

COMPARATIVE STUDY OF OUTCOMES BETWEEN LAPAROSCOPIC SINGLE ANASTOMOSIS SLEEVE ILEUM BYPASS (SASI BYPASS) VERSUS LAPAROSCOPIC MINI-GASTRIC BYPASS IN MORBID OBESE PATIENTS

By

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ABSTRACT

Background: The single anastomosis sleeve ileal (SASI) bypass is a Novel Metabolic/Bariatric Surgery operation based on mini gastric bypass operation and Santoro's operation in which a sleeve gastrectomy is followed by a side to side gastro-ileal anastomosis.

Objective: To evaluate the short-term outcomes between laparoscopic single anastomosis sleeve ileal bypass and mini gastric bypass, with respect to postoperative weight loss and metabolic and nutritional effects on patients.

Patients and methods: This study was done at Al-Azhar University Hospital and Al-Nhar Hospital. It was a prospective randomized study which compared between single anastomosis sleeve ileum bypass (SASI bypass) Versus Laparoscopic Mini-gastric Bypass, in outcome. The study included 40 patients scheduled for elective laparoscopic bariatric surgery, due to morbid obesity, divided into two groups. The first group (group A) was operated by gastric mini bypass and the second group (group B) where single anastomosis sleeve ileum bypass was done.

Results: The results of the study revealed that that there was high significant difference between before and after SASI surgery as regard FBG, HbA1C, triglycerides, cholesterol, HDL and LDL. Conclusion: SASI bypass is a promising operation that offers excellent weight loss and diabetic resolution.

Keywords: SASI, Bariatric, Mini-gastric, laparoscopic, anastomosis, sleeve, prospective, bypass.

INTRODUCTION

The words 'obese-obesity' come to English via French from the Latin, where the verb 'obedere' means 'over eat' and 'obese' means being very fat (Thomas, B. 2010).

In practice, obesity is diagnosed by body mass index (BMI), which is taken as a surrogate of percentage fat mass. However, BMI has some obvious

limitations related to the assessment of fat mass as well as the diagnosis of overweight and obesity-related disturbances. BMI is a score rather than objectively measured fat mass (or fat mass-related mechanical and metabolic disturbances) (Müller et al., 2016).

Obesity is a complex health issue to address. Obesity results from a combination of causes and contributing

factors, including individual factors such as behavior and genetics. Behaviors can include dietary patterns, physical activity, inactivity, medication use, and other exposures. Additional contributing factors in our society include the food and physical activity environment, education and skills, and food marketing and promotion (*Hall et al., 2011*).

Treatment of obesity starts with comprehensive lifestyle management (i.e. diet, physical activity, behavior modification), which should include the following: Self-monitoring of caloric intake and physical activity, goal setting, stimulus control, nonfood rewards, relapse prevention. Few drugs are available for the treatment of obesity, and their effectiveness is limited to palliation (i.e. production and maintenance of weight loss) rather than cure, with benefits fading when the drugs are stopped, because all medications inherently have more risks than diet and exercise do, pharmacologic therapy should be used only in patients in whom the benefit justifies the risk (*Abell and Minocha, 2016*).

Bariatric surgery is the only intervention that gives long-standing improvement or resolution of obesity-related conditions and also survival benefit. It is highly cost-effective. Surgical procedures for the treatment of obesity can be divided into three general categories: malabsorptive procedures, restrictive procedures and combined malabsorptive/ restrictive procedure (*Mancini, 2014*).

The mini-gastric bypass, or single anastomosis gastric bypass, is an effective and well-established procedure which combines some of the properties of a

gastric sleeve and a standard gastric bypass. The upper part of the stomach is divided into a tube, similar to the top three quarters of a sleeve, and then joined to a loop of intestine (*Balsiger et al., 2012*).

