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Single Anastomosis Sleeve Ileal Bypass (SASI) for management of obese patients with type 2 Diabetes

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Abstract: **Background:** Amidst the current worldwide epidemic of type 2 diabetes mellitus (T2DM), the global diabetes health burden is projected to reach 522 million in 2030, with much of this increase occurring in developing countries. **Aim of the work:** to evaluate the role of laparoscopic sleeve gastrectomy with loop bipartition (single anastomosis sleeve ileal bypass) as a bariatric and metabolic procedure in control of type 2 diabetes in obese patients over one year post-operative. **Patients and methods:** This prospective cohort study included 20 obese adult patients with type 2 DM recently diagnosed within last 5 years. Some of them have other associated comorbidities. They were recruited at department of surgery Ain Shams University. The follow up was obtained during the first year post-operative. **Results:** In this study, complete remission of diabetes was achieved in 75% of the patients by the 3rd post-operative month and in 95% by the end of the study. This was beside marked weight reduction and improvement of lipid profile without causing micronutrients deficiencies during the study period. **Conclusion:** SASI bypass can be one of the most efficient metabolic procedures and could be associated with less risks. The procedure should be considered under investigations until enough long term data are available. Thus it is worth to be explored in research aiming for more data.

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Key words: sleeve gastroectomy, loop bipartition, type 2 diabetes, obesity

1. Introduction

Given the increasing prevalence of obesity worldwide, the epidemic of diabetes has become an even larger economic and social public health challenge. Leading to MetS and T2DM **(Xu et al., 2013).**

Most diabetic patients are unable to achieve adequate glucose control with medical therapy in the long term due to time-consuming medical interventions. (**Resnick et al., 2006)** In contrast, bariatric surgery has been shown to induce the remission of diabetes or to reduce the need for medications with durable long-term results in morbidly obese patients, thereby providing a potentially cost effective approach to treating T2DM. (**Buchwald et al., 2009)** Considering weight loss-independent mechanisms for diabetes improvement, metabolic gastrointestinal surgery is now being performed for mildly obese or even overweight patients (BMI < 35 kg/m2), with a focus on diabetes rather than obesity. The aims of metabolic surgery are glycemic control, metabolic control and cardio-metabolic risk reduction. **(Pok and Lee, 2014)**

Both bypass and restrictive procedures were reported to cause diabetes remission, but through different mechanisms, depending on the degree of the physio-anatomical alteration of the gastro-intestinal tract. Essentially, the rapid induction of a negative energy balance after surgery, limited foregut bypass, rapid nutrient delivery to the hindgut and decreased adipocyte mass may all play important roles in durable weight loss, decreased satiety, improved insulin resistance and resolution of the pro-inflammatory state associated with obesity. (**Buchwald et al., 2009)**

The selection of patients for metabolic surgery should be matched to an ideal risk-benefit profile to obtain the optimal outcomes of metabolic control. Therefore, a tailored approach should be selected for patients with T2DM. **(Pok and Lee., 2014)**

Biliopancreatic Diversion (BPD), which is a purely malabsorptive procedure has a superior glycemic control compared with other metabolic procedures, but may not be appropriate in lower-BMI individuals due to the high complication rates and long-term malnutrition risk. (**Buchwald et al., 2009)** Instead, the novel procedure of duodenal-jejunal bypass with sleeve gastrectomy (DJB-SG) should be considered for those patients. **(Lee et al., 2014)**

Santoro et al. have recently reported his long-term data regarding sleeve gastrectomy with transit bipartition (SG + TB), which is a similar operation to duodenal switch (DS) but without complete exclusion of duodenum in order to minimize nutritional complications. **(Santoro et al., 2012)** This was modified by performing a loop rather than Roux-en-Y bipartition reconstruction in Santoro's operation making single anastomosis sleeve ileal (SASI) bypass as a mode of functional restrictive and neuroendocrine modulation therapeutic option for obese T2DM patients. **(Mahdy et al., 2016)**

Sleeve gastrectomy with loop bipartition may be proven to be a very effective, safe and simple operation with numerous theoretical advantages over the current procedures for the treatment of obese diabetic patients. **(Wilfred et al., 2014)**

Aim of the work

The aim of this study was to evaluate the role of laparoscopic sleeve gastrectomy with loop bipartition (single anastomosis sleeve ileal bypass) as a bariatric and metabolic procedure in control of type 2 diabetes in obese patients.

2. Patients and methods

This study included 20 obese and diabetic patients. All of them are adults with type 2 DM that was recently diagnosed within last 5 years. Some of them have other associated comorbidities.

