

# Comparison between the Effect of Laparoscopic Sleeve Gastrectomy and Laparoscopic Mini-gastric Bypass on Type 2 Diabetes Mellitus in Obese Patients: A Prospective Study

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## ABSTRACT

**Background:** One of the major global health burdens is type 2 diabetes mellitus (T2DM). Laparoscopic sleeve gastrectomy (LSG) has recently been shown to be effective and safe for T2DM management. Laparoscopic mini-gastric bypass (LMGB) was introduced as a simple (one anastomosis) operation combining both restrictive and malabsorptive functions thus suitable for obese patients with metabolic derangements like T2DM. This study aims to compare the effect of LSG and LMGB on T2DM in obese patients.

**Materials and methods:** A cohort study was carried out on obese patients with T2DM submitted for LSG or LMGB in the department of surgery at Suez Canal university hospital and Suez Canal authority hospital, Egypt, from June 2018 to September 2020. The patients were followed up for 12 months.

**Results:** A total of 20 patients were allocated to each group. The change in the mean body mass index (BMI) was significantly higher in the LSG, compared to the LMGB group ( $p < 0.05$ ). Both groups exhibited a significant reduction in the HbA1c at the end of follow-up 12 months after surgery; however, the reduction was significantly higher in the LMGB group ( $p < 0.05$ ). Among the LSG group, 75% of the cases showed complete diabetic remission, 15% showed partial remission, and 10% showed improvement in their glycemic control at the end of follow-up. Among the LMGB group, 85% of the cases showed complete diabetic remission and 10% showed partial remission. The difference between the study groups was statistically significant.

**Conclusion:** The study showed good improvement for T2DM and a great response in losing weight with a significant superiority of LMGB over the LSG.

**Keywords:** Bariatricsurgery, Metabolic disorders, Obesity, Type 2 diabetes mellitus.

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## INTRODUCTION

One of the major global health burdens is type 2 diabetes mellitus (T2DM). It has been estimated that the global prevalence of T2DM will increase to 642 million by 2040.<sup>1,2</sup> According to current estimates, end-stage renal disease and coronary artery disease were observed in 45 and 55% of diabetic patients, respectively. Moreover, it was reported that 90% of diabetic patients were obese.<sup>3,4</sup> The present treatment for T2DM involves advising patients to lose weight by dietary changes and administering drugs to restore glycemic regulation by decreasing insulin resistance and enhancing insulin secretion.<sup>5</sup> Bariatric surgery has recently been shown to be very effective in treating not only morbid obesity but also T2DM-related obesity.<sup>6</sup>

Laparoscopic sleeve gastrectomy (LSG) has gained popularity among all bariatric procedures and is the most frequently performed bariatric surgery worldwide.<sup>7,8</sup> LSG is one of the restrictive gastric procedures that limit the gastric volume and restrict the intake of calories.<sup>9</sup> LSG has recently been shown to be effective and safe for T2DM management.<sup>10</sup> Several studies have also recommended LSG as a metabolic procedure for T2DM therapy; however, the available data were only on the short-term follow-up.<sup>11-13</sup>

The laparoscopic mini-gastric bypass (LMGB) was first presented in 2001 by Rutledge.<sup>14</sup> It assures a small gastric pouch with the rapid transfer of gastric material to the jejunum, generating both malabsorptive and restrictive results.<sup>15</sup> Regarding the effect of

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LMGB on T2DM, it was reported that complete remission rates reached up to 65%.<sup>16</sup> During the first 6 months after surgery, weight loss was greatest and then stabilized later. Comparing the long-term effectiveness of both LSG and LMGB procedures as a treatment for morbid obesity and T2DM has not been demonstrated, taking into consideration the satisfaction, complications, morbidity, and mortality of postoperative patients. Therefore, we aimed to compare the effect of LSG and LMGB on T2DM in obese patients.

