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DATABASE ANALYSIS

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Glycemic Control in Obese Type 2 Diabetic Patients Treated with Laparoscopic Sleeve Gastrectomy and Transit Bipartition

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Background: Type 2 diabetes mellitus (T2DM) and obesity are significant health challenges linked to increased morbidity and mortality. Laparoscopic sleeve gastrectomy with transit bipartition (LSG+TB) has shown promise in improving glycemic control. This study aimed to evaluate the outcomes of obese patients with T2DM treated with LSG+TB, focusing on variations in surgical techniques.

Material/Methods: This retrospective study analyzed obese T2DM patients who underwent LSG+TB at a single center. Data on preoperative and postoperative hemoglobin A1c (HbA1c) levels, body mass index (BMI), sex, and surgical technique details were collected. Changes in HbA1c levels were assessed at 3 and 12 months after surgery based on variations in stapler line distance, common channel length, and anastomotic loop diameter.

Results: A total of 420 patients were included. Baseline BMI of patients with stapler line distances of 6 cm, 8 cm, and 10 cm from the pylorus was 40.06, 34.87, and 30.42, respectively ($P<0.001$). The average percentage of excess weight loss at 1 year was 68.11%. Significant reductions in HbA1c were observed across all groups, with greater reductions in the 6 cm group compared to the 8 cm and 10 cm groups ($P=0.019$). Common channel length and anastomotic loop diameter showed no significant impact on HbA1c levels.

Conclusions: LSG+TB effectively improves glycemic control in obese T2DM patients. A 6 cm stapler line distance from the pylorus is associated with superior HbA1c reduction and comparable safety to longer distances.

Keywords: Bariatric Surgery • Diabetes Mellitus, Type 2 • Glycated Hemoglobin • Obesity, Morbid • Surgical Procedures, Operative

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Introduction

Diabetes is a major global health concern, with its prevalence steadily increasing over recent years. The World Health Organization (WHO) reported that, as of 2014, approximately 422 million people worldwide were living with diabetes mellitus (DM), a number that has quadrupled in the past 35 years, driven largely by the surge in type 2 diabetes linked to obesity and other lifestyle factors [1]. This increase is especially evident in developed nations, where obesity – a primary risk factor for diabetes – is particularly prevalent [2,3]. In managing type 2 diabetes, bariatric surgery is recommended in addition to lifestyle modifications and antidiabetic medications, particularly in obese patients, as it facilitates weight loss and improves insulin sensitivity [4]. Multiple studies have demonstrated that bariatric procedures can lead to diabetes remission in obese patients with diabetes [5]. Among the various bariatric techniques, gastric bypass and sleeve gastrectomy are widely used, with sleeve gastrectomy gaining popularity due to its low complication rate and reduced surgery-related mortality [6]. The laparoscopic sleeve gastrectomy with transit bipartition (LSG+TB) technique was first described by Santoro et al in 2012 [7] and has since become widely adopted as a bariatric procedure worldwide [8]. As a relatively novel approach, there is a limited number of studies that explore the biochemical outcomes and effectiveness of LSG+TB in managing diabetes.

Moreover, in LSG+TB surgery, the effects of surgical technical details such as the distance of the stapler line from the pylorus, the length of the common channel, and the anastomotic loop diameter on glycemic control remain unclear. This study aims to evaluate the impact of the LSG+TB technique on Hemoglobin A1c (HbA1c) levels, as well as operational factors and outcomes in obese patients with type 2 diabetes treated with LSG+TB.

Material and Methods

Ethics Statement

Ethics approval (Code: 2020/4, Date: 22.04.2020) was obtained from the Academic Ethics Committee of our institution in accordance with the Helsinki Declaration.

Study Design and Population

Data for this study were collected from the medical records of consecutive patients who chose to undergo LSG+TB surgery. These patients included individuals with type 2 diabetes and a body mass index (BMI) of ≥25, categorized as overweight, obese, or morbidly obese, admitted to our hospital for weight and obesity management between May 2015 and May 2019. The sample size was determined based on the time frame during which the surgical technique, detailed below, was routinely implemented in our practice. Patients diagnosed with type 2 diabetes based on endocrinological evaluation in their records were included in the study. Collected patient information included age, gender, BMI category (overweight, Class 1, 2, or 3), BMI values (initial, 3 months, 12 months), other simultaneous surgical interventions (e.g., cholecystectomy, liver biopsy), the length of the common channel (≤100 cm or >100 cm), the distance from the first stapler line to the pylorus (6, 8, or 10 cm), the anastomotic loop diameter (2.5 cm or 3 cm), and postoperative complications (stenosis, leakage, oral intolerance, and complications that require treatment). (These decisions were made by the surgeon after his subjective evaluation for each patient. The standards of this evaluation and surgical technique preferences may have changed during the study period.) Preoperative and postoperative HbA1c levels at 3 and 12 months were analyzed according to patient BMI subgroup, along with the impact of variations in anastomotic distance from the pylorus, common channel length, and anastomotic loop diameter, which were considered potential factors influencing these changes. Malnutrition related to malabsorption was defined as the presence of diarrhea and albumin levels below 2.5 g/dL. Excess weight loss was calculated as the ratio of actual weight loss to the weight loss required to achieve a BMI of 22.

