Predictive Factors for Remission of Diabetes Mellitus Type 2 after Sleeve Gastrectomy

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ABSTRACT

Background: obesity and its associated type II diabetes mellitus (Type II DM) are an ongoing health-care problem worldwide. Both diseases are closely related and difficult to control by current medical treatment, including diet, drug therapy and behavioral modification. There is strong evidence that bariatric surgery can cure type II diabetes mellitus in patients with obesity.

Aim of the Work: to determine different predictive factors affecting the outcome of type II diabetes mellitus after laparoscopic sleeve gastrectomy.

Patients and Methods: this prospective study included 40 obese diabetic patients with type II DM who underwent laparoscopic sleeve gastrectomy. DM type II was diagnosed according to ADA criteria: FPG > 126 mg/dl, HbA1c ≥ 6.5%, random blood glucose ≥200 mg/dl, or use of insulin or oral diabetes medication. Glycemic marker in the form of HbA1c and fasting blood sugar were measured just prior to surgery and at 3 months and 6 months postoperatively.

Results: a total of 40 patients (70% women) with T2DM were included in the study. Mean age at the time of surgery was 42.48 ± 10.95 years. Median Inter Quartile Ratio (IQR) of diabetes age (diabetes age was calculated from the diagnose date to the operation date) was 4 years (from 3 years to 6 years) with range of 1-20 years. Remission of T2DM was achieved in 42.5% of patients underwent SG.

Conclusion: This study showed that younger patients, with shorter diabetic age, not using insulin and optimum pre-operative glycemic control(normal fasting blood sugar and HbA1c) were the best candidates to achieve remission (HbA1c <6.5% and no need for antidiabetics) after SG.

Keywords: *Metabolic Disease - Diabetes Mellitus – Laparoscopic Sleeve Gastrectomy*

INTRODUCTION

Numerous studies was established comparing surgical to nonsurgical treatment of morbid obesity, bariatric surgery was associated with greater weight loss and higher remission rates of type 2 diabetes mellitus. This is part of the widely used term "metabolic surgery". So, indications for bariatric surgery are therefore sliding from weight loss management to metabolic control [(1)].

However, optimal outcomes for diabetes remission after bariatric surgery will occur if patients who are best suited to the surgery are selected and those who will predictably have a poor result are excluded as not every patient achieves remission after surgery. So, identification of patients who do not respond well to bariatric surgery is important. Previous studies have identified many preoperative predictors associated with surgical outcomes, including age, gender, diabetes duration, glycemic control (HbA1c), fasting blood glucose, baseline body mass index (BMI), andmedications used to manage blood glucose [(2)].

Although Roux-en-Y gastric bypass is considered the gold standard in bariatric surgery, providing significant and sustained weight loss and resulting in resolution or improvement of obesity-related comorbidities, during the last few years, laparoscopic sleeve gastrectomy has increasingly been performed as it achieves clearly better results than other restrictive techniques and is comparable in some aspects to the Roux-en-Y gastric bypass. These benefits have been associated with different pathophysiologic mechanisms such as increased gastric emptying and intestinal transit, and activation of hormonal mechanisms such as increased glucagon-like peptide-1 (GLP-1) hormone and decreased ghrelin. By These mechanisms sleeve gastrectomy leads to weight loss and the improvement or resolution of T2DM [(4)].

AIM OF THE WORK

The aim of the current study is to determine different predictive factors affecting the outcome of type II diabetes mellitus after Laparoscopic Sleeve Gastrectomy.

PATIENTS AND METHODS

- After approval of the ethical committee in Ain Shams University, Eldemerdash Hospital, the current study was done in a period time between December 2017 and August 2018. Informed consent forms from all patients were obtained.
- It was a prospective study including 40 morbidly obese patients with Type 2 Diabetes Mellitus who underwent Sleeve Gastrectomy from El-Demerdash and Nasser Institute hospital.
- Glycemic markers in the form of fasting blood sugar and HbA1c are recorded preoperative and postoperative at 3 and 6 months.