## MATERIALS AND METHODS

### Study Design and Population

A prospective, comparative study was carried out on obese patients with T2DM, who were elected to undergo either LSG or LMGB at surgery theater of Suez Canal University teaching hospital, Ismailia, Egypt. The study's protocol gained the official approval of local ethics committee of the University hospital, and all patients signed written informed consents before the procedure. Only patients aged more than 18 years old, had a body mass index (BMI) of  $\geq 35$  kg/m<sup>2</sup>, and documented diagnosis of T2DM were included. The diagnosis of T2DM was based on the latest version of the American Diabetes Association (ADA) criteria.<sup>17</sup> Patients with history of previous bariatric surgery, contraindications for general anesthesia, and/or cardiac, hepatic, renal, or hematologic disorders were excluded.

### Study's Procedures

Preoperatively, all patients underwent history taking and full clinical examination according to the institutions' local protocols. Besides, routine preoperative laboratory evaluation was conducted with special emphasis on fasting blood sugar (FBS) and glycosylated hemoglobin (HbA1c).

All patients were asked to follow a high-protein diet 2 weeks before the procedure. Eight hours prior to the surgery, the patients were asked to fast and were allowed fluids only 4 hours before fasting. All procedures were conducted under general anesthesia. The LSG and LMGB were performed per the institutions' local protocols. Briefly, a total of five ports were used in patients undergoing LSG, which were distributed 5 cm from umbilicus (mainly 12mm for stapling and introduction of laparoscopy), at the left flanks (mainly 15mm for stopping the blood supply to greater curvature, introduction of laparoscopy, and suturing), at epigastrium (5-mm port aiding liver elevation), at right upper quadrant, and at left lateral subcostal area for assistant. Following the devascularization of greater curvature and division of the stomach, a total of six cartridges were employed for stomach stapling. The sleeve was examined by methylene blue to confirm complete and uniform filling, and the resected stomach was removed via the umbilical port. The incision was then sutured after locating intraperitoneal drain.

Patients in LMGB were positioned at the reverse Trendelenburg position, and five ports were distributed in a diamond-like matter 5 cm from umbilicus, midclavicular line 4–6 cm from the costal margin, at 4 to 6 cm from xiphisternum, at midclavicular line 4 to 6 cm from the left costal margin, and at left anterior axillary line–6 cm from the left costal margin. Following mesentery dissection, a 45-mm blue/gold cartridge was placed perpendicular to the lesser curvature and another 60-mm blue stapler was placed parallel to the lesser curvature up to esophagogastric junction. A linear 45-mm blue stapler is used to create a gastrojejunostomy, and the stapler defect is closed with Vicryl 2-0 suture. The incision was then sutured after locating intraperitoneal drain. Throughout the whole intraoperative period, patients were observed for the amount of blood loss.

Patients were then moved to the ward, managed per institutions' protocol, and started liquid oral intake 6 hours postoperatively.

### Study's Outcomes

The patients were observed over a follow-up period of 12 months. Primarily, we aimed to compare between LMGB and LSG concerning

postoperative changes in glycemic parameters at the end of the first year after the procedure. Other comparative parameters included the incidence of T2DM complete/partial remission, as defined by ADA criteria,<sup>17</sup> change in body weight, and incidence of postoperative complications.

### Statistical Analysis

Descriptive statistics were presented as mean  $\pm$  standard deviation for continuous data and as number and percent for categorical data. Data analysis was conducted by SPSS 15.0 (SPSS Inc., Chicago, Illinois, United States), and  $p < 0.05$  was counted as significant difference. To compare continuous variables, an independent *t*-test and Wilcoxon signed-rank test were used for parametric and nonparametric data, respectively. Chi-square test was used to compare categorical variables.

## RESULTS

We constructed two groups, and each included 20 patients: group A correspond to the sleeve group, and group B for the mini-gastric bypass group. We found that the mean age of group A was 37.1 years with a range of 25–60 years. However, group B ranged from 19 to 51 with a mean of 35.4 years. The male gender was more than the female in both groups and accounts for 55% and 65% in group A and group B, respectively. There were no statistically significant differences between both groups regarding comorbidities (Table 1).