The mini-gastric bypass can be used as a primary weight loss procedure. It can also be used in patients who have had previous gastric banding or sleeve surgery, but have been unsuccessful with weight loss, or who have had band-related complications and have decided on revision surgery (*Greco, 2017*).

Single anastomosis sleeve ileal bypass (SASI) procedure appears as a new metabolic and bariatric surgery based on Santoro's operation, in which a sleeve gastrectomy is followed by a side-to-side gastroileal anastomosis (*Santoro et al., 2016*).

This study aimed to evaluate the short-term outcomes between laparoscopic single anastomosis sleeve ideal bypass and mini gastric bypass with respect to postoperative weight loss and metabolic and nutritional effects on patients.

PATIENTS AND METHODS

This study had been done at Al-Azhar University hospital and Al-Nhar Hospital. It was a prospective randomized study which had been compared between single anastomosis sleeve ileum bypass (SASI bypass) Versus Laparoscopic Mini-gastric Bypass, in outcome. The study included 40 patients scheduled for elective laparoscopic bariatric surgery, due to morbid obesity and divided into two equal groups. The first group (group A) was operated by gastric mini bypass, and the second group (group B) was operated by

single anastomosis sleeve ileum between May, 2018 and December 2019

Inclusion criteria:

1. Morbidity obese patients satisfying the criteria for bariatric surgery.
2. First stage procedure for super obese.
3. High risk patients where duration of procedure affected morbidity and mortality.

Exclusion criteria:

Patients with absolute or relative contraindication to laparoscopy, malignancy, liver cirrhosis with portal hypertension, and alcohol abuse.

All patients were subjected to the following:

A. History taking:

- Detailed history for all patients
- A designed sheet was fulfilled for every patient to document his data.

Past history of previous interventions.

B. Clinical examination:

General: Blood pressure, pulse, cardiovascular, neurological and respiration assessment.

Local: Clinical assessment of the patient.

C. Investigations:

- i. Laboratory workup: Hematologic and biochemical tests: complete blood count, fasting blood glucose, hemoglobin Alc, creatinine, fasting lipid profile, and urine analysis (for glycosuria and proteinuria).
- ii. Duplex study, CT angiography, and cardiological assessment by resting

electrocardiogram and echocardiography.

Informed consents were obtained from all patients after describing the operative and postoperative details and complications.

Routine gastroscopy was performed and abdominal ultrasound to exclude gallstones and to evaluate the degree of fatty liver.

The primary outcomes were the percent age of excess weight loss (% EWL), resolution of diabetes and improvement of comorbidity. The percent age of EWL was calculated as follows: (preoperative weight–follow up weight)/Preoperative excess weight × 100. The amount of blood loss during operation was estimated by suction device.

Resolution of comorbidity was considered if the disease was controlled without any medications.

Secondary outcomes were postoperative complications, postoperative nutritional status and multivitamins intake which include regular daily intake one tablet of (Centrum, Feroglobin, and Calcium)

And every month intake (Vit.B Complex and Vit. D 200,000 unit) measuring level of vitamins at 3,6,12 months.

Postoperative care: Patients were kept nil by mouth under supervision of critical care specialist and motivated for early ambulation, usually 6–8 hours after surgery. Meanwhile, compression stockings and low molecular heparin are continued along with spirometry and chest physiotherapy. On first postoperative day,

patients were allowed clear sips of liquid once every 10–15 min. Patients were discharged on 2nd or 3rd postoperative day with oral dispersible medicines depending on general condition, hydration, and on drain status.

Statistical analysis of the data:

Statistical analysis was done using IBM SPSS Statistics version 22 (IBM CORP., Armonk, NY, USA). Numerical data were expressed as mean and standard deviation or median and range as appropriate. Qualitative data were

expressed as frequency and percentage. Chi-square test was used to examine the relation between qualitative variables. For quantitative data, comparison between two groups was done using independent sample t-test or Mann Whitney test. Furthermore, the overall of the comparison study was assessed by computing summary estimates of sensitivity, specificity, positive and negative predictive values (PPV and NPV). A p-value < 0.05 was considered significant.

