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## Annals of Medicine and Surgery

journal homepage: www.elsevier.com/locate/amsu



#### Cohort Study

# Oversewing staple line of the gastric remnant in gastric bypass reduces postoperative bleeding

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#### ARTICLE INFO

# Keywords: Oversewing Gastric remnant Bleeding Gastric bypass One anastomosis gastric bypass Obesity

#### ABSTRACT

*Background:* Roux-en-Y gastric bypass (RYGB) is a surgery with low rate complications. However, it is not exempt from them, and 1–6% suffer complications such as postoperative bleeding. Many intraoperative techniques have been evaluated to reduce postoperative bleeding, like the oversewing or reinforcement of the staple line. This study aims to evaluate the rate of postoperative bleeding in the oversewing of the staple line of the gastric remnant group versus the stapling only group.

Methods: This is a 2-center, case-control study. We randomly selected two groups who underwent RYGB or OAGB: group A (n=225) with oversewing from 2019 to 2020 and group B (n=225) with stapling only between the period of 2017–2018; both groups with similar demographic characteristics.

Results: The overall mean age was  $37.39 \pm 9.6$  years and mean BMI was  $41.59 \pm 8.6$  kg/m2; the postoperative bleeding rate was significantly lower (p < 0,05) in patients with oversewing of the staple line of the gastric remnant. Operative time was shorter for the stapling only group and the difference between the mean operative time was 10.6 min.

*Conclusions*: Oversewing the staple line of the gastric remnant significantly reduces the incidence of postoperative bleeding regardless of BMI. Being a cost-effective technique compared to others available despite the increase in operating time.

#### 1. Introduction

Obesity is one of the most prevalent diseases worldwide and also a major risk factor for cardiovascular disease, diabetes, cerebrovascular disease, and cancer. In 2017, Afshin et al. reported that 603.7 million people worldwide were obese, a number that has been increasing in more than 70 countries since 1985 [1]. Thus, obesity represents an economic burden to public health around the world.

New advances in the surgical area have brought benefits for bariatric surgery since the introduction of minimally invasive surgery in 1985 [2]. RYGB complication rates have decreased to 1–6% [3]; rates similar to surgeries such as appendentomy or cholecystectomy. In the small percentage of complications that this surgery entails, post-operative bleeding occupies an important place among others. Postoperative bleeding could be located in the gastrojejunal anastomosis, jejunojejunal anastomosis, or in the staple line of the gastric remnant; with the latter one being the most frequent site of intra-abdominal bleeding [4].

Over the years, different ways to prevent postoperative bleeding have been studied using different types of techniques [5]. The oversewing of the staple line has been described as a technique to reduce postoperative bleeding in the gastric sleeve [6]. On the other hand, clinical studies report controversial results on the benefit of oversewing the staple line in RYGB [7]. Our objective is to evaluate the rate of postoperative bleeding in the oversewing of the staple line of the gastric remnant group versus the stapling only group.

### 2. Materials and methods

#### 2.1. Design

This case-control study was conducted in the International Unit of Bariatric and Metabolic Surgery of "Clinica La Sagrada Familia" located in Maracaibo, Venezuela, and in "Grupo Medico Santa Paula" Caracas, Venezuela. All procedures were performed by a single experienced

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https://doi.org/10.1016/j.amsu.2021.102534

Received 11 May 2021; Received in revised form 27 June 2021; Accepted 1 July 2021 Available online 2 July 2021

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bariatric surgeon during the period 2017–2020. The Ethics committees of Clinica "La Sagrada Familia" and "Grupo Medico Santa Paula" approved this study. The study protocol has been registered in National Institute of Health database (NCT04884230). We selected 225 patients (group A) from the period 2019–2020 where the stapling line of the gastric remnant was oversewn and another group of 225 patients (group B) from the period of 2017–2018 with stapling alone. The work has also been reported in line with the STROCSS criteria [8].

Our inclusion criteria were patients older than 18 years, body mass index (BMI)  $> 30 \text{ kg/m}^2$  with or without comorbidities that underwent RYGB or one anastomosis gastric bypass (OAGB). We exclude from our study any patient with psychiatric disorder, open surgery history, history of previous bariatric surgery, non-controlled comorbidity at the moment of surgery, and patients under the age of 18. Each patient is evaluated by a multidisciplinary team of bariatric surgeons, cardiologists, internists, neumonologists, endocrinologists, radiologists, nutritionists, and psychologists.

