD			
Score (0-2)	**1/1**	3.00 ± 0.00	**0/0**	-	-	-	-
Score (3-7)	**7/8**	9.00 ± 3.46	**5/5**	6.60 ± 2.51	1.315	0.218	NS
Score(8-12)	**3/6**	7.00 ± 3.46	**6/6**	8.50 ± 3.99	-0.552	0.598	NS
Score(13-16)	**2/5**	13.50 ± 2.12	**5/9**	7.80 ± 5.45	1.372	0.105	NS

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
•: Independent t-test

Group A patients underwent Laparoscopic OAGB and group B underwent Laparoscopic SADI-S. None of patients in either groups were converted to open surgery. In group A patients 2 reported complications were detected which were hemoperitoneum in postoperative day 2 and port site infection after one week and both were managed conservatively. In group B, one patient was diagnosed by DVT treated by therapeutic dose of anticoagulant with no pulmonary embolism and 2 more patients treated conservatively for port site infection. No mortality was reported within 30 days of surgery in either groups.

4. DISCUSSION

SADI-S operation was introduced to treat morbid obesity and its metabolic complications Sánchez-Pernaute (2010). The modification was devised to simplify previous successful operation of duodenal switch by Scopinaro et al. (1998), keeping the malabsorptive principles but attempting to decrease the operative complexity and, thus, the rate of surgical complications. We herein present the results of a prospective study started 2 years ago, our patients who had MGB operation (group A) and SADIS operation (group B), examined and investigated for the remission of DM in comparison with the expected value according to DIAREM Scoring System. Our study included 40 patients in the period from March 2018 to July 2020, Adult male or female patients, age (18-60 years), have BMI (30-40) and Acceptable level of C-Peptide (< 2).

The study showed statistically no significant difference between both groups as regard remission of DM (65% and 80% in Group A, B respectively). The main determinant noticed during the study influencing remission is the duration of DM and preoperative C-peptide level-in addition to HBA1C level. Control of the disease was considered when normal levels of HbA1c (<6%) were achieved, independently of antidiabetic therapy. Postoperative antidiabetic treatment was maintained upon decision of the endocrinologist, based on current ADA criteria.

Our study found that resolution of DM in SADIS patients initially occurred in 75% after 12 months increased to 80% after 15 months. However, in MGB patients it was 60% after 12 months and reached 65% after 15 months. Remission rates of SADIS patients under oral therapy is about 100% while MGB patients it was 92.3%, whereas patients under insulin therapy the number markedly goes down with shift to oral therapy or marked decrease in insulin requirements to control D.M. Del Gid et al. (2014) showed resolution of DM in patients underwent SADIS was 85 % of cases versus 67% in those who had MGB after one year. Another study done be Sánchez-Pernaute et al. (2015) showed resolution of DM in patients underwent SADIS was 82 % of cases after one year.

Rutledge et al. (2005) DM resolution 83%. Meanwhile, Noun et al. (2012) reported DM resolution in 85% of cases one year after MGB operation.

Table (1): Comparison between the resolution of DM for the present study and others after 1 year

Studies	% of DM resolution		Duration of follow up
	SADIS	MGB	
Del Gid et al. (2014)	85%	67%	One year
Sánchez-Pernaute et al. (2015)	82%	---	One year
Rutledge et al. (2005)	---	83%	One year
Noun et al. (2012)	---	85%	One year
The present study	80%	65%	One year

As Schauerre et al. (2003) marks it is difficult to compare different studies because there is a huge variation in the severity of the populations included, and different criteria are used to define improvement or remission (Ramos Levi et al., 2014).

In the present study we base on glycated hemoglobin and on the need for medical treatment, to define remission and control of the disease; HbA1c is the best way to determine diabetes control (Kilpatrick, 2000) and it was recently found that a simpler approach to evaluate remission, based on HbA1c and the absence of medication, has the same value as more complex criteria We, along with others, consider remission with HbA1c values below 6% (Ramos Levi et al., 2013). (Buse et al., 2009), which is the currently the most frequently used level.

it is quite evident that the mean HbA1c level after one year in SADIS patient is less than that of MGB patients being 5.44 ±0.47 % in SADIS group and 5.81 ± 0.68 % in MGB group which indicates more intense metabolic effect of SADIS to some extent in terms of DM control.

5. CONCLUSION

No significant difference between both groups as regard remission of DM The main determinant noticed during the study influencing remission is the duration of DM and preoperative C-peptide level-in addition to HBA1C level. We recommend OAGB as a metabolic surgery for patients with early onset DM type II with BMI ranging from 30-40 The study needs to be repeated over larger sample size and longer duration to determine the long term effects of metabolic surgery.

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Conflict of Interest

The authors declare that there are no conflicts of interests.

Informed consent

Written & Oral informed consent was obtained from all individual participants included in the study. Additional informed consent was obtained from all individual participants for whom identifying information is included in this manuscript.

Ethical approval

The study was approved by the Medical Ethics Committee of Ain shams University (ethical approval code: IRB 00006379).

Data and materials availability

All data associated with this study are available upon request to the corresponding author.

Peer-review

External peer-review was done through double-blind method.

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