

Retrospective analysis of metabolic effects of laparoscopic gastric plication and single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S)



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Retrospective analysis of metabolic effects of laparoscopic gastric plication and single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S).

AIM: The aim of this study is to investigate the clinical outcomes of patients with type 2 diabetes mellitus (T2DM) who underwent laparoscopic gastric plication (LGP) or single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) and analyze the postoperative first-year results of these two operations.

METHODS: Forty-three patients who have undergone LGP and 36 patients who had undergone SADI-S were included in this study. Baseline and postoperative first-year data of patients with T2DM who have undergone LGP or SADI-S in our clinic between January 1, 2013, and June 30, 2016, were retrospectively analyzed.

RESULTS: It is understood that both operations maintained a remarkable improvement in blood glucose parameters alongside total cholesterol and triglyceride levels. The complete diabetes remission rate was significantly higher in the SADI-S group than in the LGP group (69.4% vs. 42.1%, $p=0.018$). LGP group achieved better results than SADI-S on weight loss in terms of the percentage excess weight loss (EWL%) ($p<0.001$) and the percentage total weight loss (TWL%) ($p<0.001$).

CONCLUSION: In our study, both operations facilitated diabetes remission, and complete remission or improvement was obtained in most of the cases. In addition, statistically significant weight loss was observed in both procedures. Therefore, both bariatric techniques can be chosen for obese diabetic patients considering their priorities and needs.

KEY WORDS: Diabetes Remission, Laparoscopic Gastric Plication, SADI-S

Introduction

More than 400 million people have diabetes, and the number of cases is estimated to rise to 650 million by 2040. Although numerous medical treatment options are available in addition to lifestyle interventions, aiming to decrease micro-and macrovascular complications resulting

from diabetes, many patients with diabetes fail to achieve glycaemic/metabolic treatment goals ¹.

Obesity and being overweight are major risk factors for T2DM ². It has been reported that 86% of adults with T2DM are overweight or obese; 52% have obesity, and 8.1% have morbid obesity ³. Increasingly, the term 'diabesity' is used to describe the combined detrimental health effects of obesity and diabetes ⁴.

Bariatric surgery is currently considered the most effective treatment for T2DM, with superior improvement in hyperglycemia even compared to the best medical treatment option available ⁵.

Weight loss after surgery has been shown as one of the most important mechanisms that help to achieve better diabetes control ⁶. Changes in the secretion of gastrointestinal hormones, increased insulin sensitivity, and alter-

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ations in gut physiology and microbiota are among other proposed mechanisms that explain the improvement of glycemic control in patients with T2DM after surgery⁷. However the mechanisms leading to improvement in hyperglycemia, independent of weight loss, are still largely unknown².

Despite the fact that the type of bariatric procedure may alter the consequences, there is no conclusive evidence to determine the superiority of one procedure in patients with T2DM yet⁸. LGP and SADI-S are both shown to be beneficial in the literature with promising weight loss and resolution of comorbidities, including T2DM⁹⁻¹². As a restrictive bariatric procedure, in LGP, gastric volume is reduced by folding the greater curvature into itself and fixing it with one or multiple rows of stitches¹³. Reversibility, the absence of foreign body placement, low complication rate, and reduced costs are among the reported advantages of LGP.

Resolution and improvement rates of T2DM after LGP ranges between 4% and 100%¹⁴.

On the other hand, SADI-S is a combination of sleeve gastrectomy with a modified duodenal switch procedure with only one anastomosis. It may offer improved diabetes outcomes than one anastomosis gastric bypass (OAGB) or RYGB with a remarkable weight loss. Considering its safety, ease of technique, and metabolic outcomes, it offers a promising bariatric procedure¹⁵. Long-term results of SADI-S on patients with diabetes are so powerful¹⁶ that it could be suggested as an index operation to compare the effects of alternative procedures, such as LGP, on T2DM.

The objective of the present study was to compare the T2DM remission rates 12 months after SADI-S and LGP.