These patients were enrolled in a prospective cohort study at department of surgery Ain Shams University. The follow up was obtained during the first year post-operative. All patients were pre-operatively and post-operatively evaluated with standardization of technique in all cases.

Ethical approval was taken from Ain Shams University ethical committee and written consent was taken from every patient after explanation of all details of the operation, benefits, possible risks intra and post-operative, diet habits after surgery, realistic expectations and with the possibility of conversion to open surgery.

- **Inclusion criteria:**

1. Adult males and females patients (18-60 years).
2. Obese with BMI 30-60.
3. Diabetics, with type 2 DM. Diabetes should have been recently diagnosed, specifically within last 5 years, regardless of its control level or type of diabetic medications taken.

All patients were fit for laparoscopic surgery and fit for general anesthesia, and all have been informed about surgical details and other non-surgical alternatives.

- **Exclusion criteria:**

1. Patients younger than 18 years or older than 60 years.
2. Patients with BMI less than 30 or more than 60. Patients with higher BMI were excluded as the main target of this study is to track the metabolic effect of this novel procedure in obese patients rather than weight loss itself.
3. Patients who are unfit for general anesthesia.
4. Patients with any contraindications for laparoscopic surgery.
5. Patients who underwent previous bariatric operations were excluded to assess the metabolic effect of SASI as a primary procedure not as a Redo (revisional) one.
6. Patients with type 1 diabetes mellitus.
7. Patient refusal.

All patients were subjected to the following:

Pre-operative assessment:

Full history taking, including personal and medical history. Thus, relevant personal data and detailed past medical, surgical and family histories were considered with special concentration on patient's comorbidities. Full clinical examination, including general examination with special consideration for body weight, height, BMI and anthropometric measures. Routine pre-operative workup, including routine laboratory investigations and necessary imaging. Assessment of diabetes. Onset, duration, diabetic medications and special laboratory investigations; HbA1C, C-peptide and fasting blood glucose; lipid profile; assessment of pre-operative co-morbid conditions (e.g.: hypertension) regarding control and medications.

Operative:

The operation comprised two sections. First, a sleeve gatrectomy was performed, then a sleeve ileal anastomosis was made in an isoperistaltic way to create a common channel (alimentary limb) of 250cm.

Anesthesia:

General endotracheal anesthesia with muscle relaxant was used for all patients.

Patient positioning:

Patients were put in supine position. Arms were extended just less than 90 degrees to avoid axillary plexus injury. Legs were separated to keep patient in French position. All pressure areas were adequately padded to avoid nerve injuries and pressure sores. TEDs elastic stockings were used for all patients to avoid venous stasis during laparoscopic surgery and thus decreasing risk of DVT (part of the thromboembolic prophylaxis).

Nasogastric tube was inserted to decompress the stomach and then removed once the stomach has been deflated.

Straps were applied to keep patient stable during manipulation of position.

This position was adjusted following the induction of pneumoperitoneum to bring the patient into forced reverse trendelenberg position, what helps using gravity to retract bowel downward for better field exposure.

Sleeve gastrectomy:

The procedure began by exploration of the abdominal cavity, with particular attention to potential adhesions, mobility of the omentum and length of small intestine mesentery, checking out the position of nasogastric tube and emptying the stomach.

Once the operative field was clearly exposed, the operation began with identification and mobilization of angle of His using Harmonic scalpel.

Dissection started distally along the greater curve of the stomach devascularizing the greater curve of the stomach from the pylous up to the gastro-esophageal junction with adequate mobilization of the gastric fundus with careful dissection along the short gastric vessels, upper pole of the spleen and post gastric wall. Clips were occasionally used for more safe dissection through short gastric vessels.

The left cruswas completely freed of any attachments to avoid leaving a posterior pouch when constructing the sleeve in this region. Posterior attachments between the stomach and pancreas were then divided.

40 French boujie was inserted orally to reach pylorus. This was used as a calibration tube. Stapling started using linear stapler with articulating 60mm green cartridge. This first one was introduced through the surgeon's left hand side port to start stapling 6cm proximal to the pylorus. Then stapling was continued using 60mm blue cartridges inserted through the surgeon's right hand side port.

Stapling along the tubularized stomach around the 40 French calibration tube helped to avoid narrowing at some points, especially incisura and also managed to avoid posterior sagging.

We ensured adequate haemostasis using titanium clips at staple line whenever needed.

1. Identification of ileal site for anastomosis:

After being done with the sleeve gastrectomy, the table position was changed to the horizontal position and the surgeon moved to the left hand side of the patient.