RESULTS

The mean age of the patients at the time of operation was 38.3 ± 3.61 years gastric mini bypass group versus 38.9 ± 3.4 years for single anastomosis sleeve

ileum bypass group. There was no significant difference between the studied groups as regard baseline data (**Table1**).

Table (1): Baseline data in between the studied groups

| <div>Groups</div> <div>Variables</div> | Group1 (n=20) | | Group2 (n=20) | | T test | P value |
|----------------------------------------|------------------------|------|-----------------------|------|--------|---------|
| Age: (Years): | | | | | | |
| Mean ± SD Range | 38.3 ± 3.61 (32-47) | | 38.9 ± 3.4 (31-46) | | 0.928 | 0.887 |
| BMI | | | | | | |
| Mean ± SD Range | 48.7 ± 7.6 (39-54) | | 47.9 ± 6.9 (38-54) | | 1.23 | 0.712 |
| | No. | % | No. | % | χ2 | P value |
| Gender | | | | | | |
| Female | 10 | 50.0 | 9 | 45.0 | 0.092 | 0.911 |
| Male | 10 | 50.0 | 11 | 55.0 | | |

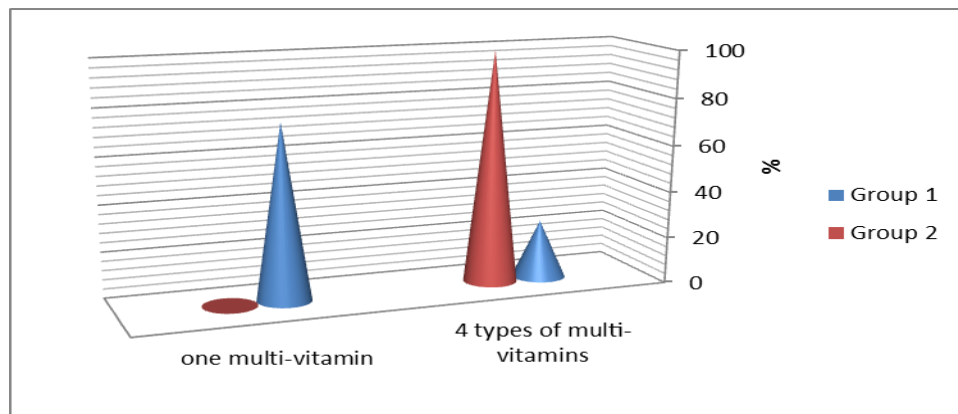
There was no significant difference between the studied groups as regard comorbidities (**Table 2**).

Table (2): Comorbidities distribution among the studied groups

| Variables \ Groups | Group1 (n=20) | Group2 (n=20) | P-value |
|--------------------------|------------------|------------------|---------|
| Diabetes mellitus | | | 0.056 |
| Yes | 8 (40%) | 14 (70%) | |
| No | 12 (60%) | 6 (30%) | |
| Hypertension | | | 0.197 |
| Yes | 6 (30%) | 10 (50%) | |
| No | 14 (70%) | 10 (50%) | |

After 12 months, 75% of patient weaned from the four types of multivitamins regimen to one multivitamin regimen without apparent

nutritional deficiency with high significant difference between the two techniques as regard multivitamins regimen (**Fig 1**).



Fig(1): Comparison between the studied groups as regard multivitamins intake after 12 months

There was no significant difference between the two included techniques as regard duration of surgery (**Fig 2**).

