

## Evaluation of Single Anastomosis Duodeno-Ileal Bypass with Sleeve Gastrectomy (SADI-S) as a New Operation for Morbid Obesity

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### Abstract

**Background:** Obesity is a serious worldwide health problem; it has been shown to predispose to various diseases particularly cardiovascular diseases, diabetes disease, sleep apnea and osteoarthritis. There are non-surgical methods for weight loss as behavior modification, dietary control, exercise and drug therapy, but there are many surgical techniques that has less recurrence rate.

**Aim of the Study:** Is to evaluate Single anastomosis duodeno-ileal bypass with sleeve gastrectomy as a suitable operation for the morbidly obese patient and for those with significant metabolic disorders.

**Patients and Methods :** A prospective study was held in Al-Azhar University Hospitals and Ain Sham University Hospitals between January 2016 and January 2018. A total of 30 patients with fulfilled the criteria for bariatric surgery e.g., BMI >40kg/m<sup>2</sup> or >35kg/m<sup>2</sup> with associated comorbidity with failed diet for more than two years.

**Results:** Male to female ratio was 40% (12 male patients) to 60% (18 female patients). Mean age was 32 years ranging from 20 years to 56 years. The mean preoperative weight was 142.53kg ranging from 100kg to 210kg, the maximum weight was for a 28 years old male with BMI 77.13kg/m<sup>2</sup> and the minimum weight was for a 25 years old female with BM 43.28kg/m<sup>2</sup>. The mean operative time was 216.6 minutes ranging from 150 to 360 minutes. The mean postoperative hospital stay was 6 days ranging from 3 days to 13 days. The table shows weight loss through the follow-up period; mean weight decreased from 142.53kg±32.174kg preoperatively to 131.697kg±29.0021 kg at one month, 111.200kg±23.1774 kg at six months, 97.713kg±19.5476 kg at one year and 81.753 kg±14.8329kg at two years.

**Conclusion:** Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy is a novel bariatric operation based on the principles of biliopancreatic diversion (BPD). SADI-S can be done either laparoscopically or through an open access. In this study, we have found that the Laparoscopic Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy provides an innovative approach to one of our major health problems.

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**Key Words:** Duodeno-ileal bypass – Gastrectomy – Laparoscopy – Obesity.

### Introduction

**OBESITY** is a serious worldwide health problem; it has been shown to predispose to various diseases particularly cardiovascular diseases, diabetes disease, sleep apnea and osteoarthritis. The mortality rate from obesity exceeds 4000-000 patient a year, and obesity is considered to be the second cause of preventable death after cigarette smoking [1].

Obesity is a disease in which the natural energy reserved, stored as fat, is increased to appoint where it compromises the patient's state of well-being. The etiology of obesity is multi factorial and is related to genotypic and environmental factors. Environmental factors as social and culture aspects, in association with genotypic factors cause the abnormal physiology, metabolism, behavior and psychological pathways, that results in the obesity phenotype. There are non-surgical methods for weight loss as behavior modification, dietary control, exercise and drug therapy that decrease appetite or decrease fat absorption from GIT but these measures not give the wanted results also there is high rate of recurrence [2].

### Patients and Methods

Thirty morbidly obese patients who fulfilled the criteria for bariatric surgery e.g., BMI >40kg/m<sup>2</sup> or >35kg/m<sup>2</sup> with associated comorbidity with failed diet for more than two years were included in this study. These patients were enrolled in a prospective study at Al-Azhar University Hospital and Ain-Shams University Hospitals.

Inclusion criteria met the National Institutes of Health of USA criteria for bariatric surgery which

includes BMI was more than 40kg/m<sup>2</sup>, less severely obese patients (BMIs between 35 and 40kg/m<sup>2</sup>) were considered for surgery if they had comorbidities such as diabetes type II, hypertension and sleep apnea syndrome. As well as they include history of failure of non-surgical treatment for more than two years.

Exclusion criteria are patients with more than 65 years old age, patients who will not psychologically accept surgery, psychological instability, alcoholic or drug abuse, unfit for surgery (major organ failure), and patients with history of gastric ulcer disease.