Identification of caecum and ileo-caecal junction with great caution during manipulation, especially if patient has adhesions from previous operation (e.g.: caeserian section).

Counting 250cm of ileum from distal to proximal with adequate visualization, preparing the ileal site for anastomosis.

Then, the surgeon returned back to his previous position in between the patient's legs. The table position corrected back to the reverse trendelenberg position. The surgeon then approximated the ileal loop with the inferior of the remaining part of the pyloric antrum with two 3/0 Vicryl stitches.

2. Sleeve-ileal anastomosis:

Using the Harmonic scalpel, a small gastrotomy was done at the infero-lateral end of the sleeve, and a small enterotomy was done adjacent to it.

A 45mm articulating green cartridge was introduced through the surgeon's right hand side was used to perform a side to side sleeve-ileal anastomosis in an isoperistaltic horizontal direction. The 2 limbs of the stapling cartridge were introduced in the way that the anastomosis didn't exceed 3cm.

The staple defect was then closed with a one layer running 3/0 Vicryl sutures.

3. Final steps:

A hypnotic stitch was taken between the afferent ileal loop and the sleeve to decrease tension on suture line.

With boujie in place and control of both afferent and efferent ileal loops. A methylene blue test was done to test water tightness.

The transected stomach was then removed through the 15mm trocar site.

The anesthetist was informed to follow appropriate measures to avoid hypotensive anesthesia at this stage together with lowering intra-abdominal pressure, to make sure of adequate haemostasis and to minimize the risk of reactionary hemorrhage.

An intra-abdominal tube drain was inserted alongside the sleeve and the anastomosis before the liver retractor was removed.

Gradual abdominal deflation, removal of trocars under vision and skin closure with subcuticular monofilament absorbable sutures were the last steps.

Post-operative management / care:

Patients remained in recovery room until clear to be transferred to ward and this happened only when they were vitally stable with no hot signs.

Patients were closely and regularly monitored for:

- Vital signs (blood pressure, pulse, temperature and respiratory rate)
- Blood sugar level (with sliding scale correction of any glycemic derangement)
- Intra abdominal drain (quantity and quality of drain output)
- Abdominal examination

Pain was adequately controlled and patients received IV antibiotics for the first 48hrs. Use of parentral antibiotics continued furthermore only if needed for certain reason. Also the received IV fluids for the first 24hrs until being capable of drinking adequate amounts enough to keep them well hydrated.

Post-operative outpatients clinic visits:

These were routinely scheduled; 10 days post-operative then at 1, 3, 6 months and 1 year postoperative. Also, patients were clearly instructed to be reviewed in outpatients clinic at any time if they have any alarming complaint in between the previously scheduled follow up visits.

Primary outcome:

This was focused on the degree of remission of diabetes mellitus throughout the study.

Fasting blood sugar and diabetes medications were assessed at 3, 6 and 12 months visits, while HbA1C and fasting C- peptide level were assessed only at 6 and 12 months.

Secondary outcomes:

These were including weight and other metabolic outcomes. Weight loss was assessed by comparing pre-operative BMI to that measured 1 year post-operative.

Calcium and vitamin B12 were assessed pre-operative and the end of the study.

Baseline for lipid profile was noted pre-operative, while gradual improvement was assessed at 6 and 12 months post-operative regarding main profile components (Cholesterol, Triglycerides, LDL and HDL).

Hypertensive patients were assessed in all visits regarding their blood pressure control and medications.

Statistical Analysis

Data were collected, revised, coded and entered to the statistical package for social science (SPSS) version 23. Qualitative data were presented as number and percentages while quantitative data were presented as mean, standard deviations and ranges when their distribution found parametric.

The comparison between groups with qualitative data were done by using **Chi-square test and Fisher exact test** was used instead of Chi-square when the expected count in any cell found less than 5.

The comparison between two paired groups with quantitative data and parametric distribution were done by using **Paired t-test** while the comparison between more than two paired groups with quantitative data and parametric distribution were done by using **Repeated Measures ANOVA** followed by post hoc analysis using **Bonferoni test.**

The confidence interval was set to 95% and the margin of error accepted set to 5%. So, the p-value was considered significant as the following:

$P > 0.05$: Non significant

$P < 0.05$: Significant

$P < 0.01$: Highly significant.

3. Results

Our study included 20 patients; 16 females and 4 males. Female patients represented 80% of the total cases. The mean age of the patients included in this study was 40.55 ± 6.86 years (range, 29 – 50).