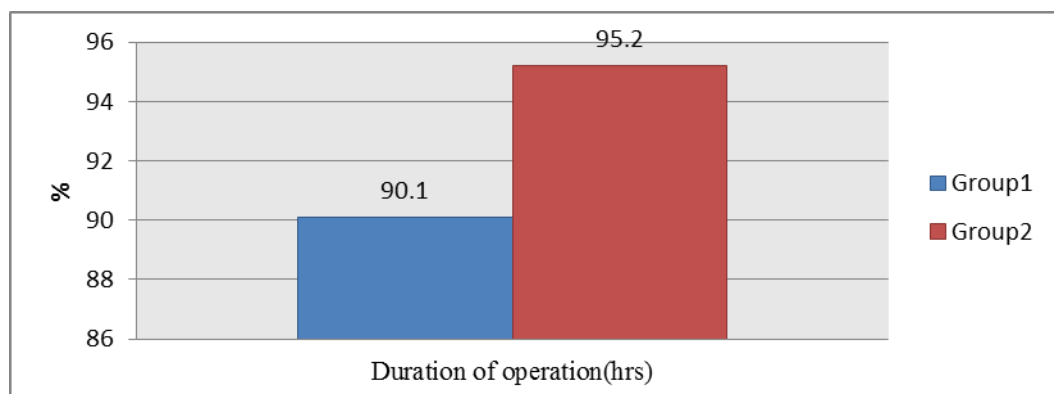


Fig (2): Mean duration of operation of the studied groups

There was a significant difference between before and after surgery as regard

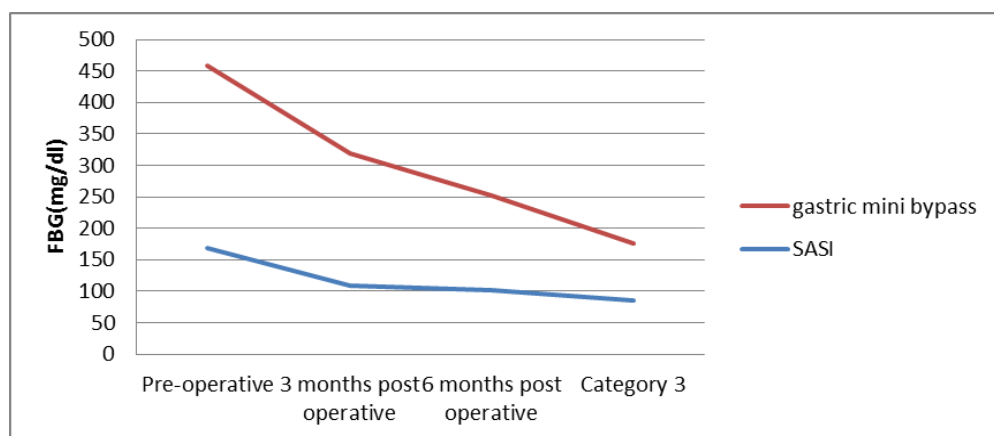
FBG, HbA1C, triglyceride, cholesterol, HDL and LD (**Table 3**).

Table (3): Pre and postoperative mean values in SASI group

| Values Variables | Pre- operative | 3 months post- operative | 6 months post- operative | 12 months post- operative | P value |
|-------------------------------|-------------------|--------------------------------|--------------------------------|---------------------------------|------------------|
| FBS (mg/dl): | | | | | |
| Mean \pm SD | 169.2 \pm 74.2 | 109.5 \pm 11.8 | 101 \pm 9.8 | 85 \pm 11.8 | <0.001 |
| HbA1c (%): | | | | | |
| Mean \pm SD | 9.9% \pm 2.7% | 6.1% \pm 0.7% | 5.7 \pm 0.8% | 5.1 \pm 0.8% | <0.001 |
| Triglycerides (mmol/L) | | | | | |
| Mean \pm SD | 2.7 \pm 0.7 | 1.4 \pm 0.6 | 1.1 \pm 0.2 | 1.2 \pm 0.4 | <0.001 |
| Cholesterol (mmol/L) | | | | | |
| Mean \pm SD | 6.9 \pm 1.8 | 4.6 \pm 0.9 | 3.9 \pm 1.2 | 3.1 \pm 1.1 | <0.001 |
| HDL (mmol/L) | | | | | |
| Mean \pm SD | 1.2 \pm 0.9 | 2.3 \pm 0.8 | 2.5 \pm 1.9 | 2.9 \pm 1.2 | <0.001 |
| LDL (mmol/L) | | | | | |
| Mean \pm SD | 4.9 \pm 1.9 | 2.5 \pm 0.8 | 2.2 \pm 0.9 | 2.1 \pm 0.8 | <0.001 |