The documented preoperative, operative and postoperative follow-up data for all patients were collected and reviewed and the outcome of surgery was evaluated.

Patients were subjected to preoperative assessment which included age and gender, plus full clinical assessment and medical history with special notes on history of attempts to lose weight for more than two years, detailed dietary history. Also these data were noted as associated comorbidities, weight loss trials, eating habits, psychological status, history of previous laparotomy especially gastrointestinal surgery and full laboratory investigations (Complete blood picture, liver function tests, kidney function tests, lipid profile, thyroid profile, hemoglobin A1C for diabetic, serum cortisol and pulmonary function test). Radiological imaging were included as plain X-ray chest, pelvi-abdominal ultrasonography, upper GIT endoscopy, echocardiography, duplex. Each patient was routinely thoroughly evaluated by a multidisciplinary team (nutritionist, endocrinologist, psychologist, and surgeon).

A fully informed consent is taken from the patients discussing with them the operative procedure and the possible intraoperative and postoperative complications.

Preoperative medications were given as two grams of ceftazidime as antibiotic, H2-blocker, anti-emetic and prophylactic anticoagulant (low molecular weight heparin) given 12 hours before surgery.

General endotracheal anesthesia with muscle relaxant was used for all patients. Patients were put in supine position and brought into a Trendelenburg position with extended arms and the patients were secured to the table using adhesive strips. All contact zones were checked and padded to avoid nerve and arterial compression and pres-

sure sores. The surgeon stood between patients' legs with two monitors placed above the patient's shoulders and elastic stocking around legs up to the knees.

• *Creation of pneumoperitoneum and trocars insertion:*

A small stab was made at the left hypochondrium allowing the introduction of the Veress needle; insufflation was done to establish carbon dioxide pneumoperitoneum up to 14mmHg. Then the first 10mm. port was inserted slightly left of midline and 16 cm from the xyphoid. In which a 30 telescopic camera was inserted after that laparoscopic exploration of the whole abdominal cavity was done as following:

- Two trocars of 12mm. one at the right midclavicular line and the other at the left midclavicular line midway between the xiphisternum and the umbilicus.
- One trocar 5mm. at the left anterior axillary line.
- One trocar 10mm. at the epigastrium for the liver retractor.

• *Sleeve dissection:*

The technique commences with the devascularization of the greater curvature of the stomach with the harmonic scalpel. The stomach is then tubularized over a 54 French oral bougie, with a linear gold cartridge, commencing 6 to 8 cm proximal to the pylorus. The dissection of the greater curvature is prolonged through the first portion of the duodenum down to the gastroduodenal artery. An important step of the SADI procedure is the complete dissection of the duodenum by identifying also the pyloric artery coming from the gastroduodenal artery. We preserved the artery.

• *Duodenal dissection and section:*

Once the duodenal dissection was performed over 2cm after pylorus, duodenum was separated from the pancreas down to the pancreatoduodenal groove and the gastroduodenal artery.

After opening the peritoneum at the right margin of the duodenum, you should take care not to damage the right gastric artery. At this point the duodenum is divided with a linear blue cartridge stapler, preserving all the vascularization to the lesser curvature, i.e., the right gastric artery and the supraduodenal artery. This first part of the operation is performed with the operating table under forced anti-Trendelenburg position and the surgeon positioned between the legs of the patient; when finished, the table is changed to the horizontal position and the surgeon moves to the left-hand

side of the patient to perform the second part of the operation. The ileocecal junction is identified and 250cm is measured upwards. The selected loop is ascended ante-colically without division of the greater omentum, and a stapled isoperistaltic side-to-side duodenoileal anastomosis is completed. The staple defect is closed with a two-layer running 4/0 polydioxanone suture. Duodenoileal anastomosis may be also done by four-layer anastomosis using polypropylene (3/0). First a posterior polypropylene layer was made; then the duodenum and the ileum were opened by the use of monopolar. A posterior continuous resorbable suture (vicryl 3/0) was performed and then the anterior layer was constructed in similar fashion, first with a vicryl continuous layer and finally with a polypropylene 3/0 anterior closure. A methylene blue test is performed. For this maneuver, the console surgeon blocks the outlet at the level of the ileal loop in order to visualize the shape, the apparent volume, and any leak of the anastomosis. A drain was left in place under the anastomosis and close to the duodenal stump.