Operative time was 125.2 ± 15.63mins (range 97 – 149), being the maximum in highest BMI patients and in those who had intra-operative difficulties, and minimum in lower BMI patients and those with uneventful operations.

1^{ry} outcome results:

Fasting blood glucose (FBG). HbA1C, C-peptide and diabetes medications were used as parameters for both pre and post-operative diabetes assessment.

The pre-operative FBG was 165.75 ± 26.44 mg/dl (range, 123 – 210). 3 months post-operative it was markedly dropped to 110.45 ± 8.71 mg/dl (range 100 – 130) with only 3 patients above 110 mg/dl. Values were progressively improving to reach 93.85 ± 8.98 mg/dl (range 81 – 109) at 6 months post-operative and 83.05 ± 5.26 mg/dl (range 75 – 92) at 1 year post-operative.

Pre-operative HbA1C was 9.55 ± 1.58 % (range 7.6 – 12.9). Further results were 5.60 ± 0.44 % (range 4.9 – 6.4) and 4.96 ± 0.50 % (range 4.4 – 5.9) at 6 months and 1 year post-operative respectively. All the 20 patients had their HbA1C returned to normal range at the 6th month post-operative review, denoting marked glycemic control.

Also, diabetes medications were reviewed pre-operative and at different times during the post-operative year of follow up. It was clear that in pre-operative assessment, all patients were on oral hypoglycemics and only 3 out of the 20 patients were also using insulin together with the oral medications in order to control their diabetes. 3 months post-operative, only 4 patients were completing their diabetes medications but only in the form of oral hypoglycemic. Those were including the 3 patients who were on insulin pre-operative. Fortunately, none of our patients was using insulin by the 3rd month post-operative. Follow up after 6 months and after 1 year showed only one patient, who was previously on insulin and oral medications, continued treatment for his diabetes, but only with oral hypoglycemic that was enough for good glycemic control. Figure 1 shows diabetes medications used at different times of follow up:

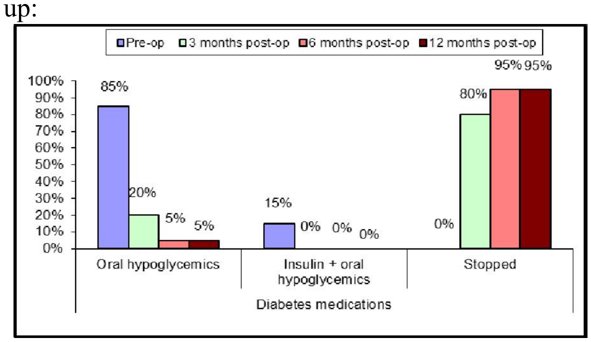

Figure 1: Diabetes medications used at different times of follow up

2ry outcome results:

BMI was the parameter used to assess the effect of SASI operation on weight loss. Pre-operative BMI was 45.80 ± 7.60 (range 36 – 60). While 1 year post-operative it dropped to 28.00 ± 3.09 (range 24 – 35), with a P-value > 0.001 of high significance. This is simply described in the following bar chart in figure 2.

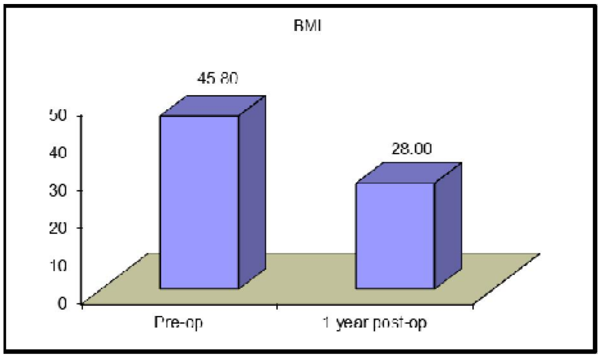

Figure 2: Comparison between BMI preoperative and after 1 year postoperative.

As SASI was mainly reviewed as a metabolic procedure, it is no surprise that we have also assessed its effect on lipid profile and some micronutrients (calcium and vitamin B12).

Precisely, 6 patients had a documented hyperlipidemia pre-operatively representing 30% of the total number of cases. Even though, all cases were evaluated as regard of their lipid profile at different times (pre-operative, 6 months post-operative and 1 year post-operative). Patients who were not hyperlipidemic, had different values of their lipid profile mostly within the higher average values.