Preoperative patient characteristics (age, gender, and body mass index); operative details (total surgical time, oversewing time; and postoperative adverse events, including post-operative bleeding (melena, administration of blood transfusions), reintervention and mortality, were recorded by the surgical team. As previously mentioned, postoperative bleeding was assessed by taking into account the amount of melenas, which was marked as an important episode of intraluminal bleeding if the stool was greater than 100 ml. Another point we also collected, was the need to administer blood transfusions in case of bleeding episodes where the hemoglobin dropped below 10 g/dL and was accompanied by clinical manifestations of compromised hemodynamic status. Any other cause of bleeding was ruled out by clinical and diagnostic studies.

#### 2.2. Operative technique

The surgical technique used was Roux-en-Y gastric bypass with a 150-cm biliopancreatic limb and a 100-cm alimentary limb, and a 30-mL gastric pouch. For one anastomosis gastric bypass, the gastrojejunal anastomosis is made at 200-cm. All patients left the operating room wearing an abdominal drain (Blake 19F; Ethicon), which was left in place up to the third postoperative day before the patient was discharged. For stapling, we use an automatic linear stapler, using a blue 45 mm cartridge for the horizontal fire and two blue 60 mm vertical cartridge for the pouch. We performed a 25 mm gastrojejunal anastomosis with a blue cartridge and a jejunojejunal anastomosis with a 45 mm Gy cartridge. The oversewing of the staple line is performed with continuous stiches with unabsorbable 2.0 polypropylene monofilament suture for group A (n = 225) on the gastric remnant. Group B (n = 225) was left with stapling alone, no reinforcement method was used.

#### 2.3. Statistical analysis

All statistical tests were carried out by using the SPSS 25 version for macOS. Descriptive analysis of our categorical and numerical data was performed. Posteriorly using parametric test (unpaired t-student) for comparing baseline data of both groups and nonparametric test ( $\mathbf{X}^2$  or Chi-square) to compare our categorical data. Data were presented by mean  $\pm$  standard deviation (SD), percentage, and confidence interval when appropriate. Statistical significance was set at p < 0.05. Significance values with a confidence limit higher than 5% as p > 0.05 were not reported.

#### 3. Results

Of the 450 patients who were included in this study, the RYGB and OAGB was successfully performed in all patients without conversion to open surgery and no mortality. Among the descriptive characteristics (Table 1) of our subjects, 60.7% were women (n = 273) and 39.3% were

 Table 1

 Comparison between baseline data of both groups.

	Oversewing Group A	Non-Oversewing	p- value
		Group B	
Sex			
M	83 (36.9%)	92 (40.8%)	
F	142 (63.1%)	133 (59.1%)	
Age	37.8 (95% CI, 35.4-40.1)	37.1 (95% CI, 35.9-38.4)	
Surgery			
BGYR	192 (85.3%)	175 (77.8)	< 0.05
OAGB	33 (14.7%)	50 (22.2%)	
BMI	42.1 (95% CI, 40.8-43.4)	41 (95% CI, 40-41.9)	
Classification			
Obesity I	45 (20%)	39 (17.3%)	
Obesity II	59 (26.2%)	81 (36%)	
Obesity III	80 (35,5%)	79 (35.1%)	
Super	28 (12.4%)	20 (8.8%)	
obesity			
Super S-O	13 (5.7%)	6 (2.6%)	

men (n = 177). 100% of our patients of both groups were Hispanic/Latino. The overall mean age was 37.39  $\pm$  9.6 years. The mean preoperative BMI was 41.59  $\pm$  8.6 kg/m² and the mean operative time from the entire population was 88.03 min.

For group A of patients with oversewing of the staple line of the gastric remnant, the mean oversewing time was 6.6 min (95% CI, 6.4–6.8) and the mean operative time was 93.31 min (95% CI, 90.4–96.1). The percentage of melena reported in this group was 2.2% (n = 5) and the administration of blood transfusions was only required in 2 patients.

In group B of patients with no reinforcement of the staple line, the mean operative time was 82.7 min (95% CI, 78.8–86.6). The percentage of melena was 10.7% (n=24), of which 25% (n=6) merit blood transfusions (Table 2).