In addition, we also aimed to analyze the effect of both operations on weight loss and to assess the changes in blood parameters.

Materials and Methods

After approval from the institutional Ethics Review Board, we retrospectively analyzed 79 bariatric surgery patients with T2DM who were operated on by two senior surgeons in Bağcılar Training and Research Hospital between January 1 st, 2013, and June 30, 2016. Patients who have undergone LGP or SADI-S with T2DM were included.

Patients with type 1 diabetes (2 patients) and missing follow-up data (6 patients) were excluded. Baseline and postoperative first-year data of patients with T2DM who have undergone LGP (43 patients) or SADI-S (36 patients) were obtained from patient files, an electronic patient record system, and patient telephone calls. Before surgery, all patients were reviewed by the multidisciplinary team (surgeon, endocrinologist, psychiatrist, dietitian, e.g.).

Baseline and postoperative first-year weight, body mass index (BMI), fasting blood glucose, insulin, homeostasis model assessment of insulin resistance (HOMA-IR), hemoglobin A1C (HbA1c), total cholesterol and triglyceride values of the patients were analyzed. Diabetes treatment plans were examined. The effect of both operations on weight loss was also evaluated.

The study's primary endpoint was to detect the diabetes remission rates at postoperative first year. Diabetes remission was defined as normoglycemia and HbA1C < 6.5% without diabetes medications. The secondary outcome was to analyze the effects of operations on weight loss.

OPERATIVE TECHNIQUES

Preoperative preparations included prophylactic heparin, lower limb bandage, and antibiotic therapy.

Postoperatively, all patients were given proton pump inhibitors (PPIs) for a few days (less than a week).

Laparoscopic Gastric Plication (LSG)

The patients were placed in reverse Trendelenburg position with an angle of 30 degrees. A five-trocar technique was chosen. One 12-mm optical trocar was placed 5 cm above the umbilicus, one 12-mm trocar placed under the xiphoid for liver retraction, one 12-mm trocar placed at the left upper quadrant, one 5-mm trocar placed at the right upper quadrant, and one 5-mm trocar placed below the costal margin of the mid-clavicular line. After the dissection of the greater gastric curvature, 4-6 cm from the pylorus up to the angle of His, gastric plication was achieved by imbricating the greater curvature over a 34F bougie. Then the first row of extramucosal interrupted stitch sutures were applied. This was the template for a second row of extramucosal running suture line. The stomach resembled a gastric sleeve at the end of the procedure (Fig. 1). A suction drain was inserted along the greater curvature as a routine.

Laparoscopic single anastomosis duodenal-ileal bypass with sleeve (SADI-S)

The patients were positioned similar to the LGP, as described above. The procedure is performed using five trocars; one 12-mm optical trocar was placed nearly 20 cm below and few centimeters left to the xiphoid, one 5-mm trocar placed under the xiphoid for liver retraction, one 5-mm trocar placed at the left upper quadrant, one 12-mm trocar placed at the right upper quadrant, and one 10-mm trocar placed to umbilicus. Sleeve gastrectomy is performed using a 54 Fr bougie catheter. The sleeve stapler line was reinforced with running monofilament sutures. An isoperistaltic, hand-sewn, dou-