Table 1shows different values of cholesterol, triglycerides, LDL and HDL for all the 20 patients at different occasions; pre-operative, 6 months post-operative and 1 year post-operative. It is obvious that improvement of lipid profile was highly significant. So that cholesterol level dropped gradually from 191.00 ± 33.63 mg/dl (range 142 – 263) pre-operative to 150.10 ± 19.70 mg/dl (range 119 – 179) after 1 year. Triglyceride level was 152.20 ± 31.15 mg/dl (range 122 – 213) pre-operative and decreases to reach normal value of 100.55 ± 19.57 mg/dl (range 70 – 137) in a year. LDL was initially high with a mean of 101.75 ± 31.41 mg/dl (range 73 – 170) and was markedly decreased to be 75.65 ± 11.63 mg/dl (range 62 – 112) at the end of the study. Finally, HDL was 47.50 ± 9.51 mg/dl (range 32 – 64) at the beginning of the study and reached higher values of 59.90 ± 7.05 mg/dl (range 47 – 69) at the end of the first year post-operative which are considered good values representing lesser risk.

Table 1: Lipid profile values at different times of follow up.

		Pre-op	**6 months post-op**	**12 months post-op**	**Test value•**	**P-value**	**Sig.**
Cholesterol (mg/dl)	Mean ± SD	191.00 ± 33.63	169.60 ± 21.18	150.10 ± 19.70	74.841	0.000	HS
	Range	142 – 263	135 – 200	119 – 179			
Triglyceride (mg/dl)	Mean ± SD	152.20 ± 31.15	126.45 ± 16.52	100.55 ± 19.57	132.664	0.000	HS
	Range	122 – 213	100 – 153	70 – 137			
LDL (mg/dl)	Mean ± SD	101.75 ± 31.41	82.55 ± 14.93	75.65 ± 11.63	22.510	0.000	HS
	Range	73 – 170	64 – 123	62 – 112			
HDL (mg/dl)	Mean ± SD	47.50 ± 9.51	52.80 ± 7.38	59.90 ± 7.05	134.377	0.000	HS
	Range	32 – 64	42 – 67	47 – 69			

Post hoc analysis by Bonferroni

Variables	**Pre-op vs 6 months**	**Pre-op vs 12 months**	**6 months vs 12 months**
Cholesterol (mg/dl)	0.000	0.000	0.000
Triglyceride (mg/dl)	0.000	0.000	0.000
LDL (mg/dl)	0.000	0.000	0.006
HDL (mg/dl)	0.000	0.000	0.000

P-value > 0.05: Non significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant

Repeated measures ANOVA test

Calcium and Vitamin B12 were the parameters used for assessment of the effect of SASI operation on micronutrients. Considering normal values of 8.5-10.5 mg/dl for Calcium and 174-878 pg/ml for Vitamin B12, none of our patients was deficient in these micronutrients in the pre-operative evaluation. Fortunately, no drop in micronutrients was noticed during post-operative follow up.

Regarding peri-operative difficulties and complications, 4 patients were found to have different incidents and they represent only 20% of our 20 patients.

Post-operative mild chest infection occurred in 1 patient. She was a 46 year old lady with a BMI of 57 pre-operative and her operative time was 145mins which is considered within the high range of all recorded operative times. This started on the second post-operative day in the form of low grade fever and productive cough. That was treated by antibiotics and chest physiotherapy. Second case was a 49 years gentleman with a pre-operative BMI of 60 and was a poorly controlled hypertensive patient. He had a difficult operation due to high BMI and difficult dissection through the short gastric vessels during the initial phase of the operation (sleeve gastrectomy). Adequate control of the bleeding was aided by repeated compression with swabs and thorough control with clips application on visualized bleeding points making sure that splenic blood supply was not compromised. Furthermore, a 30 year old hypertensive female patient, with a pre-operative BMI of 52 who had an average operative time and a straight forward surgical procedure, had an some dizziness and drowsiness on the first post-operative day. Intra-abdominal drain on the second day showed a bloody output of 600 ml. Thus, Hb level was checked to show a drop of Hb level from 11.3 g/dl to 8.1 g/dl, while her abdominal examination was fair. 1 unit of packed RBCs was cross matched and transfused. Close observation of vital data and drain output were crucial. Hb level was rechecked on the next day, and was found 8.9 g/dl. The patient was vitally stable and the drain output was much more clear than the day before. Patient was admitted for another day to make sure that there was no more suspicion of post-operative bleeding.

Finally, a 29 year old female patient, among those with high BMI, had a difficult surgical procedure and had the longest operative time among all cases. During surgery, after formation of the sleeve and the sleeve-ileal anastomosis, the methylene blue leak test revealed minor leak denoting that the anastomosis was not water tight. Thus, a second layer of interrupted Vicryl stitches was applied at the site of leak. The test was repeated showing no leak. Patient then resumed the same post-operative management like other cases.