The total mean operative time was 105 minutes (98 minutes and 116 minutes among the LSG and LMGB groups, respectively). The difference between both groups was statistically significant. Regarding intraoperative blood loss, the total mean blood loss was 72 mL (70 and 79 mL among the LSG and LMGB groups, respectively). No reoperations were observed in both groups. The mean hospital stay among the LSG group was 3.9 days, and that of the LMGB group was 2.8 days; the difference between the two groups was statistically significant. None of the study groups showed any mortality. Among LSG group regarding intra- and postoperative complications, 5% of the patients showed vascular injury (short gastric artery injury), 5% of the patients suffered from reflux, 15% suffered from marginal ulcer, 20% had iron deficiency anemia, and 15% suffered from wound infection. Among LMGB group, 15% showed vascular injury (left gastric and short gastric artery injury), and one patient had a detected anastomotic leak that was treated intraoperatively. As for the early postoperative complications, one patient suffered from persistent vomiting (treated conservatively) and one patient had DVT (treated medically). Regarding late complications, 30% of the patients suffered from reflux, 25% suffered from marginal ulcer, 35% had iron deficiency anemia, and 5% suffered from wound infection. The

**Table 1:** Baseline characteristics of the studied subjects (N = 40)

Variable		Group A (sleeve) (n = 20)		Group B (bypass) (n = 20)		p value
		No	%	No	%	
Age (years)	Mean $\pm$ SD	37.1 $\pm$ 8.4		35.4 $\pm$ 8.2		>0.05
	Range	25–60		19–51		
Male		11	55%	13	65%	>0.05
	HTN	5	25%	8		
Comorbidities	OSA	3	15%	5		>0.05
	Dyslipidemia	7	35%	9		

difference in the perioperative complications between the study groups was statistically significant (Table 2).

Among the LSG group, the mean preoperative BMI was 53 kg/m<sup>2</sup>, it decreased to 50.6 kg/m<sup>2</sup> 1 month after surgery, then to 49.6 kg/m<sup>2</sup> after 3 months, 45.5 kg/m<sup>2</sup> after 6 months, 40 kg/m<sup>2</sup> after 9 months, and finally 37 kg/m<sup>2</sup> at the end of follow-up 12 months after surgery. Regarding LMGB group, the mean preoperative BMI was 52 kg/m<sup>2</sup>, it decreased to 48.1 kg/m<sup>2</sup> 1 month after surgery, then to 43.2 kg/m<sup>2</sup> after 3 months, 40 kg/m<sup>2</sup> after 6 months, 37.4 kg/m<sup>2</sup> after 9 months, and finally 35.1 kg/m<sup>2</sup> at the end of follow-up 12 months after surgery. The difference in the perioperative changes in the mean BMI between the study groups was statistically significant (Fig. 1).

Concerning the primary outcome, among the sleeve group, the mean preoperative HbA1c was 10.1%, it decreased to 8.6% 3 months after surgery, then to 8.1% after 6 months, 7.4% after 9 months, and finally 7% at the end of follow-up 12 months after surgery. Regarding bypass group, the mean preoperative HbA1c was 10.9%, it decreased to 8.1% 3 months after surgery, then to 7.2% after 6 months, 6.9% after 9 months, and finally 6.6% at the end of follow-up 12 months after surgery. The difference in the perioperative changes in the mean HbA1c between the study groups was statistically significant (Fig. 2).

Among the LSG group, 75% of the cases showed complete diabetic remission, 15% showed partial remission, and 10% showed an improvement in their glycemic control at the end of follow-up. Among the LMGB group, 85% of the cases showed complete diabetic remission and 10% showed partial remission. The difference between the study groups was statistically significant (Fig. 3).

**DISCUSSION**

Laparoscopic bariatric surgery has been widely accepted by surgeons for its efficiency, safety, minimally invasive nature, and physiologic benefits.<sup>18</sup> These benefits are obtained in weight reduction and getting rid of the obesity mechanical comorbidities like obstructive sleep apnea, disk prolapse, and advanced osteoarthritis.<sup>19</sup> Many studies discussed these benefits and the effects of the aforementioned procedures on T2DM, hyperlipidemia, and hypertension either for short-term follow-up or for long-term follow-up with the presence of promising results in controlling many of these comorbidities.<sup>20,21</sup>