Inclusion criteria:

1. Patient age between 18 to 65 year-old.
2. Patient with type II diabetes mellitus.
3. Patients with BMI >35 kg/m2.

Exclusion criteria:

1. Inability to tolerate anesthesia.
2. Patients refuse to participate in the study.
3. Patient with reversible endocrine or other disorder that may cause obesity.
4. Patient with hiatus hernia.

Ethical considerations:

1. All patients had been informed that they were participating in a research.
2. Operative steps, expected results, side effects and operative complications have been explained to all participants.
3. All information taken from patients are secret.

- **Preoperative evaluation of patients:** done for all patients including:

- Laboratory investigations including Fasting blood glucose and HBA1C.
- ECG, Chest X-ray.
- Pulmonary function test for obstructive sleep apnea.
- Pelvi-abdominal ultrasound to exclude gall bladder stones.
- Upper GI endoscopy to exclude hiatal hernia, gastritis or gastric erosions.

Operative steps:

- Anesthesia: General
- Patient positioning:
    1) Patient in the supine position with both arms away from the body. During operation the patient is positioned in a modified reverse Trendelenburg position.
    2) Footboard secured to bed.
- Surgeon stands in between the patient's legs with assistant on the left.
- Establish carbon dioxide pneumoperitoneum to 15 mm Hg.
- Enter abdomen with a 12-mm optical viewing trocar just left and superior to the umbilicus.
- Ports insertion under vision : two 12-mm port in the right and left midclavicular line, assistant 5-mm port in the left midaxillary line. Sub-xiphoid incision for the liver retractor. Initial decompression of the stomach with nasogastric tube. After exploration of the abdomen and the anterior wall of the stomach, the fifth port is introduced for liver retractor.

- Once trocars are in position, patient placed in slight reverse Trendelenburg. The liver retractor is fixed to the bed with a mechanical arm.
- The greater omentum is then dissected from the greater curvature of the stomach 5 cm proximal to the pylorus creating a window.
- Short gastric vessels and gastrophrenic attachments are divided using a harmonic scalpel or ligasure. Proximal dissection is complete when the left crus is identified.
- Inspect the hiatus for a hiatal hernia.
- A 36 Fr round, non-tapered tip bougie is advanced and situated along the lesser curve of the stomach.
- Starting 2-3 cm proximal to the pylorus on the greater curve of the stomach use a surgical stapler starting with 60-mm green cartridge the 4.8 mm staple height loads and transition to the 3.5 mm blue cartridge 60mm. Sometimes, staple line reinforcement is done. Care is taken to avoid narrowing the gastric pouch at the incisura.
- The Sleeve Gastrectomy continues, using the bougie as a guide.
- Intraoperative testing with diluted methylene blue with concurrent compression of prepyloric area is a complementary step.
- The resected stomach is retrieved with endocatch bag and removed via the 15-mm trocar site.
- The bougie is removed and replaced with an orogastric tube then drain is inserted.
- Remove all trocars under direct vision.

Postoperative:

Early Patients ambulating was recommended. A Gastrografin swallow was ordered if suspect a complication. A liquid diet was allowed on the first postoperative day, LMW heparin according to the patient weight to prevent DVT, tube drain was removed 24 hours after the surgery then patients were discharged home if they are able to tolerate liquids without complications.

The first follow up visit was usually a week after surgery, Subsequent visits are scheduled at 1 month, 3 months, and at 6 months.

surgical and nutritional was evaluated at each visit, follow up with BMI, Fasting blood sugar, HbA1c has been done and even if patients experience diabetes remission, glycemic control is continued for the potential for relapse.

Statistical analysis of the data:

Demographic (age and sex), anthropometric (BMI) and analytical (FPG and HbA1c) variables were collected during follow-up.

