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Midterm follow up Outcomes of Single Anastomosis Sleeve Jejunal Bypass (SASJ) in Management of Morbid Obesity.

A thesis study protocol submitted for partial fulfillment of Master Degree in General Surgery

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Introduction

Obesity is a critical health problem associated with an increased risk of cardiovascular disease, diabetes, and cancers, affecting both the quality of life and life expectancy [1]. The increasing prevalence of obesity and comorbid conditions requires effective treatment and prevention [2]. Previous evidence has demonstrated that bariatric surgery is associated with greater and longer-term weight loss than non-surgical management [3, 4].

Thus, in patients with a body mass index of ≥ 40 or ≥ 35 kg/m^2 with co-morbidities, bariatric surgery is the most effective treatment option that not only promotes weight loss but also improves comorbid conditions [5]. However, like any surgical procedure, several complications can occur [6]. The development of nutritional deficiencies is a complication which may be life-threatening; therefore, bariatric surgery requires careful consideration [7].

The most frequently performed surgery for obesity worldwide is the laparoscopic sleeve gastrectomy (LSG), the Roux-en-Y gastric bypass (RYGB), and more recently, the one anastomosis gastric bypass (OAGB) [8, 9].

One newly developed weight loss procedure, the single sleeve ileal anastomosis bypass (SASI), has been developed as a modification to Santoro's operation (sleeve gastrectomy with transit bipartition SG + TB) [10]. Since no duodenal division or manual anastomosis is required, the procedure allows easy endoscopic access to the duodenum [11].

Mahdy et al., noted that SASI has the following advantages over other bariatric procedures: SASI has a shorter operative time compared to other procedures; 2) easy access to the duodenum and biliary tree endoscopically; 3) SASI does not divide the duodenum, thus eliminating the possibility of duodenal stump leakage, a serious complication with an incidence range between; 4) the tension on the anastomosis lower than other techniques; 5) there are no blind loops, excluded segments, or foreign bodies; 6) SASI is completely reversible [12].

Single anastomosis sleeve jejunal (SASJ) bypass, which is the focus of this study, is a modification of SASI using a shorter biliopancreatic limb length compared

to SASI to prevent long-term nutritional complications [13]. The SASJ bypass appears to be safer than the SASI procedure in patients with excessive weight loss and nutritional deficiencies and is simpler due to its improved surgical ergonomics [14].

Aim of the Work

This study aims to evaluate the three-year outcomes of SASJ bypass as a primary bariatric procedure in a tertiary bariatric center for weight loss, comorbidity resolution, and both early and late complications.

Patients and Methods

Place of the study:

Sohag University Hospitals after approval from the institutional ethical committee.

Type of the study:

Retrospective study with prospective collective data.

Study period:

The study will include all SASJ bypass patients who were operated in sohag university hospitals in the period from January 2019 to june 2023.

Inclusion Criteria:

- Age from 18 to 65 years old.
- Both sexes.
- Body mass index (BMI) > 35 with comorbidities or BMI > 40 with or without comorbidities.
- Primary bariatric procedure.
- Follow up period 2 years or more after SASJ.

Exclusion Criteria:

- Follow up period less than 2 years.
- Previous laparoscopic metabolic surgery
- Patients with huge anterior abdominal wall hernias.
- Cirrhotic patients.
- Pregnant or lactating females.
- Unfit patients for anesthesia.
- patients requiring revisional bariatric surgery.
- Patients with any contraindications to laparoscopic surgery.

Method of the study:

A retrospective study with prospective collected data included a case series of consecutive bariatric patients who underwent SASJ bypass in Sohag university hospitals between the 1st of January 2019 and the 31st of june 2023. The

analysis in the present study included data of all the patients who underwent SASJ as bariatric procedure. All patients were approved as candidates for bariatric surgery by a multidisciplinary screening team, between 18 and 65 years of age and a BMI more than 40 kg/m2 or BMI of more than 35 kg/m2 combined with comorbidities.

All the required data have been collected from the patients' files at Sohag university hospitals out-patient clinic. To update follow up data for missing patients, a postal questionnaire will be sent to all patients to retrieve the latest outcome. Patients who will not respond will receive a phone call and email if applicable. The postal questionnaire contained questions about:

a) Current and lowest weight after surgery.
b) Current comorbidities and medication.
c) Possible complaints / complications.
d) Any surgical intervention related to the SASJ bypass.