4. Discussion

It was shown that consumption of "modern diet" - food processing - affects its digestibility and hence, the concept of glycemic index was developed **(Brand et al., 1985).** A high-glycemic-index diet provokes fast, early, and intense absorption, that in turn occurs mainly in proximal segments of the small bowel which are forced to overwork, whereas distal parts are exposed to proportionally fewer nutrients **(Santoro et al., 2012).**

Being produced from proximal bowel, Glucose-dependent insulinotropic polypeptide (GIP) is overproduced in patients with obesity and T2DM **(Vilsboll et al., 2003),** whereas the production of GLP-1 **(Lugari et al., 2002)**, and Polypeptide YY (PYY) **(Le Roux et al., 2006),** which are mainly distal bowel hormones, is deficient, as expected.

High GIP released by proximal bowel following consumption of such modern diet, does not suppress glucagon, which has a diabetogenic effect. On the other hand, GLP-1 does suppress it. **(Lund et al., 2011)** GLP-1 is more efficient in blocking glucagon and in sustaining a strong late phase of insulin secretion. Both GLP-1 and PYY secretion, as indicators of the ingestion of a significant amount of food, cause satiety and thus, delays gastric emptying, and contributes to the decision to terminate a meal **(Lund et al., 2011).**

Many studies have suggested that combined GLP-1 and GIP agonism might be beneficial in T2DM **(Asmar and Holst. 2010).** SASI operation aims to benefit obese, T2DM patients by counterbalancing the harmful effects of the modern diet. Without exclusions and with a simple surgical procedure, amplifying the nutritive stimulation of the distal gut whereas simultaneously diminishing the exposure of the proximal bowel to nutrients without completely deactivating duodenum and jejunum **(Santoro et al., 2012).** The stimulus to distal bowel is potent as the whole ileum is brought up, right after the stomach.

The rationale of the SASI bypass is to allow the rapid entrance of undigested chyme into the distal intestine, causing a more effective secretion of GLP-1 and PYY. These hormones reduce the rate of gastric emptying (making the stomach functionally even smaller), so called "functional restriction". Thus, improving insulin secretion, and promoting central satiety **(Batterham and Bloom, 2003).**

In our study patients were assessed according to different parameters. The results can be discussed illustrating possible explanations with occasional comparison with previous reliable studies. This, taking in consideration that SASI operation should be considered a new technique that has to be more investigated in the foreseeable future in order to be well established based on enormous data and research.

Regarding operative time, we had a mean operative time of 125.2 ± 15.63mins (range 97 – 149) that is considered a bit longer duration compared to **Mahdy et al. (2016)** that was 114 ± 30.5mins. This could be explained by the difference in experience. So that, T. Mahdy is considered the inventor of SASI operation and he had a larger number of cases.

On the other hand, it is considered a shorter duration compared to **Santoro et al. (2012)** who recorded operative time of 110 to 280mins (average 170mins), as Santoro performed a double anastomosis operation that in obviously more time consuming.

Diabetes remission was assessed based upon different parameters. That was including FBG, HbA1C, diabetes medications beside assessment of the C-peptide. 16 patients out of the 20 had their FBG and HbA1C levels down to normal values by the 3rd post-operative month, while all of the 20 patients had normal values by the 6th post-operative month. Not only we have recorded highly significant values for the drop in FBG and HbA1C levels, but also, highly significant value for the drop in use of diabetic medications.

We started the study with 100% T2DM, 3 of them were poorly controlled and were on insulin beside their oral hypoglycemic. Then, we finished the study with only 5% (only 1 patient out of the 20) with T2DM that was in much better control compared to his pre-operative state. The next table can clearly describes this:

Mahdy et al. (2016) had results showing complete resolution of diabetes in the first month postoperatively except five patients who had resolution after 3 months and required the gradual withdrawal of insulin and hypoglycemic drugs. While **Santoro et al. (2012)** presented his results with 86% went into complete remission and 14% were much improved but still required some oral diabetes medication.

Results are more or less comparable, and this is probably due to differences in number of patients, duration of follow up, severity and duration of diabetes pre-operative and selection of cases.

Considering weight loss results post-operative, our study showed highly significant results in the first post-operative year. So that the BMI dropped from a mean of 45.8±7.60kg/m^2 pre-operative to 28.0 ± 3.09 kg/m^2 one year post-operative. This result is quite comparable to other reliable studies. Although **Mahdy et al. (2016)** has used Percentage Excess Weight Loss as a parameter to judge weight loss, he considered his results excellent with EWL being 75% at 6 months and 90% at a first year.