The SPASS program was used in this study. In the descriptive analysis, qualitative variables in each category are expressed as absolute frequencies and percentage. Quantitative variables are expressed with their mean ± standard deviation (SD). The chi-square analysis was used to test the association between qualitative variables. Independent t-test was used to compare the means of a normally distributed interval dependent variable for two independent groups. ANOVA was used to compare means between non-dichotomous variables. Mann-Whitney test a non-parametric test used for variables that you do not assume a normally

distributed interval variable. P-value >0.05 is considered non-significant. P-value <0.05 is considered significant. P-value< 0.01 is highly significant**.**

RESULTS

40 Diabetic obese patients underwent Laparoscopic Gastric Sleeve between December 2017 and August 2018. 28 were females and 12 were males. Their average age was 42.5 years and average BMI was 46.84kg/m2. 12 patients were on Insulin and remaining 28 were on Oral Hypoglycemic agents (OHA) before surgery. Post operatively, 17 out of 40 i.e. 42.5% patients were off all medications for Diabetes. 11 patients were still on OHAs and all the 12 patients on insulin still require it for control of blood sugar. However all patients witnessed improvement in sugar levels with a reduction in dosage of medications.

Remission of type 2 diabetes was defined according to American Diabetes Association (ADA) criteria; Partial remission was defined as HbA1c concentration of 6.0- 6.4 % and no use of antidiabetic drugs. Complete remission was defined as HbA1c concentration of less than 6.0 % and no use of antidiabetic drugs. No remission is a HbA1c ≥6.5 % without any medication or using any medication for diabetes regulation. The results of the current study are shown in table 1. According to this definition, patients who developed improvement in glycemic control but still on antidiabetic drugs in the current study (11 patients) were excluded from the remission groups.

Table (1): Results of the study (Remission, partial remission and non remission).

Complete Remission		**Partial Remission**		**No remission**	
3 months	6 months	3 months	6 months	3 months	6 months
10(25%)	13(32.5%)	4(10%)	4(10%)	26(65%)	23(57.5%)

Patients in partial and complete remission were combined in this study for analysis at 6 months. Multiple analysis to evaluate predictors for remission, pre-operative glycemic control (HbA1c and FBG), age, duration of diabetes and presurgical insulin requirement were the best preoperative predictors of HbA1c <6.5 % at 6 months as shown in table 2. 17 out of 40 patients i.e. 42.5% patients had remission of Diabetes.

Table (2): Remission and non remission results of the study.

Remission (HbA1c < 6.5%, with no need for diabetes medication).		**No remission** (HbA1c ≥ 6.5% or active hypoglycaemic treatment)	
No.	%	No.	%
17	(42.5%)	23	(57.5%)

Multiple predictive factors for remission is studied;

Age:

Mean age for remission was 34.76 ± 78 and for non-remission was 48.17 ± 9.40. P-value was highly significant (P-value = 0.000) as shown in table 3.

Table (3): Age and diabetes remission.

Variable		Remission	Non remission	Test value	P-value	Sig.
		No. = 17	No. = 23			
Age	Mean±SD	34.76 ± 78	48.17 ± 9.40	-4.787•	0.000	HS
	Range	22 – 51	29 – 62			

•: Independent t- test. HS: Highly significant.

Gender:

In this study, 76.5% of patients who underwent remission were females and 23.5% were males whereas 65.2% of patients who had no remission were females and 34.8% of them were males. P-value was non-significant (p-value= 0.443) as shown in table 4.

Table (4): Gender and diabetes remission.

Variable		Remission	Non remission	Test value	P-value	Sig.
		No. = 17	No. = 23			
Gender	Female	13 (76.5%)	15 (65.2%)	0.589*	0.443	NS
	Male	4 (23.5%)	8 (34.8%)			

*:Chi-square test. NS: non significant.

Duration of diabetes:

Median diabetic age was 3 (2 - 4) years for patients who developed remission and 5 (4 - 10) years for patients who had no remission. P-value was highly significant (P-value = 0.000) as shown in table 5.

Table (5): Duration of diabetes and its remission.

Variable		Remission	Non remission	Test value	P-value	Sig.
		No. = 17	No. = 23			
Duration of Diabetes	Median(IQR)	3 (2 - 4) Y.	5 (4 - 10) Y.	-3.884‡	0.000	HS
	Range	1 – 5 Y.	2 – 20 Y.			

‡:Mann Whitney test. HS: Highly significant.

Pre-operative antidiabetic medications:

All patients who developed remission were using one type of antidiabetic drugs. Patients who had no remission were on insulin pre-operative. P-value was highly significant (P-value = 0.000) as shown in table 6.