There was a significant difference between before and after surgery as regard

FBG, HbA1c, triglyceride, cholesterol, HDL and LDL (**Fig 3**).

**Fig (3): Overtime change in FBG in both groups**

There was a significant difference between the two included techniques as

regard amount of blood loss during operation (**Fig 4**).



Fig (4): Mean amount of blood loss during operation of the studied groups

There was no significant difference between the two studied groups as regard complications (**Table 4**).

Table (4): Comparison between the studied groups as regard complications

| <div>Variables \ Groups</div> | Group1 (n=20) | | Group2 (n=20) | | P value |
|---------------------------------|------------------|-----|---------------|------|---------|
| | No. | % | No. | % | |
| During surgery: | | | | | |
| Leak during Methylene blue test | 0 | 0.0 | 2 | 10.0 | 0.723 |
| Convert to open | 0 | 00 | 0 | 0.0 | |
| Post-operative: | | | | | |
| Bleeding | 0 | 0.0 | 1 | 5.0 | 0.893 |
| Stenosis | 1 | 5.0 | 0 | 0.0 | |
| Biliary gastritis | 0 | 0.0 | 0 | 0.0 | |
| Leak | 0 | 0.0 | 0 | 0.0 | |

DISCUSSION

Obesity is a worldwide epidemic. Morbidly obese subjects are at risk of numerous physical and metabolic comorbidities that severely impair their health and increase mortality (*Flegal et al., 2012*).

Bariatric surgery not only allows sustained weight loss, but also reduces comorbidities and improves survival.

Therefore, it is not surprising that the number of bariatric surgeries worldwide has grown rapidly over the past decades (*Buchwald and Oien, 2013*).

There was no significant difference between the studied groups as regard baseline data.

Our results were in agreement with study of *Khalil et al. (2019)* as they found that there was no significant difference between the two groups regarding sex distribution.

Our results were supported by the study of *Mahdy et al. (2016)* as they reported that 50 patients were evaluated, 33 women, and 17 men, with a mean BMI of 48.7 ± 7.6 kg/m², mean age 40.5 ± 7.9 years.

The present study showed that there was no significant difference between the studied groups as regard comorbidities.

Our results were in line with study of *Khalil et al. (2019)* as they reported that among the common obesity-related comorbidities, diabetes was seen in 100% of all patients, followed by hypertension (19.6%) and hyperlipidemia (13.7%). There was no significant difference between the studied groups regarding comorbidities.

Furthermore, *Noun et al. (2012)* found that comorbidities were present in 26.5% patients, and included diabetes (19%), hyperlipidemia (24.6%), hypertension (23%), sleep apnea (17.8%), arthritic pain (22%), gastroesophageal reflux (21%). There were no significant differences between the studied groups regarding comorbidities.

According to *Lee et al. (2015)* metabolic syndrome as defined by the ATPIII criteria affected 56% of the morbidly obese patients in this trial. There was no significant difference between the studied groups regarding comorbidities.

Our results were supported by the study of *Mahdy et al. (2016)* as they reported that the mean operative time was 114 ± 30.5 min.

Our results were in contrary with study of *Khalil et al. (2019)* as they reported that the mean operative times were significantly different compared among

studied groups. In laparoscopic sleeve gastrectomy with loop bipartition, the majority of nutrients and food mainly pass through gastroileostomy rather than physiological pathway, and this observation is functionally similar to single anastomosis duodenal-ileostomy and duodenal-jejunal bypass, with less nutritional and surgical complications.

