Research Proposal

Title: **Laparoscopic sleeve gastrectomy**

Three versus six centimeter distance from the pylorus A prospective randomized study

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Contents

Abstract ……2
1. Introduction……2
2. Study and objectives……..4
3. Patient and method……4
4. Results and outcome……5
References……5

Abstract

Obesity is a major worldwide problem in public health, reaching epidemic proportions in many countries, especially in urbanized regions. Bariatric procedures have been shown to be effective in the management of morbid obesity, compared to medical treatments in terms of weight loss and its sustainability. One of the most commonly performed procedures is laparoscopic sleeve gastrectomy (LSG). The main objectives of this research are directly related to evaluation the outcome of two different LSG techniques, three and six cm distance from pylorus regarding clinical, radiological and endoscopic within a long term follow-up after the discharge for one year. Results will be compared as regard the experimental and clinical data of both groups.

1. Introduction

Obesity is an increasingly serious public health problem on a global level and associated with increased mortality and a high burden of obesity related morbidities, For the purpose of our study we used Garrow's grading of obesity based on the BMI which is weight in kg \ height in m^2 (normal: 20-24.9 kg\$m^2$), overweight (25-29.9 kg\$m^2$), obese (30-40 kg\$m^2$)، morbidly obese (>40 kg\$m^2$) and super-obese (> 50kg kg\$m^2$) (1).

Sleeve gastrectomy is a surgical approach for treatment of morbid obesity. This procedure was first applied to the treatment of super-obese patients (those with both a BMI and an age over 55) in 1993 (2). The introduction of Laparoscopic sleeve gastrectomy (LSG) as a part of the duodenal switch procedure was first carried out at Mount Sinai Hospital in New York in 1999 (3), and some years later it become the first step in gastric bypass surgery as an alternative for decreasing morbidity and mortality in high-risk obese patients (4).

LSG is a restrictive procedure which removes the greater curvature and leaves a small gastric tube. This procedure has recently been validated as an isolated bariatric procedure (5). Previous studies have shown that LSG beside its restrictive effect, it has an accelerated gastric emptying effect and hormonal effects; it reduces the level of ghrelin, an appetite-stimulating hormone (6, 7, 8), by eliminating the gastric fundus, producing early satiety (9, 10, 11). However, there are many points of controversy regarding the procedure creating a range of possibilities without consensus: the size of the bougie used as calibrator, the distance from the pylorus to the first line of section, the section shape at the gastroesophageal junction, the necessity and options available for reinforcing the staple line and the routine use of intraoperative seal testing. All of these are issues that are constantly debated among the most experienced surgeons (12).

A controversial point, which is related to the fore mentioned discussion, is the distance from the pylorus at which gastric division begins. The most conservative surgeons prefer to perform the section at more than 4 cm from the pylorus with the aim of improving gastric emptying and thus decreasing intraluminal pressure. In contrast, other surgeons support sectioning close to the pylorus on the grounds that the technique is purely restrictive, and therefore, greater tubularization will achieve better results (13-14). Other surgeons begin the resection at 6–7 cm from the pylorus in order to preserve the gastric antrum and theoretically preserve its contractile function, promoting gastric emptying (15–17). Few studies have looked at starting stapler line whether 3 or 6 cm distance from pylorus and its outcome (15–17). On this study we will compare between two different technique of LSG regarding beginning of the stapler line 3 or 6 cm distance from pylorus.
A number of studies have been published using bariatric surgery-specific quality of life instruments including: the Swedish Obese Subjects (SOS), Quality of Life Survey, the Bariatric Analysis and Reporting Outcome System (BAROS) and the Bariatric Quality of Life (BQL) (18).

2. Study and objectives

A Prospective randomized study to evaluate the outcome of two different LSG techniques, three and six cm distance from pylorus within one year regarding clinical, radiological, and endoscopic.

3. Patient and Method

A prospective randomized study of patients with morbid obesity BMI > 40 kg\m^2 and BMI > 35 kg\m^2 with co-morbidity in the department of general surgery at Mansoura university.

- **The Inclusion criteria for this study are**:

1. Morbid obesity BMI > 40kg/m^2.
2. Morbid obesity BMI > 35kg/m^2 with comorbidity.

- **The exclusion criteria for this study are**:

1. Morbid obesity with cardiovascular disease or respiratory disease unfit for surgery.
2. Morbid obesity with hypothyroidism.

Preoperative data:

BMI, co-morbidity, upper GIT endoscopy, thyroid profile, serum cortisol level, pulmonary function test, and imaging study in the form of abdominal ultrasonography.

Operative details:

1. With the patient in a modified lithotomy position, the camera port is introduced via a visualizing trocar. In total, 4–5 trocars are inserted in the upper abdomen.
2. The greater curvature vessels are divided 3cm proximal to the pylorus. Dissection is performed until the complete mobilization of the gastric fundus and the visualization of the angle of His and the left crura.
3. A 38 F bougie is inserted transorally and advanced to the pylorus.
4. The stomach is transected along the bougie with the use of a laparoscopic stapler.
5. The bougie is removed, and the staple line is examined for leakage by the instillation of methylene blue through a nasogastric tube.
6. In cases of intraoperative hemorrhage, the staple line is reinforced either with the application of intermittent 10 mm clips or with a continuous 3/0 absorbable suture and the leakage test is performed afterward.
7. The stomach is then resected and sent for histopathology.
8. In our randomized study we compare distance of starting stapler line from pylorus 3 or 6 cm during the technique of LSG.
9. Data collected intraoperative, time of operation, blood loss and the need for blood transfusion in the two groups:
    - Group (A) starting stapler line 6 cm distance from pylorus.

- Group (B) starting stapler line 3 cm distance from pylorus.

10. The randomization will be done by closed envelope method and will be withdrawn by a nurse in the operative theatre after the dissection step in the two groups.

Postoperative period:

The two group patient will be evaluated in follow up visits in out-patient clinic for any upper gastrointestinal symptoms (Heart burn, regurgitation and vomiting) and BMI every month for 1 year. Postoperative complications such as gastric leak, peritonitis and abdominal bleeding will be recorded. The quality of life will be evaluated by using the Bariatric Analysis and Reporting Outcome System (BAROS).

The two group patients will be evaluated early post operative radiologically by abdominal US and by esophago-gastroscopy at 3 and 6 months post operative.

5. Outcomes and Impact

Results derived from this study would provide useful information to surgeons who are interested in bariatric surgery in general, and laparoscopic sleeve gastrectomy (LSG) in special, the clinical and experimental data of both groups.

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