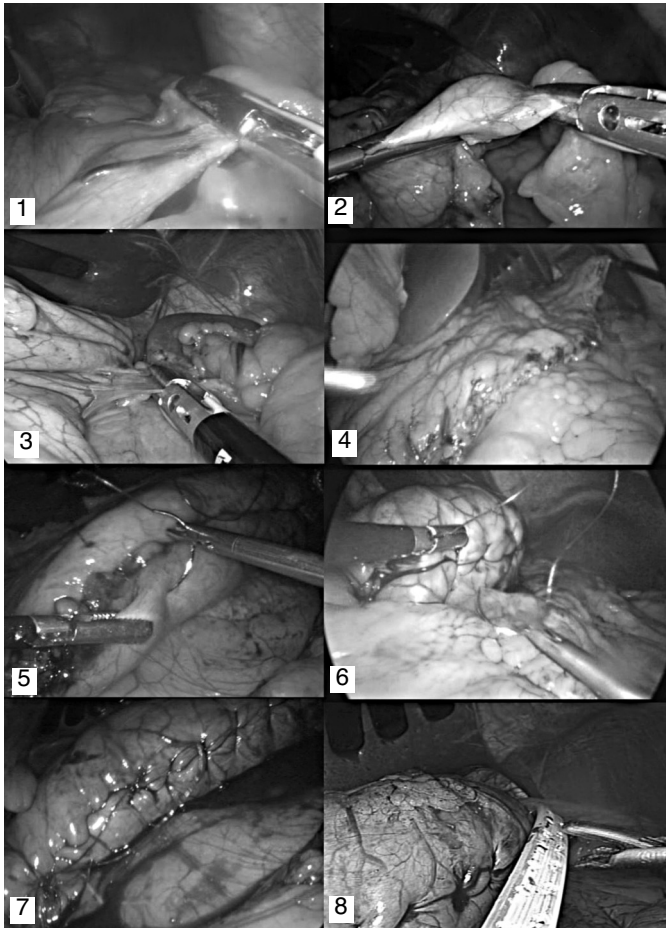


Fig. 1: Operatin Steps of LGBP.

1: Start of dissection; 2: Dissection of greater curvature; 3: Fundus dissection; 4: end of dissection; 5: First layer of plication; 6: Second layer of plication; 7: Final view; 8: Drail placement

ble-layered end-to-side duodeno-ileal anastomosis was created, 250 cm proximally from the ileocecal valve. Intraoperative metilene blue test was performed. A suction drain was inserted near the anastomosis.

STATISTICAL AND ANALYSIS

Quantitative variables were summarized using means, standard deviations (SD), and standard error of means (SEM). The distribution of variables was tested with the

Kolmogorov-Smirnov test. Independent t-test and paired t-test were used to compare the normally distributed variables, while Mann-Whitney U test and Wilcoxon tests were used to compare variables that were not normally distributed. Comparison of qualitative data was tested with chi-square test. When the power analysis was performed, 78 patients were required for 80% strength with the HbA1c value, and 99.9% strength was obtained based on the HOMA-IR value. The results were evaluated at the significance level of $p < 0.05$. Statistical analysis in this study was performed by NCSS 2007 and MedicRes e-Picos.

Results

In the selected period, 46 LGP and 41 SADI-S operations were performed on patients with T2DM. After exclusion criteria were applied, data of 43 LGP and 36 SADI-S patients were included in the study. The mean age of patients was 48.4 ± 7.8 years, ranging from 19 to 72 years. Thirty-one patients were male (39%), and 48 patients were female (61%). All the operations were performed laparoscopically without conversion.

The median procedure time was significantly shorter for LGBP surgery (83.8 ± 9.3 min) than SADI-S (87.8 ± 7.3 min; $p=0.04$). The median length of stay was two days in both groups. There was no mortality in the study group. Five mild complications (Clavien-Dindo classification $\leq$ grade II) occurred.

The complication rate was 4.6% (2 complications) in LGBP and 8.3% (3 complications) in SADI-S group, respectively ($p=0.5$). Wound infection was observed in two SADI-S patients and one LGBP patient. One patient experienced nausea and vomiting in LGBP group. A patient in SADI-S group had basal atelectasis after surgery. All these complications were medically managed. The demographic characteristics and complications of both groups are shown in (Table I).