Table (6): Preoperative antidiabetic medications and diabetes remission.

Variable		Remission	Non remission	Test value	P-value	Sig.
		No. = 17	No. = 23			
Preoperative Antidiabetic Medications	Insulin	0 (0.0%)	12 (52.2%)	32.677*	0.000	HS
	one type oral	17 (100.0%)	2 (8.7%)			
	more than one type oral	0 (0.0%)	9 (39.1%)			

*:Chi-square test. HS: Highly significant.

Pre-operative HbA1c:

Mean Preoperative HbA1C was 6.36 ± 1.02 for patients who developed remission and 8.18 ± 1.44 for patients who had no remission. P-value was highly significant (P-value = 0.000) as shown in table 7.

Table (7): Preoperative HbA1c and diabetes remission.

Variable		Remission	Non remission	Test value	P-value	Sig.
		No. = 17	No. = 23			
Preoperative HbA1C	Mean±SD	6.36 ± 1.02	8.18 ± 1.44	-4.454•	0.000	HS
	Range	4.9 – 8.6	5.9 – 11			

•: Independent t- test. HS: Highly significant.

Pre-operative fasting biood sugar:

Mean Preoperative Fasting blood sugar was 130.00 ± 37.38 for patients who developed remission and 173.65 ± 38.28 for patients who had no remission. P-value was highly significant (P-value = 0.000) as shown in table 8.

Table (8): Preoperative fasting blood glucose and diabetes remission.

Variable		Remission	Non remission	Test value	P-value	Sig.
		No. = 17	No. = 23			
Preoperative Fasting blood sugar	Mean±SD	130.00 ± 37.38	173.65 ± 38.28	-3.600•	0.001	HS
	Range	90 – 234	117 – 280			

•: Independent t- test. HS: Highly significant.

Preoperative BMI:

Mean Preoperative BMI was 45.61 ± 6.40 for patients who developed remission and 47.74 ± 8.01 for patients who had no remission. P-value was non-significant (P-value = 0.371) as shown in table 9.

Table (9): Preoperative BMI and diabetes remission.

Variable		Remission	Non remission	Test value	P-value	Sig.
		No. = 17	No. = 23			
Preoperative BMI	Mean±SD	45.61 ± 6.40	47.74 ± 8.01	-0.906•	0.371	NS
	Range	37.6 – 58	37.7 – 63.6			

•: Independent t- test. NS: non significant.

Postoperative BMI at 6 Months:

Mean Postoperative BMI at 6 months was 34 ± 4.80 for patients who developed remission and 37.3 ± 6.62 for patients who had no remission. P-value was non-significant (P-value = 0.089) as shown in table 10.

Table (10): Postoperative BMI at 6 months and diabetes remission.

Variable		Remission	Non remission	Test value	P-value	Sig.
		No. = 17	No. = 23			
BMI at 6 Months postoperative	Mean±SD	34 ± 4.80	37.3 ± 6.62	-1.743•	0.089	NS

•: Independent t- test. NS: non significant

DISCUSSION

Remission of T2DM is one of the major goals of SG. Identification of the best candidates to achieve this goal is so important. In this study, identification of potential predictors of diabetes remission after SG was the main goal. At the end of this study, 42.5% of patient developed remission of type 2 diabetes. (either complete or partial) of type 2 diabetes, patients who reduced the dose of the antidiabetic drug used or developed improvement in glycemic control but still on antidiabetic drugs (11 patients; 27.5 %) were not considered in remission according to ADA criteria used for diabetes remission in our study, although they are expected to be in remission in longer term follow up.

In the ASMBS 2009 position statement, data from ten studies (n = 754 patients) on the evolution of comorbidities after SG were analyzed. T2DM remission ranged from 14 to 100 %. In 2006, Cottam et al. reported T2DM remission in 81 % of T2DM patients submitted to SG. In the Moon Han et al. study at 6 months follow–up, T2DM remission was 100 %. In the 2007 Vidal et al. study, SG and gastric bypass (GBP) had a similar impact on diabetes (51.4 and 62 %, respectively, P =.332) in the short term (4 months) and an identical remission rate (84.6 %, P =.618) at 12 months [(5)].