Deep Vein Thrombosis Prophylaxis

All patients received pharmacological DVT prophylaxis with enoxaparin (0.5 mg/kg) in the preoperative period. In the postoperative period, mechanical prophylaxis using intermittent pneumatic compression devices was employed until patient mobilization. After mobilization, pharmacological prophylaxis was continued for 10 days postoperatively (0.5 mg/kg, daily in 2 doses).

Operative Technique

All LSG+TB surgeries performed within the specified period were conducted by the same surgeon using these techniques: Following the administration of antibiotics and deep vein thrombosis prophylaxis, patients were positioned on the operating table. After inducing general anesthesia, pneumoperitoneum was established using a Veress needle. Trocar placements are presented in **Figure 1**. Initially, the omental bursa was accessed, and the greater curvature of the stomach was freed by dissecting the greater omentum up to the angle of His, stopping 2 cm proximal to the pylorus, using a radiofrequency sealing device (LigaSure™, Covidien, Medtronic, Minneapolis, MN, USA). The stomach was divided at 6, 8, or 10 cm from the pylorus with laparoscopic linear staplers. This preference was primarily based on patient BMI, with a higher BMI corresponding to a closer stapler line. Endo GIA™, Covidien, Medtronic, Minneapolis, MN,

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Figure 1. Trocar placements for laparoscopic sleeve gastrectomy with transit bipartition.

USA) and a 46F orogastric tube is used routinely in our institution, preserving the remnant stomach along the lesser curvature. The specimen was subsequently extracted, and the stapler line was routinely sutured seromuscularly in a continuous manner, covering the entire stapled line from top to bottom.

Following the sleeve gastrectomy, the ileocecal junction was identified, and the small intestine was transected 250 cm proximal to the ileocecal valve using an endoscopic stapler. The distal end was then anastomosed (antecolic) to the gastric antrum with a linear stapler of either 2.5 cm or 3 cm in diameter. The diameter of the anastomosis was determined based on the length of the tissue-cutting stapler section during side-to-side anastomoses. Considering a narrowing of 0.5 cm due to the closure of the remaining defect, the anastomosis diameters were calculated accordingly. The proximal end of the ileal transection was connected side-to-side to the distal ileum to establish the common channel length, which ranged between 80 cm and 200 cm. This distance was determined intraoperatively by the surgeon. This approach has evolved over the years, with increasing personal experience leading to the use of progressively longer distances. Residual anastomosis gaps were closed with 3/0 absorbable sutures. Drains were positioned near both anastomoses, and the trocar entry sites were sutured to complete the surgery.

Data Extraction and Quality Assessment

Patients aged 18 years or older were included in the study, while those under 18 were excluded. Additionally, patients who underwent different procedures for obesity treatment or were lost to follow-up at 3, 6, or 12 months, as well as those with incomplete demographic, BMI, or HbA1c data, were excluded.

Follow-Up

The changes in HbA1c values from baseline (admission), postoperative short-term (3 months), and long-term (12 months) were analyzed for all patients.

Statistical Analysis

Data were analyzed using SPSS version 25.0 (IBM Corporation, Armonk, New York, USA) and PAST3 software (PAST: Paleontological Statistics Software Package for Education and Data Analysis, Oslo, Norway). Univariate normality was assessed using the Lilliefors-corrected Kolmogorov-Smirnov test, and variance homogeneity was evaluated with Levene's test. Multivariate normality was assessed with Mardia's test (Dornik and Hansen omnibus), and variance homogeneity was tested with Box's M test. Quantitative data comparisons between 2 independent groups were performed using the independent-samples *t* test with bootstrap results, or the Mann-Whitney U test with Monte Carlo simulation. For comparisons involving more than 2 groups, one-way ANOVA (Robust Test: Brown-Forsythe) was used for parametric data, while the Jonckheere-Terpstra test was used with Monte Carlo simulation results. Friedman's two-way test was used for repeated measures, with Dunn's test for post hoc analysis. Categorical data were compared using Pearson's chi-squared test with exact Monte Carlo results, or the Fisher-Freeman-Halton exact test with Monte Carlo simulation. Repeated measures ANOVA was used to compare weight changes of patients. Excess weight loss percentage (EWL%) is calculated as the ratio of the change in BMI for each patient to their initial excess BMI, which is determined by subtracting the target BMI (set at 25) from the initial BMI. Column rates were compared and expressed according to Benjamini-Hochberg adjusted *P* values. Quantitative data were presented as mean±SD (standard deviation) (minimum-maximum) or median±IQR (interquartile range), while categorical variables are expressed as n (%). A 95% confidence level was applied, and a *P* value of ≤0.05 was considered statistically significant.