Diabetes remission rate was significantly higher in SADI-S group than LGBP group (69.4% vs. 42.1%, $p=0.018$). In SADI-S group, before the surgery 24 patients were taking insulin treatment. However, 21 of 24 patients (87%) stopped taking any medication in the first year. Only three patients continued to take oral antidiabetics

TABLE I - Patient demographics and complications

Parameters	LGP (n 43)	SADI-S (n 36)	p-value
Age (year)	47.5 ± 9	50.9 ± 7.5	0.07
Female/Male	25/18	23/13	0.6
Operation Time (min)	82.7 ± 17	91 ± 9.0	0.26
Length of stay (days)	2.2 ± 0.9	2.4 ± 0.9	0.44
Complication Rate (%)	4.6	8.3	0.5
Wound infection	1	2	
Basal atelectasis	—	1	
Nausea	1	—	

TABLE II - Baseline and first-year follow-up values of the patients

	Timeline	LGP n:43 (Mean $\pm$ SEM)	SADI-S n:36 (Mean $\pm$ SEM)	p-value
Weight (kg)	Initial	125.12 $\pm$ 2.93	91.17 $\pm$ 2.52	0.0001
	First-year	95.98 $\pm$ 1.87	75.31 $\pm$ 2.23	0.0001
	p	0.0001	0.0001	
BMI (kg/m ²)	Initial	44.45 $\pm$ 0.81	34.20 $\pm$ 1.14	0.0001
	First-year	34.30 $\pm$ 0.72	28.11 $\pm$ 0.82	0.0001
	p	0.0001	0.0001	
Fasting blood glucose (mg/dl)	Initial	160.72 $\pm$ 9.60	239.64 $\pm$ 22.26	0.001
	First-year	121.72 $\pm$ 5.55	132.03 $\pm$ 5.99	0.211
	p	0.0001	0.0001	
Insulin (mcU/mL)	Initial	32.10 $\pm$ 2.23	16.38 $\pm$ 2.78	0.0001
	First-year	22.67 $\pm$ 1.99	5.92 $\pm$ 0.47	0.0001
	p	0.0001	0.0001	
HOMA-IR (mg/dL)	Initial	12.59 $\pm$ 1.20	10.12 $\pm$ 2.13	0.298
	First-year	6.79 $\pm$ 0.63	1.91 $\pm$ 0.19	0.0001
	p	0.0001	0.0001	
HbA1c (%)	Initial	7.49 $\pm$ 0.20	8.65 $\pm$ 0.37	0.006
	First-year	6.66 $\pm$ 0.16	6.36 $\pm$ 0.28	0.339
	p	0.0001	0.0001	
Total cholesterol (mg/dl)	Initial	212.28 $\pm$ 5.45	218.61 $\pm$ 13.33	0.642
	First-year	193.58 $\pm$ 5.02	159.36 $\pm$ 7.14	0.0001
	p	0.0001	0.0001	
Triglyceride(mg/dl)	Initial	181.84 $\pm$ 10.63	167.47 $\pm$ 12.31	0.377
	First-year	142.86 $\pm$ 8.05	131.85 $\pm$ 8.15	0.343
	p	0.0001	0.002	

TABLE III - Percentage decrease in values at postoperative First-year compared to baseline

