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The effect of stoma size on the midterm weight loss outcome of single anastomosis gastric bypass (SAGB): A double-blinded prospective randomized trial

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Abstract: Background: Single anastomosis gastric bypass (SAGB) is gaining a wide spread acceptance among bariatric surgeons all over the world because of technical simplicity and documented efficacy. Till now the relation between stoma size in SAGB and weight loss outcome had not been addressed. Objectives: To evaluate the effect of stoma size on the mid-term weight loss outcome for obese patients underwent SAGB. **Materials and Methods**: This is a double-blinded prospectively randomized trial. From March 2014 to September 2016, morbidly obese patients who were submitted for SAGB were included in the study. SAGB was performed according to the known technical procedures, with the exception of for the size of the GJ. Patients were divided randomly into two equal group; narrow GJ group (30 mm) and wide GJ group (45mm). After procedure the percentage of excess weight loss (%EWL) was estimated at a period of 6, 12 and 24 months. **Results:** Eighty three patients were eligible for enrollment in the study. They were randomly classified into 2 groups; narrow GJ group (n = 42) and wide GJ group (n = 41). The mean ages were 32 and 39.4 years, and there were 32 and 34 females in the narrow GJ and wide GJ groups, respectively. The decline in the BMI was greater in the narrow GJ group at 6 months follow up, while, generally, over time the two groups had significant decline of BMI. At 12 and 24 months the %EWL difference between the two groups disappeared. **Conclusion:** The size of GJ at SAGB has no significant impact on weight loss at mid-term follow up.

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Keywords: Obesity, single anastomosis gastric bypass, gastrojejunostomy size.

1. Introduction

It is now out of discussion that bariatric surgery is a durable and effective therapy regimen for sever obesity. Bariatric surgery is not merely accompanied with an efficient method for reducing body weight a long-term in addition to reduces overall obesity-linked mortality and enhances quality of life. [1-4]. A myriad of bariatric methods has been used, for each of these methods their owning its disadvantages and advantages. Rutlege was the first to describe the procedure and termed it 'mini-gastric bypass'. [5] Many termed were used to describe the procedure such as mini-gastric bypass (MGB), single anastomosis gastric bypass (SAGB), one anastomosis gastric bypass (OAGB), and others. SAGB was proved to be safe and rapid procedure, which have become the second most common of the bypass operations, and is increasing internationally. SAGB is associated with superior resolution of co-morbidities, good quality of life, and durable weight loss [6]. Lately, IFSO has accepted SAGB as a mainstream bariatric/metabolic method. [7]

The construction of gastrojejunostomy (GJ) of the SAGB is a critical part of the procedure. There is no general agreement some technical details of GJ such as the method of GJ construction (linear stapler vs hand sewn) and the use of hanging stitch to reduce the risk of biliary reflux. More importantly, the size of GJ is not standardized and the optimal GJ widthstills not familiar and up to now, there is no well standard parameters for comparison with dissimilar lengths of linear-stapler method in SAGB with respect to weight loss outcome. The purpose from the current work is to assess the impact of GJ size in the mid-term SAGB weight loss results.

2. Patients and methods

This is a double-blinded prospective randomized trial that was conducted on morbidly obese patients submitted for SAGB in the period between March 2014 and September 2016. The study was conducted

in Gastrointestinal Surgery Center (GISC), Mansoura University and Ein Shams University Hospital. Local institutional review board (IRB) endorsement was obtained before the start of the work and all participating patients signed a knowledgeable informed consent. Preoperative preparation, comprising clinical and multidisciplinary and anesthetic assessements were performed on all participating subjects. Cardio-pulmonary function assessment, abdominal ultrasound, upper GI endoscopy and routine laboratory tests were ordered for all patients. the same dietary instructions were given for all subjects during pre- and post-operation in order to mitigate their effect on weight loss outcome.

Study population

The study included morbidly obese patients aged between 18 and 65 years with body mass index (BMI) of over 35 kg/m^2 associated with at least one co-morbidity factors or over 40 kg/m^2. Patients were excluded from the trial when unwilling to have SAGB or refusing to participate, patients with previous upper GI procedures, patients admitted for revisional bariatric surgeries, or patients who the follow up did not complete the 2-year.

A standard preoperative preparation, such as clinical and multidisciplinary assessments were performed for all participating patients. Cardio-pulmonary function assessment, abdominal ultrasound, Gastroscopy, and general laboratory examinations were done in every chosen morbid obese subject.

Surgical technique

All patients were operated by the two authors using a standardized technique. A long narrow gastric tube using endo-GIA stapler with 60 mm long blue reloads (Medtronic, USA) was created and calibrated a 36 Frbougie. The limb length varied according to the preoperative BMI. For superobese subjects (BMI of 50 kg/m2 or more) the limb length as measured from ligament of Treitz was 200 cm, otherwise we utilized a limb length of 150 cm only. GJ was done using 60 mm long blue cartridge of linear staplers (Endo-GIA, Medtronic). Participating patients were divided into two groups depending on the size of the GJ; wide GJ group (45 mm) and narrow GJ group (30 mm). After full insertion of the 60 mm blue reload into the jejunum and the gastric tube, the narrow GJ of 30 mm was made by using two squeezes of the stapler, as each squeeze gives 15 mm. Three squeezes were needed to create a wide GJ of 45 mm. The stapler aperture was closed with a single layer of 3-0 absorbable running suture from either angle to join each other in the middle of the anastomosis. At the end of the procedure, the anastomosis integrity was examined by methylene blue injection.

Randomization

Randomization was accomplished by drawing a numbered card by a nursing staff not otherwise involved in the study. Card drawing was done after anesthesia had been induced. All subjects have still blinded to the stapler size all over the procedures. At the same time, surgeons seeing patients at the follow up visits were not those involved in the surgery and were prevented from looking at the operative report when seeing patients at follow up.