A drain was placed posterior to the anastomosis. All trocars wounds were closed. Postoperative gastrografin swallow after a loop duodenal switch. The water-soluble contrast comes through the duodeno-ileal anastomosis and fills the efferent-alimentary-common limb. With the progression of the contrast, part of the afferent biliopancreatic loop is also filled with contrast. Patients received nothing by mouth postoperatively till an upper gastrointestinal water soluble contrast study was performed on the third postoperative day. Patients received an anticoagulant therapy; elastic stocking and subcutaneous low molecular weight heparin as a prophylactic measures against postoperative pulmonary embolism. Patients received intravenous broad spectrum antibiotic together with intravenous analgesia (drip method) to provide more consistent pain relief than intermittent injections. The patients received proton pump inhibitors to avoid stress ulcers Nasogastric tube was commonly removed in the third postoperative day after the contrast study. After removal of the nasogastric tube the patients were instructed to start clear oral fluids. Patients were usually discharged in the fourth postoperative day. Patients were instructed to follow-up five stages diet regimen under supervision of the nutritionists as follow: The first stage started when the patient started oral fluids in the form of clear fluids for five days, the second stage started in the second week post operatively for three weeks in the form of protein rich fluids, the third stage started in the second month post oper-

atively for one month in the form of smashed diet, the fourth stage started in the third month post operatively for one month in the form of low calorie soft diet and the fifth stage started in the fourth month post operatively in the form of low fat low sugar small frequent meals.

Postoperative diet regimen includes 4-6 meal/day (each meal should not exceed the volume of a measuring cup, eat and drink slowly, take small bites and chew very well, avoid red meat, vitamin/mineral daily, drink low calorie liquids between meals at least 6-8 cups/day, avoid raw vegetables and raw fruits, low fat solid diet: Chew all food very well, sip only small amounts of water, add one new food at a time, add breads last, and take vitamin/mineral supplement with iron and zinc daily).

Discharge the patient when he is mobile, tolerate liquid diet, has pain controlled with oral analgesia and complication free. Postoperative overeating is as exceeding the capacity of the stomach causes nausea and vomiting. Many patients will need to take a daily multivitamin pill for life to compensate for reduced absorption of essential nutrients as patients can't eat a large quantity of food, physicians recommend a diet high in protein and low in fats.

Follow-up of cases was done by serum chemistry is obtained at 3, 6, 9 and 12 months and then yearly, CBC, serum calcium (total & ionized), blood glucose level, serum creatinine, serum Mg, SGOT-SGPT, Vit. D, serum Iron serum albumin, zink lipid profile, PT and representative B complex vitamin levels.

Postoperative complications as hernia, food intolerance or reflux were recorded. Success rate of surgery was determined according to criteria after 6 months. Excellent results if % excess weight loss (PEWL) is >75%. Good results if PEWL is 50-74%. Fair results if PEWL is 25-49%. Failure if PEWL is <25%.

On discharge, patients were instructed to receive oral treatment in the form of broad spectrum antibiotic, analgesic and proton pump inhibitor for one week

In the second stage, patients continued to receive the proton pump inhibitor and started to receive intramuscular vitamin B 12.

In the third stage, patients stopped the proton pump inhibitor and continued the rest of the drugs and started to receive oral calcium together with vitamin D.

In the fourth stage, patients continued on the same treatment and started to receive oral iron supplement to continue on that treatment for the next three months.

Operative time which was defined as the time from the first incision to the placement of the last suture.

#### Statistical analysis:

The collected data were tabulated and statistically analyzed using SPSS software (Statistical Package for the Social Sciences, version 13, SPSS Inc. Chicago, IL, USA) using Chi-square test (X<sup>2</sup>) and student *t*-test. Significance was adopted at *p*-value <0.05 for interpretation of results of tests of significance.

### Results

Our studies involved thirty morbidly obese patients who presented to our outpatient clinic in Ain Shams & Al-Azhar University Hospitals. They were selected upon the selection criteria adopted for this study. Epidemiological studies as shown in Table (1).