Results

Study Population

A total of 510 diabetic patients underwent LSG+TB surgery for the treatment of obesity during the study period. Ninety patients with incomplete data were excluded from the study. The remaining 420 patients, comprising 228 (54.2%) females and 192 (45.7%) males, were included in the analysis. All patients completed at least 12 months follow-up.

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Table 1. Weight and body mass index changes.

	Initial	3rd Month	12th Month	Roux-en-Y value*
Weight (kg)	107.61 (11.77)	99.85 (10.69)	81.95 (7.49)	<0.001
BMI (kg/cm^2)	34.86 (4.14)	32.35 (3.84)	26.11 (1.49)	<0.001
EWL (%)		29.12 (7.054)	68.11 (6.67)	<0.001

BMI – body mass index; EWL – excess weight loss – the ratio of weight lost to the difference between starting weight and ideal weight at 22 BMI; * Pearson correlation.

Table 2. Hemoglobin A1c changes according to obesity classification.

HbA1c (Median±IQR)		Body mass index				*P*
		Overweight (n=53)	Class 1 (n=161)	Class 2 (n=136)	Class 3 (n=70)	
Baseline (A)		9.03±2.98	9.03±2.00	9.035±2.07	9.05±2.99	0.712
3-month (B)		7.04±1.98	7.03±1.74	7.04±1.96	7.04±1.93	0.896
12-month (C)		6.02±1.00	6.02±1.01	5.09±1.04	6.5±1.05	0.062
Pairwise comparison	A→B	*<0.001*	*<0.001*	*<0.001*	*<0.001*	
	A→C	*<0.001*	*<0.001*	*<0.001*	*<0.001*	
	B→C	*<0.001*	*<0.001*	*<0.001*	*<0.001*	

IQR – interquartile range; HbA1c – hemoglobin A1c.

Excess Weight Loss

Significant weight loss was observed across all subgroups (**Table 1**). The baseline average body mass index of patients with stapler line distances of 6 cm, 8 cm, and 10 cm from the pylorus was 40.06, 34.87, and 30.42, respectively (P<0.001). At the end of 1 year, the average percentage of excess weight loss (EWL) was 68.11%. When EWL was evaluated according to the subgroups, it was 68.77 (±5.35) for 6 cm, 67.87 (±4.99) for 8 cm, and 67.82 (±6.72) for 10 cm, and when EWL was compared among subgroups, the highest EWL was observed in the 6 cm group; however, this difference was not statistically significant (P>0.082).

HbA1c Comparison

Across all obesity groups (overweight, Class 1, Class 2, Class 3), there was a significant reduction in HbA1c values at 3 months and 12 months compared to baseline values (P<0.001 for all). Additionally, there was a significant decrease in HbA1c levels at 12 months compared to 3 months across all groups (P<0.001). No significant differences were found in the initial values or changes in HbA1c levels between the different obesity classifications. Detailed changes in HbA1c values by obesity class are presented in **Table 2**.

Simultaneous Surgeries

In the same session as the LSG+TB, 124 patients (29.5%) underwent cholecystectomy due to cholelithiasis, and 17 patients (4%) with chronic liver disease underwent liver biopsy. There were no significant differences in HbA1c changes between patients who underwent cholecystectomy for cholelithiasis or liver biopsy for chronic liver disease in the same session as LSG+TB and those who underwent only LSG+TB surgery.

Anastomosis and Stapler Line Distance to Pylorus

The comparison of HbA1c levels based on the preferred distance of the stapler line from the pylorus is presented in **Table 3**. No significant differences were observed in serious complication rates between the groups.