In case of non-response, the data of the last visit either in hospital or out-patient clinic were used as a final outcome.

Ethical standards:

An oral and written consent will be taken from the patients included in the study and will be introduced to ethics scientific committee at Sohag university hospital for approval.

Preoperative:

As for any bariatric procedure, all patients had a routine preoperative evaluation including history, examination, and laboratory investigations.

If symptomatic GERD was present, an endoscopy was performed. An abdominal ultrasound had been routinely carried out to evaluate the state of the liver and to exclude the presence of gallstones. Low molecular weight heparin had been given subcutaneously for all patients 12 h before surgery as prophylaxis against deep vein thrombosis.

Surgery technique:

The patient had been placed in the French position in a steep reverse Trendelenburg position with the surgeon standing between the patient's legs. All

patients had been operated under general anaesthesia with endotracheal intubation. In the classic sleeve gastrectomy, the operation had been started with the separation of the greater omentum from the stomach. The dissection had been continued upward to dissect the short gastric vessels and to clear the left crus from any attachments. Any adhesion between the stomach and pancreas had been dissected. The dissection had been continued downward till the pyloric ring.

A 36-French calibration tube had been used as a guide for a proper sleeve. Using a linear cutting stapler, stapling had been begun at 6 cm proximal to the pylorus and continued upward to separate the stomach. The staple line has been overseen using a running proline suture 3/0. The sleeve had been routinely fixed to the left crus to prevent pouch migration into the chest and to decrease the reflux.

When the duodenojejunal (DJ) junction is identified, a point 200–250 cm from the DJ had been measured. The intestinal loop had been brought up to the gastric sleeve without dividing the greater omentum and had been fixed with a stay suture to the sleeved stomach at the pyloric ring. A stapled isoperistaltic side-to-side anastomosis had been performed using a forty-five linear cutting stapler at the dissected inferior side of the pylorus. The defect of the gastro-jejunal anastomosis had been closed with a two-layer running suture, and a methylene blue test had been performed to assess for the presence of leaks.

Early ambulation and clear fluids had been started 6 h after surgery. Thrombosis prophylaxis had been continued for 2 weeks, and proton pump inhibitors has been administrated for 4 months postoperatively.

Follow-up:

All patients have been seen in the outpatient clinic weekly for 1, 3,6 and 12 months followed by every 6 months in the second year, and every 6 months in the third year. Patients have been also seen in the clinic if they developed symptoms between their follow-up visits. The minimal follow-up period will be 2 years after the SASJ bypass.

The patients will be evaluated with regard to weight loss and improvement in comorbidities. All patients have been continued on a liquid diet for 2 weeks, followed

by a soft diet in the next week. Subsequently, patients have been put on a high protein, low-calorie diet. Other elements will be introduced sequentially under dietitian supervision. high concentration multivitamin supplements had been prescribed to all patients to be taken regularly for two years then gradually withdrawn, ending with taking only Centrum® in the third year.

Complete blood count including liver function, complete blood panel, HBA1c, fasting blood sugar, serum albumin, serum iron, and serum vitamin D have been performed every three months. The specific investigations have been performed on request according to the patient clinical condition. In addition, any early or delayed complications will be recorded.

The clinical outcomes

I. Primary outcome (weight loss outcomes):

- **Percentage of excess weight loss (%EWL),** which is calculated as follows: $\frac{\text{(preoperative weight – follow up weight)}}{\text{preoperative excess weight}} \times 100$
- **Percentage of total weight loss (%TWL)**, which is calculated as follows: $\frac{\text{(preoperative weight – follow up weight)}}{\text{preoperative weight}} \times 100$

II. Secondary outcomes:

- Comorbidity resolution which will be categorized as remission, improvement, no change, relapse, and worsen.
- Early (within 30 days of the procedure) and late (after 30 days from the procedure).
- Rate of the readmission and reoperation.

– Statistical analysis:

Statistical analysis will be done by SPSS v26 (IBM Inc., Chicago, IL, USA). Shapiro-Wilks test and histograms will be used to evaluate the normality of the distribution of data. Quantitative parametric data will be presented as mean and standard deviation (SD). Quantitative non-parametric data will be presented as median and interquartile range (IQR). Qualitative variables will be presented as frequency (%).

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