Using the previously mentioned statistical test to determine if there is a statistical significance between groups. The postoperative bleeding rate was significantly lower  $p<0,05\ (p=0,0002)$  in patients who had their gastric remnant stapled line oversewn. Also, another interesting result we have to mention and need further research is that we found a significant statistical difference between the postoperative bleeding rate and the surgical technique used when statistical analysis was performed.

#### 4. Discussion

In this 2-center case-control study, postoperative bleeding rate was significantly lower in patients who underwent RYGB and OAGB with oversewing of the staple line of the gastric remnant compared with patients with stapling alone. These results are similar compared with reports of a reduced rate of staple-line failures in LGS with different types of reinforcement of the staple line [9].

**Table 2** Surgical outcomes.

	Oversewing Group A	Non-Oversewing Group B	p- value
Melena			
Yes	5 (2.2%)	24 (10.7%)	< 0.05
No	220 (97.8)	201 (89.3%)	
Blood transfusion			
Yes	2 (0.9%)	6 (2.7%)	< 0.05
No	223 (99.1%)	219 (97.3%)	
Operative time	93.3 (95% CI,	82.7 (95% CI,	
	90.4-96.1)	78.8-86.6)	
Oversewing time	6.6 (95% CI, 6.4–6.8)		< 0.05

According to the review of articles in known search engines, to this date, there is no actual research with a considerable sample of patients in which the oversewing is performed, and even more, specifying the site of the oversewing of the staple line in this case the gastric remnant compared to a control group in which it was not performed.

In this case-control study, a significant decrease in the incidence of melena and administration of blood transfusions was obtained in the group in which the remnant was oversewn. Similar and even lesser results compared with the results published by Shikora et al. [10]. Despite having other reinforcement methods, absorbable suture represents an important alternative, lowering the costs of surgery and preventing bleeding.

Comparing the manual oversewing of the staple line of the gastric remnant with other techniques of reinforcement with permanent and non-permanent materials. This study reports a lowers bleeding rate (2.2%) in the manually oversewn group than reinforcement with Peristrips Dry (PSDs), Seamguards (SGs), and PSD Veritas (PSDV) are respectively 4.6%, 2.6%, and 5.8% respectively [11].

The feasibility of the technique of oversewing the remnant stapling line is also discussed. The average duration of the manual oversewing was 6.6 min and in this study only represents a difference of 10 min in the mean surgical time between the two groups. Therefore, the oversewing of the staple line of the gastric remnant represents a safe, viable, and cost-effective technique in the hand of an experienced surgeon.

Among the limitations of this study, the main one was the incapacity to compare the manual oversewing between other reinforcement methods due to the cost that represents. More studies are needed to establish if the oversewing of the staple line should be a regular practice in bariatric teams.

#### 5. Conclusions

In conclusion, Roux-en-Y gastric bypass is still a safe technique to perform to achieve weight loss. Oversewing of the staple line of the gastric remnant during RYGB and OAGB is an easy cost-effective method to decrease the incidence and severity of the postoperative bleeding; even though it increases the operating time.

#### **Funding information**

No funding was received for this study.

#### Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The Ethics committees of Centro Clinico "La Sagrada Familia" and "Grupo Medico Santa Paula" approved this study.

#### Provenance and peer review

Not commissioned, externally peer reviewed.

#### Consent

Informed consent was obtained from the patient for publication of this case report and accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request

#### **Author contribution**

Borjas, Guillermo M.D: study concept, design, data collection, data analysis, data interpretation, patient management, and writing the paper.

González, María M.D: study concept, design, data collection, data analysis, data interpretation, and writing the paper.

Maldonado, Andres M.D: study concept, design, data collection, data analysis, data interpretation, and writing the paper.

Urdaneta, Ali M.D: study concept, design, data collection, data analysis, data interpretation, and writing the paper.

Ramos, Eduardo M.D: study concept, design, data collection, data analysis, data interpretation, and writing the paper.

#### Registration of research studies

NCT04884230

https://www.clinicaltrials.gov/ct2/show/NCT04884230

#### Guarantor

Dr. Guillermo Borjas.

#### Declaration of competing interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publications of this article.

#### Appendix A. Supplementary data

Supplementary data to this article can be found online at  $\frac{\text{https:}}{\text{doi.}}$  org/10.1016/j.amsu.2021.102534.

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