Common Channel Length

For both common channel length groups (<100 cm and >100 cm), there were significant reductions in HbA1c values at 3 and 12 months compared to baseline values (P<0.001 for all). Additionally, HbA1c values at 12 months were significantly lower than those at 3 months (P<0.001), showing sustained glycemic improvement over time. When comparing common channel

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Table 3. Changes in hemoglobin A1c values based on different distances from the stapler line to the pylorus.

HbA1c (Median±IQR)		Distance to the pylorus			*P*
		6 cm (n=110)	8 cm (n=181)	10 cm (n=129)	
Baseline (A)		9.065±2.98	9.03±2.04	9.03±2.01	0.168
3-month (B)		7.05±1.59	7.03±1.95	7.04±1.98	0.679
12-month (C)		5.545±1.01	6.01±1.05	6.02±1.01	0.019
Pairwise comparison	A→B	*<0.001*	*<0.001*	*<0.001*	
	A→C	*<0.001*	*<0.001*	*<0.001*	
	B→C	*<0.001*	*<0.001*	*<0.001*	

IQR – interquartile range; HbA1c – hemoglobin A1c.

lengths, no significant differences were observed in the HbA1c reductions between patients with a common channel length of <100 cm and those with a length of >100 cm. Similarly, for both anastomotic loop diameters (2.5 cm and 3 cm), significant reductions in HbA1c were observed at 3 and 12 months compared to baseline (P<0.001 for all), with further improvements at 12 months compared to 3 months (P<0.001), without significant differences based on loop diameter. No significant differences were observed between the groups for either variable in terms of serious complication rates.

Postoperative Complications

In the study cohort, serious postoperative complications were observed in 22 patients (5.24%). These included 1 case of portal vein thrombosis, which occurred on postoperative day 28 in a patient with a history of splenectomy 30 years prior, successfully managed medically (0.24%). Anastomotic leaks were observed in 3 patients: 1 gastro-jejunal leak managed with pigtail drainage (0.24%), 1 gastro-jejunal leak requiring reoperation (0.24%), and 1 entero-enterostomy leak requiring reoperation (0.24%). One patient developed an intra-abdominal abscess without evidence of a frank leak, managed with percutaneous drainage (0.24%). Gastro-jejunal strictures were reported in 7 patients (1.67%), with 6 managed via balloon dilatation and 1 requiring laparoscopic reoperation. One patient experienced postoperative pulmonary embolism, successfully treated medically (0.24%), and another had an acute myocardial infarction, also managed medically (0.24%). No cases of surgical site infection were recorded.

Malnutrition was not observed in 2 patients (0.05%) with a common channel length greater than 100 cm and in 5 patients (21.7%) with a common channel length shorter than 100 cm (P<0.001). These patients underwent reoperation to lengthen the common channel, and all recovered without complications.

When comparing postoperative complications among subgroups, it was found that the pyloric stapler distance did not affect the frequency of complications (P=0.965).

Discussion

This study assessed glycemic changes in obese T2DM patients following LSG+TB surgery. The key findings of the study demonstrated that patients who underwent LSG+TB showed significant loss in excess weight with an average of 68.11%. Our study also demonstrates significant reductions in HbA1c levels across all obesity classes. The results confirmed that this technique is effective for improving glycemic control in obese patients with type 2 diabetes, with a notable reduction in HbA1c maintained up to 12 months after surgery. Additionally, our study is the first to reveal that a 6 cm distance from the stapler line to the pylorus is significantly associated with greater reductions in HbA1c levels.

As expected, significant reductions in weight and BMI were observed across all subgroups at both the third postoperative month and the first year. An average EWL of 68.11% and a mean BMI of 26.11 at 1 year postoperatively were consistent with findings in the literature [9-11]. Surgical and patient selection criteria, shaped by the surgeon's preferences, revealed that patients with higher BMI were more likely to have a shorter pyloric stapler line distance. Conversely, it should be noted that patients with shorter pyloric stapler distances had higher baseline BMI values. This explains the variations in weight loss observed among the different pyloric distance subgroups.

Poor glycemic control in obese patients increases mortality and morbidity risks [12]. Long-term weight loss exceeding 5% has been reported to improve HbA1c and blood pressure in T2DM patients [13]. Our study found that preoperative baseline

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HbA1c values for both male and female patients across all obesity groups were significantly higher than their postoperative values at 3 and 12 months. This shows that LSG+TB is very effective in controlling T2DM, with ongoing improvements in blood sugar levels observed beyond the 3-month mark across all obesity groups. Additionally, the 12-month HbA1c values were significantly lower than those at 3 months, reinforcing the sustained impact of the surgery.