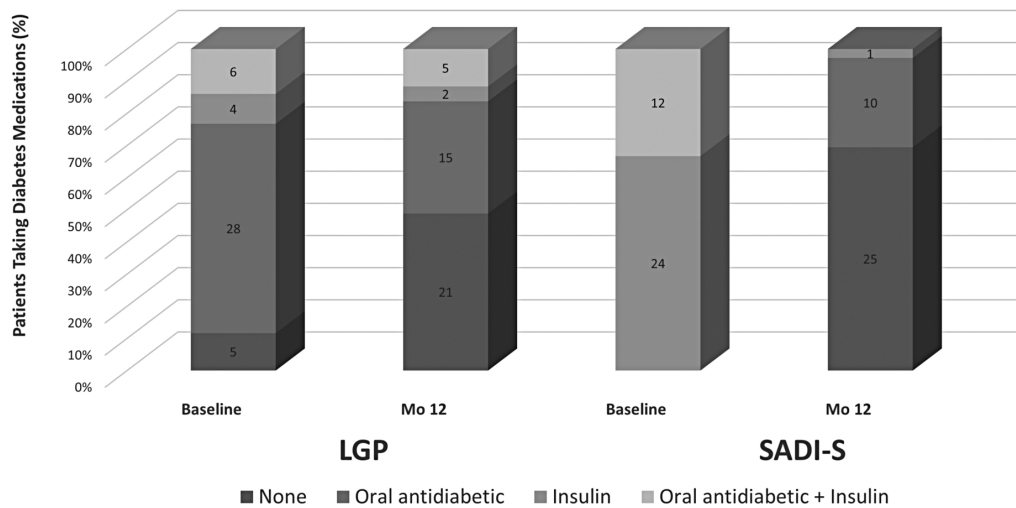
	LGP n:43	SADI-S n:36	p-value
Total Weight Loss(TWL%)	29.14% $\pm$ 12.87	15.86% $\pm$ 8.74	0.0001
Excess Weight Loss (EWL%)	54.62% $\pm$ 15.14	22.87% $\pm$ 16.59	0.0001
Body Mass Index Loss (BMIL%)	22.64% $\pm$ 7.76	16.98% $\pm$ 8.69	0.003
Fasting blood glucose (mg/dl)	20.23% $\pm$ 18.4	30.56% $\pm$ 30.63	0.068
Insulin(mcU/mL)	24.49% $\pm$ 29.57	52.76% $\pm$ 26.59	0.0001
HOMA-IR(mg/dL)	38.35% $\pm$ 31.26	65.13% $\pm$ 31.8	0.0001
HbA1c (%)	10.23% $\pm$ 9.89	23.48% $\pm$ 22.64	0.001
Cholesterol(mg/dl)	8.27% $\pm$ 9.89	22.96% $\pm$ 21.73	0.0001
Triglyceride (mg/dl)	17.99 $\pm$ 22.58	12.08% $\pm$ 34.53	0.364

(OAD) at the first year. Preoperatively, twelve patients were taking OAD in addition to insulin therapy. Four patients (33%) in insulin + OAD receiving patients stopped taking any medication. Seven patients (58%) continued to take only OAD, and one (9%) resumed taking insulin therapy. In the LGP group, five patients were recommended to obey a strict diet. They were not taking any medication before LGP and were not taken into account when calculating diabetes remission of LGP. Of 38 patients taking medication, 28 patients used OAD. Four patients were getting insulin therapy, and six patients were getting both. Diabetes remission was achieved in fifteen patients in OAD group and one

patient in insulin group in the first year after LGP (Fig. 2). Both LGP and SADI-S operations secured statistically significant ameliorations on fasting blood glucose, HbA1c, HOMA-IR, and insulin levels.

Cholesterol levels were also significantly lower in SADI-S than LGP group in the first year ($p < 0.001$). Triglyceride levels were statistically lower after both operations. No significance was observed in triglyceride levels between operations ($p = 0.34$). SADI-S was more effective in lowering HbA1c as well as HOMA-IR and insulin (Table III).

One of the other aims of the study was to find the efficiency of both operations on weight loss in patients with



T2DM. The percentage of excess weight loss (EWL%) was $54,6 \pm 15,1$ and $22,8 \pm 16,5$ in LGP and SADI-S patients, respectively ($p < 0.001$). Statistically significant weight loss was achieved by both operations (Table II). In terms of EWL%, total weight loss (TWL%), and body mass index loss (BMIL%), LGP provided better results than SADI-S (Table III).

Discussion

We herein present the results of SADI-S and LGP in diabetic patients submitted to surgery for severe or morbid obesity. SADI-S was first described in 2007 to simplify a complex surgical technique, the biliopancreatic diversion with duodenal switch (BPD-DS)¹⁷. Many mechanisms get involved in diabetes resolution besides weight loss in biliopancreatic diversions.

Caloric intake is restricted with gastric restriction, which also accelerates gastric emptying. Duodeno-pancreatic region, with its incretin effect, is bypassed. The stomach or duodenal emptying into the distal bowel with its pro-incretin effect, is also accelerated and fat absorption is reduced to the minimum. In addition to all these, SADI-S maintains the good effects of a malabsorptive surgery with a single anastomosis¹².