According to *Lee et al. (2015)*, there was asinificant difference in operation time among studied groups. Surgical time was significantly different among studied groups.

As regard glycemic and lipid profile pre and postoperative mean values in SASI group, in the study in our hands, there was a high significant difference between before and after surgery as regard FBG, HbA1C, triglycerides, cholesterol, HDL and LDL.

Our results were in agreement with study of *Mahdy et al. (2016)* as they reported that there was a significant difference between before and after surgery as regards FBG, HbA1C, triglyceride, cholesterol, HDL and LDL.

Furthermore *Khalil et al. (2019)* found that the laparoscopic sleeve gastrectomy with loop bipartition) group had significantly lower fasting blood glucose and glycated hemoglobin (HbA1c) levels in 1 month, 3 months, 6 months, and 12 months postoperatively.

As regard glycemic and lipid profile pre and postoperative mean values in gastric mini bypass group, the present study showed that there were significant differences between before and after surgery as regard FBG, HbA1C, triglyceride, cholesterol, HDL and LDL.

Our results were in agreement with study of *Lee et al. (2015)* as they reported that there was a significant difference between before and after surgery as regard Hb. In their study, MGB proved to be effective in the long term, significantly outperforming even RYGB in several parameters including BMI reduction, resolution of metabolic syndrome, and the need for revision surgery due to both bowel obstruction and internal hernia.

According to *Musella et al. (2014)* there was a significant difference between before and after surgery regarding control of DM.

The present study showed that there was a significant difference between the two included techniques as regard amount of blood loss during operation. There was no significant difference between the two studied groups as regard complications.

Our results were in agreement with study of *Sayadishahraki et al. (2019)* as they found that there was no significant difference between the two studied groups as regard complications.

Furthermore, *Khalil et al. (2019)* reported that no significant difference between the two groups regarding postoperative complications and hospital stay. Only two patients with an internal hernia required reoperation. Other patients underwent endoscopic and conservative treatments for other postoperative complications.

Our results were supported by study of *Mahdy et al. (2016)* as they reported that an adequate initial weight loss was predicted; because the function restrictive component of the operation was, a sleeve gastrectomy and the gastro-ileal bypass

induce neuroendocrine modulation. Thus, in terms of weight loss and co-morbidities resolution, SASI bypass initially provides satisfactory results. The weight loss was excellent from the beginning. The percentage of excess weight loss (% EWL) was 75% by the first 6 postoperative months and had reached a mean value of 90% at 12 months postoperatively.

These data were maintained during the whole follow-up period and were significantly greater than those obtained with other bariatric procedures (*Alobaid et al., 2015*). Previous versions of the BPD and the DS (duodenal switch) had achieved a long-term (10 y) % EWL of 70–80% (*Ceneviva et al., 2018*).

In the follow-up study by *Daniel et al. (2017)* a maximum weight loss was obtained by the third postoperative year and then patients regained minimally and to plateau around 75% EWL in the long term. In contrary, our patients reached a greater peak earlier that could have been attributed to the greater gastric function restriction.

Carvalho et al. (2012) observed that there was no significant difference between both groups regarding anemia, vitamins deficiency, and hypoalbuminemia, and these were still low in comparison with other bariatric bypass operations owing to the elimination of two ways of food passage. The postoperative undernutrition program makes patient malnutrition evaluation difficult.

Regarding *Sánchez-Pernaute et al. (2010)*, there were no intraoperative complications. Two gastric leaks (4%) presented one of them visible only in the

barium swallow, while the other had a clinical repercussion. The stomach thickness, along with technical errors in the gastric stapling, is responsible for these leaks. Currently they protected the staple line with an invaginating serosa-to-serosa running suture, as recommended by *Baltasar et al. (2017)* and they covered it with hemostatic sponges. No leaks have been detected in the duodeno-ileal anastomosis or in the duodenal stump, which is never invaginated.