It is uncertain if the widely varied remission rates between the studies of SG are related to patient characteristics (ethnicity), or to the absence of a clear definition of resolution of T2D. Another explanation could be that these studies used different definitions of "improvement," "resolution," "remission," or "cure" of diabetes.

In this study, there was no association between gender and T2DM remission after SG (insignificant p value=0.443)

These results are similar to a meta-analysis by ***Wang et al.*** [(2)]**,** with a total of 1,113 T2DM patients in 13 studies included in it showing an insignificant association between gender and T2DM remission [(2)]**.**

Another issue confirmed by this study is that *Older age* is also associated with lower remission rates(p. value **<**0.001). Hence, older age is considered in this study as negative prognostic factor for remission of T2DM. Nedelcu et al., confirmed this results. A German study also found that increasing age was an independent significant predictor for postoperative metabolic failure**.** These observations were confirmed by a metaanalysis of 13 studies (n=1149) which showed a significant negative association between preoperative age and T2DM remission (OR: -2.46, p< 0.01) [(2)]**.**

Diabetes duration is known to reflect the residual β cell mass in T2DM patients, both in morbidly and non-morbidly obese patients. The effectiveness of the SG on T2DM remission seems to be related to the β-cell reserve of patients. In this study longer *diabetes duration* is associated with lower remission (p. value 0.001). A study by Vidal et al. reported that shorter T2DM duration were associated with T2DM remission [(Vidal)], a T2DM treatment without pharmacologic agents, and better glycemic control. Nedelcu et al., confirmed that there is strong evidence that patients with a shorter history of diabetes may benefit more than those with a longer one. ***Kheniser and Kashyap*** [(6)] had similar results [(6)]. Lee et al., concluded in an Asian study that duration of diabetes is the most important predictor of diabetes remission after surgery. Longer diabetes duration

In a study by ***Casella et al.*** [(5)]**,** a 10- year cut-off in diabetes duration yielded a 75% sensitivity and 96% specificity for diabetes remission after SG. The study demonstrated that DM remission occurred in 100 % of patients with DM duration <10 years and in 31 % of patients with DM duration >10 years [(5)]. ***Robert et al.*** [(7)]**,** demonstrated that a duration <4 years had a 79% sensitivity and 80% specificity (p=0.0001) to predict resolution at one year.

The results of this study also confirmed that HbA1c and fasting blood glucose is significantly predictor for remission (p. value<0.001 and 0.001 respectively).Hence inadequate pre-operative glycemic control is negatively associated with the T2DM remission.

Similarly, ***Robert et al.*** [(7)]**,** concluded that a fasting glucose <114mg/dL and a HbA1c <7.1% were predictors for T2DM resolution at one year, regardless of the type of bariatric operations [(7)]**.** Nedelcu et al., demonstrated that high preoperative HbA1C levels can predict failure of resolution of T2DM. In a study by ***Kheniser and Kashyap*** [(6)]**,** poorly controlled diabetes, defined as an HbA1c of 7.5%, may be predictive of poor glucose management and lower rates of diabetes remission [(6)]**.** In a study by Jurowich et al., 17 out of 82 participants did not show an improvement in their diabetes with non responders having a higher preoperative HbA1c level (p=0.033).

Furthermore, in this study baseline BMI do not play a role in diabetes remission with (p value =0.371). ***Panunzi et al.*** [(8)]**,** observed similar T2DM remission in two groups with a BMI <35 kg/m2 and a BMI >35 kg/m2 [(8)]**.**

Lee et al. [9], demonstrated that remission of T2DM was achieved in 45 (72.5%) patients after gastrointestinal surgery with SG one of them revealing the BMI was a significant factor for remission during the postoperative follow-up [9].