The most recent studies have shown that complete T2DM remission rate is 77%, which is roughly three times more effective than Roux en Y Gastric Bypass (RYGB) and four times more effective than sleeve gastrectomy (SG)^{18,19}. Diabetes remission rate was found to be 69.4% in our series at the first year in SADI-S group. In a systematic review by Spinos, T2DM resolution occurred at a rate of 72.6%²⁰. A similar percentage of DM resolution (74.1%) is reported from Shoar et al²¹. A study by Sánchez-Pernaute et al revealed

patients with diabetes duration longer than seven years before SADI-S was strongly correlated with nonremission of disease, with a sensitivity of 85% and specificity of 74%. Older age, higher preoperative glycemia, higher preoperative HbA1c, lower C-peptide, and preoperative need for insulin were also found significantly related to a lower diabetes remission rate in the same study¹². Beneficial effects of SADI-S on lipid profile are reported in many reviews^{15,20,21}. In accordance with literature, we detected a statistically significant decrease in triglycerides and total cholesterol in SADI-S group at postoperative first year (Table II) ($p < 0.001$).

In LGP patients, diabetes remission rate was 42.1% in our series. There were significant improvements in fasting blood glucose, insulin, HbA1c, and HOMA-IR levels compared to baseline in the first year. Lacking most of the mechanisms mentioned above in SADI-S, LGP was less successful in T2DM remission (Table III). The effect of LGP in T2DM resolution is controversial. In the study of Bužga et al, with a 12-month follow-up on T2DM, 33% of patients discontinued oral hypoglycemic medication and insulin, and 88% reached a target HbA1c of $< 4.8\%$ ²².

In another study by Fried et al, 96.9% of the patients with T2DM achieved remission or improvement by six months after surgery²³. Conversely, no patient could withdraw hypoglycemic medication in a study by Taha et al., while mean HbA1c levels fell to 7.5% from 7.9% at postoperative first year²⁴. Also, Li et al. reported no significant difference in HbA1c and other blood sugar profiles at the postoperative period²⁵. In a recent systematic review that focuses on the effect of LGP on obesity and T2DM by Meyer et al., most studies had a short-term-follow-up period (1-18 months)¹³.

A five-year follow-up study by Doležalová et al., encompassing 57 patients, reported an improvement rate of

65.5% at five years²⁶. In another study by Talebpour et al, all of the sixty patients suffering from T2DM achieved either remission (92%) or improvement (8%) after LGP. There was also statistically significant decrease in blood HbA1c ($p=0.002$), total cholesterol ($p=0.001$) and triglycerides ($p=0.001$). Also, in our LGP group, when compared to baseline, there was a marked decrease in these values at postoperative first-year ($p<0.001$) (Table II).

Both operations provided statistically significant weight loss at the postoperative first year. In our series, BMIL and EWL% rates were $29.14\% \pm 7.76$ and 54.62% (min 23% - max 94%), respectively, in LGP group. Gastric plication is a new restrictive bariatric procedure initially proposed by Tretbar et al in 1976 and Wilkinson et al in 1981. LGP was subsequently developed and introduced by Talebpour in 2006²⁷.

Talebpour et al published their twelve years of LGP experience in a study that included 800 patients. First-year follow-up EWL% rate in the 491 of the 800 patients operated on was 67% (min 35% - max 100%)²⁸. A review by Ji et al, which yielded 14 studies encompassing 1450 LGP patients, reported %EWL rates of 31.8%-74.4% at follow-up times ranging from six months to 24 months. One of the interesting findings in this study was that the patients with higher BMI, especially super-obese patients ($BMI > 50 \text{ kg/m}^2$), had less weight loss after LGP²⁹.