Regarding *Lee et al. (2015)*, LRYGB had significant higher complication rate in bowel obstruction and major bleeding. There was no difference in the mortality rate. *Musella et al. (2014)* reported that the postoperative complications that occurred within the first 30 days. An early surgical revision was required for 2 % of the patients. A liquid diet was started for all the patients at 2.5 ± 1.1 postoperative days.

Also, *Noun et al. (2012)* reported that in primary MGB, the complication rate was 2.7% and 11.9% for revisional MGB in forms of bleeding, leakage and stenosis. The mean length of hospital stay was comparable for patients with Lap MGB or Mini-open MGB but was significantly shorter for patients with primary vs. revisional MGB.

Geraldo et al. (2014) found that early complications (4.3%) were encountered, and 7 major complications (1.7%) occurred. Marginal ulcers were noted in 8.0% during follow-up, and anemia was found in 9.7%. *Solouki et al. (2018)* reported that the complications included gastrojejunostomy leak in 3, bile reflux in 20, intractable marginal ulcer in 5,

malabsorption /malnutrition in 8, and weight gain in 2.

Limitations of this study included the small number of patients and short follow-up period. The data in the present study remained preliminary and feasibility of this surgical procedure on a large scale requires a lot of hard work.

CONCLUSION

SASI bypass is a promising operation, based on digestive adaptation physiologic principles, easier to perform than the Santoro's operation and BPD modifications, and with very good results as duodenal switch operation in the short run without malabsorption morbidity. The absence of prostheses or excluded segments, full endoscopic access, and easy feasibility associated with an excellent weight loss and diabetic resolution. Confirmation of these data and longer follow-up would strengthen the case for the consideration of SASI bypass as the most appropriate metabolic surgery procedure.

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دراسة مقارنة بين نتائج عملية التحويل المصغر للمعدة وعملية التحويل ثنائي التقسيم (ساسى) بالمنظار فى علاج مرضى السمنة المفرطة

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خلفية البحث: تتعدد عمليات جراحات السمنة المفرطة بالمنظار ومنها عملية التحويل المصغر للمعدة التي تعتمد اعتمادا كليا علي نقص الامتصاص وعملية التحويل ثنائي التقسيم (ساسى)، والتي تجمع بين تصغير حجم المعدة كالتكميم ونقص الإمتصاص أيضا كالتحويل.

الهدف من البحث: المقارنة بين نتائج عمليتي التحويل المصغر والتحويل ثنائي التقسيم بالمنظار في مرضى السمنة المفرطة الذين يتجاوز معامل الكتلة لديهم 35 في مستشفيات جامعة الأزهر.

المرضى وطرق البحث: أجريت هذه الدراسة علي مرضى يعانون من السمنة المفرطة باستخدام عمليتي التحويل المصغر والتحويل ثنائي التقسيم بالمنظار الذين يتجاوز معامل الكتلة لديهم 35 وكانت المقارنة من خلال نسبة نزول الوزن ومتابعة مرضى السكر والضغط ونسبة الدهون ومضاعفات ما بعد العملية ومدة استمرار الفيتامينات بعد العملية خلال الفترة ما بين مايو 2018 وديسمبر 2019، حيث تم فحص المرضى بعد شهر وثلاثة أشهر وستة أشهر وبعد عام.

نتائج البحث: كانت نسبة نزول الوزن أعلى واستخدام الفيتامينات ومضاعفات ما بعد العملية أقل فى عملية التحويل ثنائي التقسيم بعد متابعة المرضى لأكثر من عام.

الاستنتاج: إجراء عملية التحويل ثنائي التقسيم مقارنة بعملية التحويل الثنائي المصغر تعتبر أفضل في نزول الوزن وعدم استمرار الفيتامينات مدى الحياة وإن كان الأمر يحتاج إلي دراسات متقدمة وأوسع مجالا.