Even when comparing to **Santoro et al. (2012)**, as we perform the single anastomosis modification of his original procedure, he presented his graph that has a comparable results with our study chart showing a drop in BMI from a mean of more than 40kg/m^2 pre-operative to record a mean BMI that was below 30kg/m^2 in 1 year after the operation.

Moreover, while analyzing the pre-operative state regarding hyperlipidemia, we had 30% hyperlipidemic patients (6 out of 20 patients). Highly significant results were noted, so that, all hyperlipidemic patients had complete remission and normal values for their lipid profile by the end of the study. Cholesterol level dropped from 233.67 ± 20.00mg/dl (range 212 – 263mg/dl) pre-operative to 172.17 ± 6.05mg/dl (range 163 – 179mg/dl) by the end of the first post-operative year. Triglyceride level was progressively decreasing from 196.00 ± 15.97mg/dl (range 171 – 213mg/dl) to reach normal values of 124.83 ± 10.61mg/dl (range 106 – 137mgdl) in 1 year duration. Also, LDL showed a significant progressive fall from 146.50 ± 13.78mg/dl (range 132 – 170) just before the operation to 102.17 ± 10.55, g/dl (range95 – 123mg/dl) at 6 months post-operative then to 86.50 ± 14.53mg/dl (range 68 – 112mg/dl) at the end of the study. HDL was initially found in low values of 36.50 ± 3.51mg/dl (range 32 – 41mg/dl) and was gradually improving and was significantly in higher cardio-protective values by the end of the year after the operation.

To sum up, there was a significant improvement in lipid profile with a P value > 0.05 in all parameters. Similarly, highly significant results were also presented by **Mahdy et al. (2016),** although in different units but still with a P-value > 0.05 in all lipid profile parameters. So that, cholesterol was 6.9 ± 1.8mmol/L, triglyceride was 2.7 ± 0.7mmol/L and LDL was 4.9 ± 1.9mmol/L in pre-operative assessment, and results dropped to 3.1 ± 1.1mmol/L, 1.2 ± 0.8mmol/L and 2.1 ± 0.8mmol/L respectively. Furthermore, HDL level jumped from 1.2 ± 0.9mmol/L pre-operative to higher protective values of 2.9 ± 1.2mmol/L in one year.

Also, **Santoro et al. (2012)** mentioned that he noted a complete resolution of 85% of hypertriglyceridemia and 70% of hypercholesterolemia and partial improvement of 15% and 30% respectively.

Hypertension was detected pre-operative in 35% of our cases (7 out of the 20 patients). Only 10% (2 patients) remained hypertensive by the end of the study, but much more controlled compared to their pre-operative hypertensive state.

Mahdy et al. (2016) had 15 hypertensive patients. Hypertension remitted in 86% (13 patients) of the cases and the other two patients are still under anti-hypertensive treatment, though both dosage and number of drugs have been reduced with better control of the disease. On the other hand. **Santoro et al. (2012)** illustrated in his results 72% complete remission of hypertension and 28% improvement. Mild variation in results is possibly related to variation in patients selection criteria.

Calcium and vitamin B12 levels were the micronutrients assessed in our study. And changes were non-significant as there was no detected deficiencies post-operative. Same happened with **Mahdy et al. (2016)** as shown in this table.

Being mainly absorbed in proximal bowel, Calcium level was not affected, possibly due to absence of exclusion in the SASI procedure. Vit B12 is absorbed in terminal ileum, thus absorption was not affected. Even though, long-term results not available to monitor the effect of the decreased intrinsic factor on Vit. B12 level, as its storage might be depleted by time.

Finally, complications/difficulties were detected only in 4 patients out of 20. Those were in the form of chest infection, intra-operative bleeding, post-operative bleeding and technically difficult sleeve-ileal anastomosis. No post-operative deaths reported and no significant permanent morbidity happened as a consequence to these complications.

Mahdy et al. (2016) had a true number of 50 patients who were evaluated. Complications were reported in 6 out of that total number. Those were in the form of pulmonary embolism, post-operative bleeding from staple line, obstruction of the sleeve-ileal anastomosis, early leak that was from a missed small bowel injury, marginal ulcer and excessive weight loss. Again, all were approached appropriately and managed without significant morbidity or mortality.