Sex and BMI could not show any role in prediction of successful treatment of T2DM. P value of sex was

This study further confirmed that diabetes remission was significantly lower in patients requiring insulin therapy compared with prescribed oral hypoglycemic agents (p. value <0.001). No remission occurred in patients using insulin pre-operatively. Insulin treatment may indicate the severity of diabetes. Specifically, patients dependent on insulin therapy may have worse β cell function. ***Robert et al.*** [7], also demonstrated that non-insulin based therapies was an independent predictor for remission one year after surgery (p=0.0001, sensitivity 96% and specificity 60%) [7].

Similarly, ***Blackstone et al.*** [10], observed that the remission rates were greater for patients not using insulin pre-operatively (53.8% vs 13.5%, p<0.001) [10].

Another study shows that preoperative T2DM patients who take insulin have substantially lower overall remission rates, regardless of their HbA1C levels [11].

There are limitations in this study. We looked at short-term postoperative changes. Also, the fact that a single-center study with all bariatric procedures performed by one same surgeon may potentially avoid bias induced from different surgical protocols adopted by multiple centers and variable operational experience in bariatric surgery performed by different surgeons. The durability and long-term safety profile of our results remain uncertain. However, follow-up of patients in the prospective part of the study with data collection will be continued. Such effort should allow additional assessment of long-term efficacy and safety results as well as identification of other important predictors such as C-peptide and excess weight loss(%EWL). We did not compare outcomes among different types of bariatric procedures. The ultimate goal of our study was to facilitate preoperative patient selection in order to achieve a short-term diabetes remission after SG, recognized as the most popular and technically simple metabolic and bariatric surgery procedure.

CONCLUSION

In conclusion, Laparoscopic Gastric Sleeve surgery can induce a significant remission and improvement of T2DM in severely obese patients. Remission of T2DM was achieved in 42.5% of patients underwent SG. This study also showed that younger patients, with shorter diabetic age, not using insulin and optimum pre-operative glycemic control (normal fasting blood sugar and HbA1c) were the best candidates to achieve remission(HbA1c <6.5% and no need for antidiabetics) after SG. However this study is a small sample size and a short follow up period. More studies with larger sample size and longer follow up period are required to confirm these results.

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INTRODUCTION

Obesity and its associated type 2 diabetes mellitus (T2DM) are an ongoing health-care problem worldwide. Both diseases are closely related and difficult to control by current medical treatment, including diet, drug therapy and behavioral modification. There is strong evidence that bariatric surgery can cure type 2 diabetes mellitus in patients with obesity ***(Lee et al., 2010)***.

Numerous studies were established comparing surgical to nonsurgical treatment of morbid obesity, bariatric surgery was associated with greater weight loss and higher remission rates of type 2 diabetes mellitus. This is part of the widely used term "metabolic surgery". So, indications for bariatric surgery are therefore sliding from weight loss management to metabolic control ***(Koliaki et al., 2017)***.

However, optimal outcomes for diabetes remission after bariatric surgery will occur if patients who are best suited to the surgery are selected and those who will predictably have a poor result are excluded as not every patient achieves remission after surgery. So, identification of patients who do not respond well to bariatric surgery is important. Previous studies have identified many preoperative predictors associated with surgical outcomes, including age, gender, diabetes duration, glycemic control (HbA1c), fasting blood glucose, baseline body mass index (BMI) and medications used to manage blood glucose ***(Wang et al., 2014)***.

Although Roux-en-Y gastric bypass is considered the gold standard bariatric surgery, providing significant and sustained weight loss and resulting in resolution or improvement of obesity-related comorbidities, during the last few years, laparoscopic Sleeve Gastrectomy has increasingly been performed as it achieves clearly better results than other restrictive techniques and is comparable in some aspects to the Roux-en-Y gastric bypass. These benefits have been associated with different pathophysiologic mechanisms such as increased gastric emptying and intestinal transit, and activation of hormonal mechanisms such as increased glucagon-like peptide-1 (GLP-1) hormone and decreased ghrelin. By These mechanisms Sleeve Gastrectomy leads to weight loss and the improvement or resolution of T2DM ***(Dejeu et al., 2016)***.

Aim of the Work

The aim of the current study is to determine different predictive factors affecting the outcome of type 2 Diabetes Mellitus after Laparoscopic Sleeve Gastrectomy.