These findings, demonstrating the effectiveness of LSG+TB in achieving glycemic control in obese patients with T2DM, align with existing research. The cornerstone study on the subject, conducted by Santuro et al, involved 1020 obese patients who underwent LSG+TB. In this study, where an 80 cm common channel was preferred, a 6% complication rate was reported alongside an 86% diabetes remission rate and a 74% excess BMI loss over a 5-year follow-up period [7]. Likewise, in Karaca's study, diabetes remission was observed in 40 out of 45 patients [8]. Similar studies have also reported positive effects on glycemic control [9,10,13]. In a randomized controlled trial comparing standard medical treatment and LSG+TB, glycemic control was found to be more effectively achieved in the LSG+TB group [14]. In another study comparing laparoscopic ileal interposition with diverted sleeve gastrectomy (IIDSG), LSG+TB, and laparoscopic sleeve gastrectomy, LSG+TB was shown to be superior to laparoscopic sleeve gastrectomy and produced similar results to IIDSG [15]. Bariatric surgeries, such as Roux-en-Y gastric bypass, biliopancreatic diversion, mini-gastric bypass, and sleeve gastrectomy, are widely recommended for obese individuals with T2DM, as they address both restriction and malabsorption to improve glycemic control [9]. On the other hand, the LSG+TB technique aims to reduce mechanical restrictions and potential malabsorption by decreasing gastric emptying time and promoting faster intestinal transit via gastroileal anastomosis [7].

This study, unlike others on obesity treatment, did not examine lipid profile changes after LSG+TB with cholecystectomy or liver biopsy. Instead, we focused on the impact of these procedures on HbA1c, concluding that they did not influence glycemic outcomes. Moreover, we explored the influence of operational variations on HbA1c changes in patients undergoing LSG+TB surgery. Notably, patients with a 6 cm distance between the stapler line and the pylorus experienced a greater reduction after a year in HbA1c compared to those with 8 or 10 cm distances. The endocrine role of the resected stomach segment in blood glucose regulation may have influenced this outcome [16]. As previously emphasized, patients in the 6 cm subgroup had higher baseline BMI values. However, there were no significant differences in baseline HbA1c values among the 6, 8, and 10 cm subgroups. Therefore, the greater weight loss observed in the 6 cm subgroup may be linked to improved glycemic control. In the context of our study, a 6 cm distance was found to be optimal for glycemic control in LSG+TB surgeries and was as safe as the 8 cm and 10 cm distances in terms of complication rates. No other study has evaluated the impact of anastomotic distance on glycemic parameters in LSG+TB surgeries, making this a novel finding.

Although malabsorption is less common in LSG+TB procedures, concerns remain about bypass surgeries with common channel lengths of 200-250 cm where the duodenum is transected [17]. Extending the common channel to 300 cm in procedures like the duodenal switch mitigates malabsorption risks [18]. Our study found no significant differences in HbA1c changes between patients with common channel lengths of >100 cm and those with lengths of <100 cm. However, malnutrition related to malabsorption was observed in 7 patients with a common channel length shorter than 100 cm. This suggests that longer common channels may safely prevent malabsorption without compromising glycemic outcomes. Finally, our study found that the anastomotic loop diameter – whether 2.5 cm or 3 cm – did not significantly impact HbA1c changes.

Recent research has highlighted a stronger impact of obesity on women than on men [10,11]. According to 2018 data from the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO), the proportion of women undergoing bariatric surgery was markedly higher than that of men, with 92.3% of men categorized as metabolically unhealthy [19]. Aligning with prior findings, our study showed a greater number of female patients in Class 2 and 3 obesity categories compared to male patients, while the opposite pattern was observed in the overweight and Class 1 obesity groups. This pattern suggests that women in higher obesity classes may be disproportionately impacted.

The primary limitations of our study are its retrospective design and short-term follow-up. Additionally, the lack of weight monitoring, a high rate of patient exclusion due to incomplete data, and variable patient dietary habits that may have influenced HbA1c outcomes are notable constraints.

Conclusions

In summary, this study underscores the efficacy of LSG+TB in enhancing blood glucose control in obese patients with type 2 diabetes. A notable finding is that a 6 cm distance from the stapler line to the pylorus correlates with significantly greater HbA1c reductions, indicating that this measurement may be ideal for optimizing glycemic outcomes. Additionally, the 6 cm distance demonstrated safety comparable to longer distances in terms of severe complications, strengthening its potential as a preferred surgical method. Additional studies are necessary to substantiate these results and assess long-term impacts.

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Declaration of Figures' Authenticity

All figures submitted have been created by the authors, who confirm that the images are original with no duplication and have not been previously published in whole or in part.

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