As the original procedure of **Santoro et al. (2012)** is technically more difficult and his study comprises larger number of patients with much more pre-operative co-morbidities, it is no surprise to find a larger list of complications -described within 30 days post-operative- that included bleeding, leak and fistula formation, ileus, pneumonia, portal thrombosis, cardiac problems, pulmonary embolism, intra-peritoneal infection, wound dehiscence in open cases, intestinal subocclusion, urolithiasis and rhabdomyolisis. Also, other late complications that included: cholelithiasis, incisional hernias, internal hernias and gastro-ileal anastomotic stricture. Moreover, mortalities were also recorded.

Marked difference between rate of complications between **(Santoro et al., 2012)** and SASI results may be due to various factors. Possibly, the most important ones are the larger number of morbid patients included in his study and the nature of his procedure that is based on a Roux-en-Y like technique of double anastomosis bypass which made it technically more difficult than SASI bypass.

Conclusion

SASI bypass is a newly introduced metabolic procedure that is based on physiological and functional adaptation rather than mechanical restriction and/or exclusion. It is safer and easier to perform and to adjust than loop bipartition originally done by Sergio Santoro. Also, it preserves a full endoscopic access post-operative.

Although the data about the procedure outcomes are still few, the results regarding diabetic control and weight loss are excellent.

SASI bypass can be one of the most efficient metabolic procedures and could be associated with less risks. The procedure should be considered under investigations until enough long term data are available. Thus it is worth to be explored in research aiming for more data.

References

1. Xu Y, Wang L, He J et al. (2013) Prevalence and control of diabetes in Chinese adults. JAMA; 310: 948-959.
2. Resnick HE, Foster GL, Bardsley J et al. (2006) Achievement of American Diabetes Association clinical practice recommendations among U.S. adults with diabetes, 1999-2002: the National Health and Nutrition Examination Survey. Diabetes Care; 29: 531-537.
3. Buchwald H and Oien DM. (2009) Metabolic/bariatric surgery worldwide 2008. Obes Surg.; 19:1605–1611.
4. Pok EH and Lee WJ. (2014) Gastrointestinal metabolic surgery for the treatment of type 2 diabetes mellitus. World J Gastroenterol; 20(39): 14315-14328.
5. Lee WJ, Lee KT, Kasama K et al. (2014) Laparoscopic single-anastomosis duodenal jejunal bypass with sleeve gastrectomy (SADJB-SG): short term result and comparison with gastric bypass. Obes Surg; 24: 109-113.
6. Santoro S, MD, Luis Carlos Castro, Manoel Carlos Prieto Velhote et al. (2012) Sleeve Gastrectomy With Transit Bipartition; A Potent Intervention for Metabolic Syndrome and Obesity. Ann Surg; 256:104–110.
7. Mahdy T., A. Al wahedi and C. Schou. (2016) Efficacy of single anastomosis sleeve ileal (SASI) bypass for type-2 diabetic morbid obese patients: Gastric bipartition, a novel metabolic

surgery procedure: A retrospective cohort study. International Journal of Surgery 34; 28-34.
8. Wilfred Lik-Man Mui, Danny Wai-Hung Lee and Katherine Kar-Yee Lam. (2014) Laparoscopic sleeve gastrectomy with loop bipartition: A novel metabolic operation in treating obese type II diabetes mellitus. International Journal of Surgery.; Case Reports 5: 56– 58.
9. Brand CJ, Nicholson PL, Thornburn AW et al. (1985) Food processing and glycemic index. Am J Clin Nutr; 42:1192–1196.
10. Lugari R, Dei Cas A, Ugolotti D et al. (2002) Evidence for early impairment of glucagon-like peptide 1-induced insulin secretion in human type 2 (non insulindependent) diabetes. Horm Metab Res; 34:150–154.
11. Le Roux CW, Batterham RL, Aylwin SJ et al. (2006) Attenuated peptide YY release in obese subjects is associated with reduced satiety. Endocrinology; 147:3-8.
12. Lund A, Vilsboll T, Bagger JI et al. (2011) The separate and combined impact of the intestinal hormones, GIP, GLP-1 and GLP-2, on glucagon secretion in type 2 diabetes. Am J Physiol Endocrinol Metab; 300: 1038-1046.
13. Asmar M and Holst JJ. (2010) Glucagon-like peptide 1 and glucose-dependent insulinotropic polypeptide: new advances. Curr Opin Endocrinol Diabetes Obes; 17:57–62.
14. Batterham R.L. and S.R. Bloom. (2003) The gut hormone peptide YY regulates appetite, Ann. N. Y. Acad. Sci. 994; 162-168.

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