A subgroup analysis by Skrekas et al. revealed the relation between preoperative BMI and %EWL after LGP. Patients with BMI lower than 45 kg/m^2 had statistically significant higher %EWL rate compared to BMI higher than 45 kg/m^2 group (69.86% vs 55.49%, $p=0.006$). Inadequate weight loss in the higher BMI group was doubled compared with the lower one (36% to 18.2%, $p<0.001$)³⁰. The risk of weight regain was a concern for LGP, threatening the procedure unsustainable and inferior in the long term¹³. The largest study up to date concerning LGP by Talebpour et al, 5.5% of patients experienced weight regain after four years, and 31% of all patients after 12 years²⁸.

In our SADI-S group, which had 36 patients, preoperative BMI was 34.2 ± 1.14 . The postoperative first-year EWL% rate was found to be 15.86% (min 0.25%-max 44%). A recent review including 14 studies on SADI-S reported EWL% rates ranging from 60.9% to 91% at twelve months after surgery. Studies included in the review had patients with a preoperative mean BMI ranging from 36.5 to 58.4 kg/m^2 ²⁰. We think that the great variability in EWL% rates is arising from the differences in the length of the common canal and the bougie diameters preferred in the sleeve gastrectomy. SADI-S group had significantly lower preoperative BMI than the LGP group in our series ($p<0.001$). We believe that this significance is primarily due to the conscious guidance of patients to SADI-S who apply for T2DM regulation rather than losing weight. This may also help us to

explain our low EWL% rates in these selected patients, considering the postoperative nutritional choices.

Our study has limitations, including the bias due to the retrospective study design, lack of longer follow-up for the assessment of weight loss, and resolution of T2DM. Therefore, prospective randomized trials with a longer follow-up are needed to investigate the efficiency of these relatively less applied surgical techniques in obese patients with T2DM.

Conclusions

SADI-S offers very successful results similar to traditional malabsorptive operations with the technical ease of a single anastomosis and low postoperative complication rates. When we consider the first position statement from the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO), which recognized the potential benefits of SADI-S, it looks like we will come across more studies about it. On the other hand, LGP is a restrictive surgical procedure that attracts attention, especially with its low cost and simple reversibility in case the desired results cannot be achieved. In our study, both operation groups experienced an improvement in T2DM and statistically significant weight loss. SADI-S was more efficient in lowering insulin, HOMA-IR, HbA1c, and total cholesterol levels than LGP. LGP proved better results on weight loss. Further studies with long follow-up periods are necessary to identify the metabolic efficiency of both surgical techniques.

Riassunto

Scopo di questo studio: indagare gli esiti clinici di pazienti con diabete mellito di tipo 2 (T2DM) sottoposti a plicatura gastrica laparoscopica (LGP) o bypass duodeno-ileale con singola anastomosi con gastrectomia a manico (SADI-S) e analizzare il decorso postoperatorio ed i risultati del primo anno di queste due operazioni.

La casistica studiata consta di 43 pazienti sottoposti a LGP e 36 pazienti sottoposti a SADI-S della nostra clinica tra il 1° gennaio 2013 e il 30 giugno 2016, tutti affetti da diabete di tipo II (insulino indipendente). Sono stati analizzati retrospettivamente i dati di base e postoperatori del primo anno dopo l'intervento.

RISULTATI: premesso che entrambi gli interventi hanno ottenuto un notevole miglioramento dei parametri glicemici, come pure quelli dei livelli di colesterolo totale e trigliceridi. Il tasso di remissione completa del diabete è stato significativamente più alto nel gruppo SADI-S rispetto al gruppo LGP (69,4% vs. 42,1%, $p=0,018$). Il gruppo LGP ha ottenuto risultati migliori rispetto a SADI-S in termini di percentuale di perdita dell'eccesso di peso (EWL%) ($p<0,001$) e di percentuale di perdita di peso totale (TWL%) ($p<0,001$).

CONCLUSIONE: nel nostro studio, entrambe le operazioni hanno facilitato la remissione del diabete e nella maggior parte dei casi è stata ottenuta una remissione completa o un miglioramento. Inoltre, in entrambe le procedure è stata osservata una perdita di peso statisticamente significativa. Pertanto, entrambe le tecniche bariatriche possono essere scelte per i pazienti diabetici obesi considerando le loro priorità e necessità.

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