Table (1): Epidemiological data.

Parameter	No.	%
Sex:		
Male	12	40
Female	18	60
Age:		
Mean ±SD	32±11.7	
Range	20-56 years old	

The operations that were done in 150 minutes was for a 26 years old and 35 years old female, patients with BMI 55.55kg/m<sup>2</sup> and 52.36kg/m<sup>2</sup> respectively while the operation that was done in 360 minutes was for a 28 years old male patient with BMI 60.44 kg/m<sup>2</sup>.

In the postoperative period, two patients had postoperative leakage. The first one was discovered on the fourth postoperative day by the gastrografen meal although the intra-operative methylene blue test was negative. The patient was explored laparoscopically revealing a minor leak (1-2mm) close to the gastroesophageal junction. Repair and drainage were done. The patient had a smooth postoperative course, follow-up gastrografen meal revealed no leakage and the patient was discharged under oral diet at the 13th postoperative day. The other

One was admitted after experiencing clinical symptoms of leakage at home for 2-3 days. He was resuscitated and CT revealed abscess cavity below gastro esophageal junction without free drainage into the peritoneal cavity. Radiologist put a drain. Total parenteral nutrition, endovenous therapy with broad spectrum antibiotic and somatostatine analogue was initiated. Clinical condition not improved. This patient developed adult respiratory distress syndrome due to sepsis and died from multiple organ failure 7 days after admission to the ICU. These patients that stayed for 13 days in hospital were a 24 years old female patient with BMI 57.37kg/m<sup>2</sup> and a 28 years old male patient with BMI 60.44kg/m<sup>2</sup>. One patient with postoperative leakage has been diagnosed, 8 months after the operation, with a sub-phrenic abscess, which has been properly drained under radiological guidance. We also had two patients (6.7%) with bleeding which was discovered from the suction drain (>250 cc blood in the first 24 hours) but it stopped spontaneously on conservative treatment (fluid resuscitation) and didn't need blood transfusion. We had no anastomotic stenosis, port site infection, internal hernia or DVT in the early postoperative period. There was only one case died in the early postoperative period.

Our study shows weight loss through the follow-up period; mean weight decreased from 142.53 kg ± 32.174kg preoperatively to 131.697kg±29.0021kg at one month, 111.200kg±23.1774kg at six months, 97.713kg± 19.5476 kg at one year and 81.753kg± 14.8329kg at two years.

Obesity was considered as a significant predictive factor for difficulty (*p*<0.005) as well as conversion (*p*<0.08).

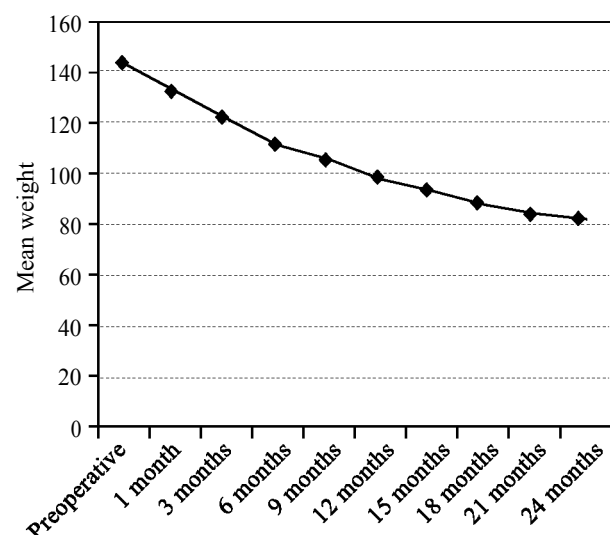


Fig. (1): Mean weight in different follow-up measurements.

The graph (Fig. 1) shows that the mean weight decreased smoothly from 142.53kg to reach 81.753kg two years postoperatively, thus the mean weight loss was 60.777kg in two years. The weight loss that had occurred was gentle, progressive and durable over a follow-up period of two years.

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The graph (Fig. 2) shows that the mean excess weight loss increased smoothly from 14.509% at one month to reach 78.9533% two years postoperatively. The excess weight loss that had occurred was gentle, progressive and durable over a follow-up period of two years.