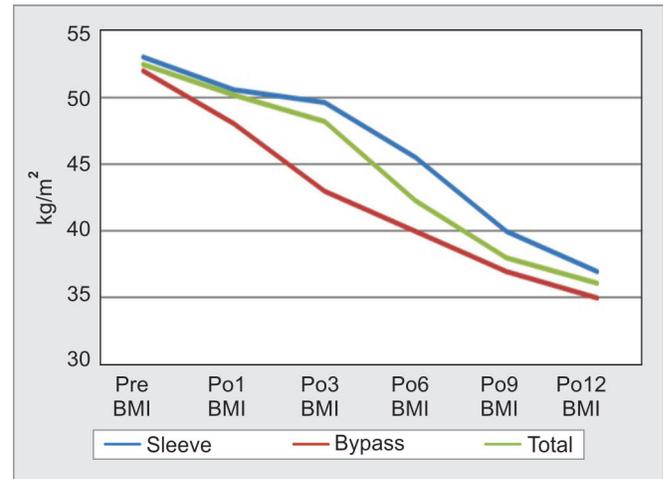
**Table 2:** Intraoperative and postoperative characteristics (N = 40)

Variable		Group A (n = 20)	Group B (n = 20)	p-value
Hospital stay (days)	Mean ± SD	3.9 ± 0.5	2.8 ± 0.3	<0.05
	Range	3–5	2–5	
Intraoperative	Mortality	0	0	—
	Bleeding	1	3	5% vs 15%
	Intraoperative leak	0	1	0% vs 5%
	Postoperative leak	0	0	0% vs 0%
Early postoperative	DVT	0	1	0% vs 5%
	Bleeding	0	0	0% vs 0%
	Reflux	1	6	5% vs 30%
Late postoperative	Iron deficiency anemia	4	7	20% vs 35%
	Wound infection	3	1	15% vs 5%

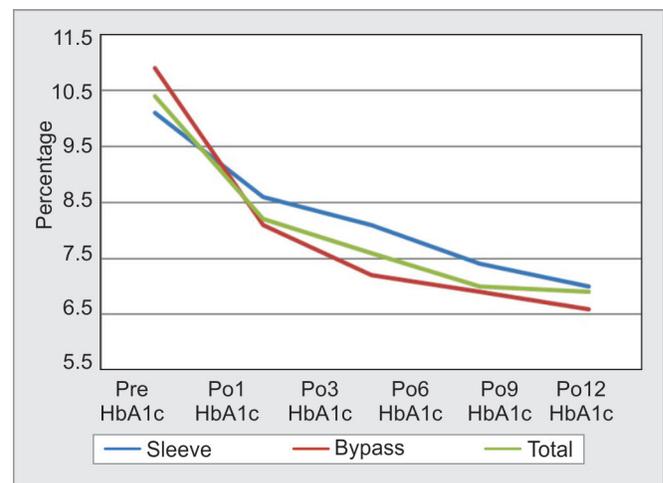
\*X<sup>2</sup> = 0.03, p value

Our study has focused on the effect of both LSG and LMGB on T2DM as our primary objectives; however, other comorbidities (hypertension, dyslipidemia, and obstructive sleep apnea) were also observed. The mean operative time for group A (LSG) was 98 minutes, and that of group B (LMGB) was 116 minutes, which was consistent with a Korean study comparing the two procedures by Park et al. The mean operative time was 100 minutes and 130 minutes for LSG and LMGB, respectively.<sup>22</sup> Also, Piazza et al., reported a mean operative time of 120 minutes;<sup>23</sup> Lee et al. reported 114 minutes of operative time for LMGB.<sup>24</sup> Other studies showed shorter operative duration, as Kular et al., who reported a mean duration of 76 minutes for LSG,<sup>25</sup> and Rutledge, who reported that the average time of LMGB was 37 minutes.<sup>26</sup> These times were obtained due to the increased learning curve of these procedures.