Follow up

At the end of all steps, the patients were observed for a periods of 1, 3, 6, 9, 12, 18, and 24 months, in the same time both the BMI and reduction in the weight were determined. In addition, the side effects and complications of the GJ such as stenosis, ulcer and hemorrhages were recorded also.

Statistical analysis

SPSS (College Station, TX, USA) software was used for estimation of statistical analysis. weights were measured by kilograms, while the height was determined by meters during calculation. Dichotomous variables such as gender (male vs. female) and surgical approach (narrow vs. wide). Weight, initial weight, height, initial body mass index (BMI), age, follow-up time and percentage of excess weight lost (%EWL were continuous variables. %EWL was determined at 6, 12 and 24 months post surgical operation. For comparison of %EWL between groups, an independent samples Student's t test was applied. P value less than 0.05, was considered significant.

3. Results

The work comprised 86 consecutive morbidly obese patients. We lost contact with three patients and they were excluded. The remaining 83 patients were randomly divided into two groups; the narrow GJ (30 mm) group which included 43 patients and the wide GJ (45 mm) group which included 42 patients. A non statistically significant variations were detected between the two groups concerning total number, gender, age, preoperative body weight or BMI. [Table 1]

Both groups postoperatively had significant decrease in BMI during statistical analysis of the obtained raw results (ANOVA time factor—$p < 0.001$). Post 6 months in favor of the narrow group, the weight loss demonstrated a significant difference statistically, however, this difference disappears at 12 and 24 months. [Table 2] Fortunately enough, there were no recorded complications or mortality and all procedures were completed laparoscopically.

Table 1. Demographic data, body weight, BMI of the two groups.

	Narrow GJ	Wide GJ	P value
Number of patients included	42	41	NS
Age in years (mean ± SD (range))	32 ± 11.5 (23-62)	39.4 ± 10.3 (26-58)	NS
Gender (F/M)	32/12	34/7	NS
Weight in kg at operation (mean ± SD (range))	118 ± 12.7 (105-176)	109 ± 10.5 (103-186)	NS
BMI in kg/m2 at operation (mean ± SD (range))	43.6 ± 7.2 (36.3-59)	44.2 ± 9.3 (35.6-63.2)	NS

Table 2. Preoperative BMI and %EWL at 6, 12 and 24 months in the two groups.

	Narrow GJ	Wide GJ	P value
Preoperative BMI	43.6 ± 7.2 (36.3-59)	44.2 ± 9.3 (35.6-63.2)	NS
% EWL			
6 months	53 ± 10.3 (46-58)	42 ± 7.5 (39-56)	<0.05
12 months	67 ± 8.4 (54-69)	64 ± 9.4 (52-71)	NS
24 months	74 ± 11.8 (67-88)	75 ± 12.7 (66-85)	NS

4. Discussion

Despite too much controversies, SAGB is gaining a wide scale popularity among bariatric surgeons world-wide. This may be attributable to its simplicity linked with a effectiveness and simplicity of amendment and turnaround and shorter learning curve [8, 9]. In a recent meta-analysis reporting the cumulative results of 12,807 SAGB procedures the authors concluded that there is a great confirmation supporting the proposal to consider SAGB as a mainstream bariatric method. [10]

Unfortunately, there is no a single standard technique for SAGB. There are a great variations among SAGB surgeons such as; the bougie size used for calibration of the gastric tube (varies from 28 Fr up to 42 Fr), limb length (varies from 150 cm to 300 cm as measured from ligament of Treitz), the use of the hanging antireflux suture, and the method of gastrojejunostomy formation (hand sewn, stapling, lineal stapler with hand sewn closure of the aperture). The size of gastrojejunostomy, which is our point of interest is not exempt. There is no general agreement about the size of GJ in SAGB. Many surgeons make the stoma 45 mm [11-20], others prefer it to be as larger as 60 mm [19, 21, 22] or as small as 30 mm. [19, 23]

Unlike RYGB, many SAGB surgeons see the procedure a malabsorptive rather than a restrictive one. GJ in SAGB differs in its goals and formation than in RYGB. [5] Since RYGB is mainly a restrictive procedure, GJ should be restrictive and obstructive. But this usually results in what is called “pathologic eating”, which means that the patient becomes intolerant to bulky healthy food and therefore she is forced to eat sweets and greasy food, and this may end in weight regain. On the other hand, in SAGB the gastrojejunostomy should be restrictive but non-obstructive. In this way, there will be rapid transit of food from the gastric tube to the jejunum resulting in what is called “post-gastrectomy eating” which means intolerance to sweets and greasy food with good tolerance to bulky low calorie foods. Therefore, they recommend constructing a wide stoma. [5]

To the best of our knowledge, this is the first randomized blinded research to assess the impact of GJ anastomotic size on weight loss outcome after SAGB. Based on our results, we concluded that the size of GJ, whether 30 mm or 45 mm, did not induce a significant impact on the %EWL practiced by the obese patient. In our results the %EWL was significantly greater in the narrow group at 6 months follow up but this difference dissolves at 12 and 24 months. This could be due to loss of restriction over time.

There were some limitations in this study that needs to be addressed by future trails. The total number of patients eligible for enrollment in this study was 83 patients, which is definitely a small sample size. Additionally, the study recorded the mid-term outcome (2 years follow up). Some issues were not discussed such as the quality of life and the risk of biliary reflux.

Conflict of interest:

The author declares that no conflict of interest among the authors.

Informed consent was obtained from all individual participants included in the study."

Ethical consideration:

All procedures performed in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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