The graph (Fig. 3) shows that the mean BMI decreased from 51.0687kg/m<sup>2</sup> to reach 29.0327 kg/m<sup>2</sup> two years postoperatively with periods of weight stabilization between 9 months and 12 months postoperatively, thus the mean BMI decrease was 22.036 kg/m<sup>2</sup> in two years.

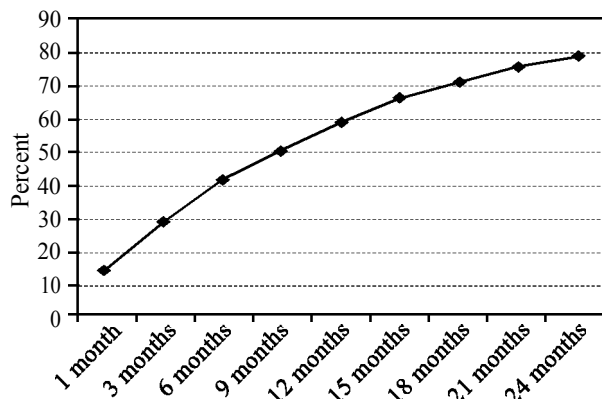


Fig. (2): Mean excess weight loss in different follow-up measurements.

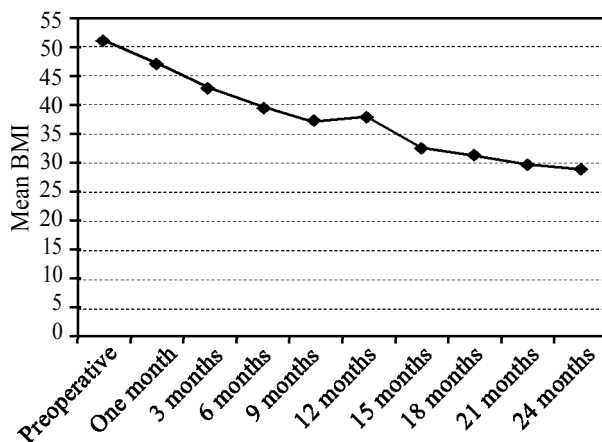


Fig. (3): Mean body mass index in different follow-up measurements.

## Discussion

In a prospective study (2 years ago), our patients who had Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy were followed-up, examined and investigated for the outcome of surgery. Weight loss results, morbidities and mortalities were discussed as well as its way of management.

The mean age for studied patients was (32 ± 11.7 years old), 60% of patients were females while the others were males (40%). This shows a higher prevalence of obesity among females than males. Our results agree with Pernaute et al., in 2010 that their results were 18men and 32 women with a mean age of 46 years old [3].

Regarding the operative time; in our study the mean operative time was 216.6 minutes compared with a study done by Mitzman in 2016, the mean procedure time was 147min. In otherwise with a study done by Pernaute A et al. in 2010 included 50 patients with mean BMI 44kg/m<sup>2</sup>, the mean operative time was 114 minutes (45-160) [3,4].

As regard hospital stay; in our study the mean postoperative hospital stay was 6 days. In 2014, Pernaute A et al., on 50 patients, the mean hospital stay was 5 days [3-7] days. In comparison to a study done by Mitzman in 2016, length of hospital stay was 2±0.9 days [3,4].

Regarding postoperative complications; in our study, over the follow-up period there were 4 patients (13.33%) with one or more postoperative complications, 12 patients (86.67%) without postoperative complications. Complications were divided into early postoperative complications that occurred within thirty days from the operation and late postoperative complications that occurred after thirty days from the operation. In the late postoperative period, there were 5 patients (16.7%) who developed anemia, 8 patients (26.7%) had hair loss, 3 patients (10%) developed peripheral neuropathy and 3 patients (10%) developed gall stones but there were no cases with anastomotic stenosis or ulceration, internal hernia, bowel habit changes or dumping syndrome in the late postoperative period. There was zero mortality in late postoperative period.