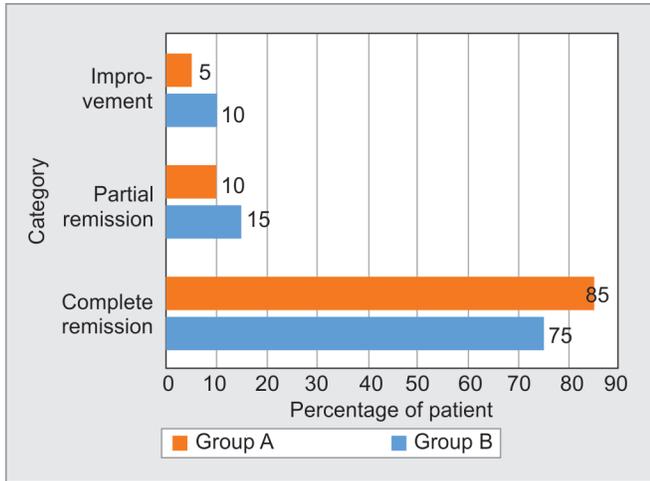
Regarding the effect of the LSG on T2DM, we reported complete remission of diabetes in 75% of patients, which was consistent with other studies. Nocca et al., reported that the complete remission was observed in 76% of 25 patients with T2DM and BMI more than 35 kg/m<sup>2</sup>, and therefore, they stopped the diabetes mellitus treatment.<sup>10</sup> Nosso et al., showed that 97% of diabetic patients got



**Fig. 1:** Graphical presentation to the perioperative change in the case of body mass index (BMI) (N = 40). X<sup>2</sup> = 0.016, p value <0.05



**Fig. 2:** Graphical presentation to the perioperative change in the case of glycosylated hemoglobin (HbA1c) (N = 40). X<sup>2</sup> = 0.001, p value <0.05



**Fig. 3:** Graphical presentation to the percentage of patients with partial/complete remission (N = 40).  $X^2 = 0.02$ ,  $p$  value <0.05

remission of the disease after 1 year of the LSG with a mean HbA1c of 6.5%.<sup>27</sup> However, they did not differentiate between the complete and initial remission. Lee et al., demonstrated a 50% remission after LSG in 20 patients with T2DM; however, their patients' BMI was between 25 and 35 kg/m<sup>2</sup>, and the mean BMI of our patients was above 50 kg/m<sup>2</sup>.<sup>24</sup> Similarly, Schauer et al., reported a 24% remission after LSG in 49 patients with T2DM who were followed for 36 months, obtaining a mean HbA1c of 6%.<sup>28</sup> This may support the hypothesis of weight regain and the relapse of T2DM with time after LSG. However, these studies may not choose the patient's proper procedure as the LSG is not well designed for sweet eaters, as weight regains in sweet eaters having LSG are well reported. The patients should give up excessive sweets following LSG.

For the LMGB, we reported complete remission of the diabetes mellitus of 85% of the studied population. Rutledge also observed this finding after performing 2410 LMGB; not all of them had diabetes, but they had various comorbidities.<sup>26</sup> After 5 years of follow-up, he found an 84% complete remission of T2DM, which is consistent with our study results. Wang et al. followed 423 patients post LMGB for 2 years and recorded a complete resolution of T2DM in 100% of patients.<sup>29</sup> These findings support the effectiveness of LMGB in the management of T2DM.

For the intraoperative complications, we reported vascular injury and liver tear in both LSG (5 and 10%) and LMGB (15 and 15%), respectively. Intraoperative leakage was reported only in one case (5%) of LMGB; however, all intraoperative complications were controlled intraoperatively and laparoscopically, which is consistent with other studies in the overall percentage of complications. Kular et al.,<sup>25</sup> reported 14% of early complications after LSG in the form of intra-abdominal bleeding (3.3%), early reoperation (0.8%), intra-abdominal abscess (0.8%), and dyspepsia (7%). Late complications were reported in 24% of the patients; however, GERD were reported in 21%, anemia 2.6%, and cholelithiasis 10.5% of the patients. Further, in the study of Park et al., intraoperative complications were reported in 1% of LSG patients in the form of bleeding, and late complications were reported in 5% of the patients; two of them (2%) required reoperation; however, in our study, reoperation was not required in any patient.<sup>22</sup>

In conclusion, the current findings showed that both LSG and LMGB are efficient and safe procedures for losing weight

and controlling high blood glucose levels in T2DM. LMGB has a significant superiority over LSG in controlling patients with T2DM and weight reduction. Health education programs should be carried out to increase the population's awareness about the risk of obesity and its concomitant comorbidities, especially diabetes mellitus, which may cost the patient losing an organ, a limb, or even his life.

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