Regarding to the changes in the BMI; in our study, the mean initial BMI for studied patients was 51.06kg/m<sup>2</sup>±9.50018kg/m<sup>2</sup>. Then BMI decreased to its lowest value 29.03±3.39 after two years. Mean excess weight loss increased from 14.5%±3.18% after one month, 41.6% ±8.8% after six months, 59.3%±11.3% after one year and 78.9% ± 12.8% after two years. One patient (3%) had poor

weight loss which is defined to be less than 50% of excess weight loss after two years. She was sweet eater with no family history of obesity.

In 2012, Pernaute made case series of 100 patients with morbid obesity or metabolic disease treated with single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI S), the mean excess weight loss [EWL calculated from an ideal body mass index (BMI) of 25 kg/m<sup>2</sup>] was 95% at 12 months [3].

Regarding to postoperative glucose level, mean glucose value returned to normal in all cases (mean glycemia, 97mg/dl), although five patients had glycemia over 110mg/dl only during the first three postoperative months. Glycosylated hemoglobin was below 6.5% in all cases with mean value of 5.4% (4.1- 6.5). Only one patient (3%) maintains reduced dose of anti-diabetic therapy 5 months after the operation with normal glycemia and glycosylated hemoglobin. After the first six postoperative months, no patient is under antidiabetic treatment. Mean glycosylated hemoglobin was 4.9% (4.1-6.1) for the 11 diabetic patients reaching a 1-year follow-up and 5.2% (4.1-6.3) for the five diabetic patients reaching a 2-year follow-up, there is no need for antidiabetic therapy.

In comparison to the study done by Pernaute in 2015 about case series of 97 patients, the overall diabetes remission rate (defined as HbA1c below 6% without antidiabetic medication for more than 1 year) was 77% at 2 years and 52% at 5 years. Remission rates were higher for those having oral therapy (n=14) than for those having insulin therapy (n=40) (97% versus 54% at 2 years; 75% versus 38% at 5 years). In the case series of 97 patients, type 2 diabetes recurred in 8% (4/97) of patients within 5 years. In the case series of 97 patients, the mean glycaemia level reduced from 167.6mg/dl at baseline to 93.0mg/dl at 1 year follow-up and to 101.6mg/dl at 5 year follow-up. The mean HbA1c level reduced from 7.6% at baseline to 5.1% at 1 year follow-up and to 5.5% at 5 year follow-up [5].

#### Conclusion:

Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy is a novel bariatric operation

based on the principles of biliopancreatic diversion (BPD). SADI-S can be done either laparoscopically or through an open access. In this study, we have found that the Laparoscopic single-anastomosis duodeno-ileal bypass with sleeve gastrectomy provides an innovative approach to one of our major health problems.

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## تقييم طريقة جديدة لعلاج السمنة بالتوصيل الأحادي للأمعاء مع اجتزاء جزء من المعدة

السمنة عى مشكلة صحية خطيرة فى جميع أنحاء العالم. وقر ثبت أنها تؤهب للأمراض المختلفة وخاصة أمراض القلب والأوعية الدموية ومرض السكرى وتوقف أثناء النوم وهشاشة العظام. معدل الوفيات من السمنة ٤٠٠٠ مريض فى السنة، وتعتبر السمنة السبب الثانى للموت الذى يمكن الوقاية منه بعد تدخين السجائر.

السمنة عبارة عن مرض يتم فيه زيادة الطاقة الطبيعية المحفوظة، المخزنة على هيئة دهون، للتعين حيث تتنازل عن حالة المريض الصحية. مسببات السمنة متعددة العوامل وتتعلق بعوامل وراثية وبيئية والجوانب الاجتماعية والثقافية، بالأشتراك مع العوامل الوراثية تتسبب فى الفسيولوجية غير الطبيعية، والتمثيل الغذائى، والسلوك والمسارات النفسية، التى تؤدى إلى النمط الظاهرى للسمنة . هناك طرق غير جراحية لفقدان الوزن مثل تعديل السلوك والتحكم فى الغذاء وممارسة الرياضة والعقاقير التى تقلل الشهية أو أمتصاص الدهون من الأمعاء ولكن هذه التدابير لا تعطى النتائج المطلوبة أيضاً هناك نسبة عالية من تكرارها.