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POUCH SIZE AND ITS ROLE IN MARGINAL ULCERATION FOLLOWING ROUX-EN-Y GASTRIC BYPASS SURGERY: A PROSPECTIVE STUDY OF ONE YEAR

Mushtaq Ahmad[1], Waqar Ahmad[2*], Maria Alamgir[3], Abdul Haseeb Sahibzada[4]

[1]Assistant Professor, International Metabolic and Bariatric Weight loss surgical center, Afridi Medical Complex,Peshawar, Pakistan
[2*]Assistant Professor, Department of Anatomy, Khyber Girls Medical College,Peshawar,Pakistan
[3] Clinical Psychologist, International Metabolic and Bariatric Weight loss surgical center, Afridi Medical Complex,Peshawar, Pakistan
[4] Research Officer, International Metabolic and Bariatric Weight loss surgical center, Afridi Medical Complex,Peshawar, Pakistan

***Corresponding Author:** Dr Waqar Ahmad
*Assistant Professor, Department of Anatomy, Khyber Girls Medical College,Peshawar,Pakistan, Email: dr.waqar84@gmail.com

Abstract:
Background: A well-known complication of RYGB is formation of marginal or stomal ulcers in the proximal Roux limb's jejunal mucosa. Larger pouches have more parietal cell mass, which produces acid, increasing the risk of ulcer development and acidity levels. The purpose of this study was to determine if pouch size had an effect on surgical outcomes in terms of formation of marginal ulcers.
Methods: This prospective observational study was carried out from January 2022 to January 2023. The patients undergoing Roux-en-Y gastric bypass (RYGB) were included in the study. Initial clinical examination and upper gastrointestinal endoscopy was used to confirm the diagnosis of marginal ulcer formation.A pouch size falling between the range of 1 to 4 cm was categorized as small pouch while those greater than 4cm contained large pouch sizes. The Chi square test was used to determine the association.
Results: A total of 135 patients performed Roux-en-Y gastric bypass surgery within the course of a year. Eighty-four patients (62%) underwent surgery using a small pouch (less than 4cm), while 51 patients (38%) underwent surgery using a large pouch (greater than 4cm). A total of 8 patients experienced marginal ulcer development over the one-year follow-up period.
Conclusion: This study concluded that although patients with larger pouches had a higher frequency of marginal ulcers, but the association was not statistically significant. Certain factors such as age, smoking status, and postoperative NSAID use, are also associated with the development of ulcers demonstrating the complex nature of ulcer pathophysiology.

Key Words: Gastric Bypass, Marginal Ulceration, Pouch Size, Roux-en-Y, Ulcer Risk Factors

INTRODUCTION:

The prevalence of obesity and its associated complications are increasing worldwide. Bariatric surgery is now considered as the most effective way to lose weight and maintain it over the long

term when the conservative methods have failed [1-2]. The most popular bariatric procedure performed globally is the Roux-en-Y gastric bypass (RYGB). The proximal jejunum is anastomosed to a tiny, fully isolated gastric pouch created during this procedure. Currently, LRYGB makes up about 49% of bariatric procedures and has been associated with a reasonable level of safety, with an acceptable 10% short-term morbidity and approximately 0.2% mortality [3-4]. RYGB, whether performed laparoscopically or openly, has been linked to improved surgical outcomes and minimal rates of complications [5, 6].

However, a well-known complication of RYGB is formation of marginal or stomal ulcers in the proximal Roux limb's jejunal mucosa. The reported incidence of marginal ulcers following RYGB varies from 0.5 to 16 % [7]. The most typical clinical signs include anemia from prolonged bleeding, vomiting, and epigastric pain. Acute bleeding and perforation are also reported occasionally [8]. Marginal ulcers pathophysiology is still debatable. The position and size of the gastric pouch (larger pouch, more acid output), the use of foreign suture material (non-absorbable suture material, staples), and tension at the anastomosis are hypothesized to have an impact on the development of Marginal ulcers [9]. While diabetes, smoking, the use of anticoagulants, and/or non-steroidal anti-inflammatory medicines (NSAIDs) are other factors that appear to be linked to development of marginal ulcers [10].

Although it has been suggested that larger pouches have more parietal cell mass, which produces acid, increasing the risk of ulcer development and acidity levels while a small pouch lowers the incidence of marginal ulcers, however the stomach pouch contains acid-producing parietal cells regardless of the size of pouch [11-12]. A retrospective study conducted in 2022 in China reported that compared to the small gastric pouch group, the large gastric pouch group had a substantially greater incidence of marginal ulcers (23.7% vs. 6.4%, P=0.023) [13]. For the past thirty years, there has been an ongoing controversy about the size of the gastric pouch. Numerous research on the postoperative effectiveness of various gastric pouch diameters has been conducted by researchers [14- 15].

The purpose of this study was to determine if pouch size had an effect on surgical outcomes in terms of formation of marginal ulcers.

Materials and Methods

This prospective observational study was carried out from January 2022 to January 2023 at the Afridi Medical Complex in Peshawar, with a one-year follow-up period. The hospital's institutional review board granted ethical approval. The informed consent was acquired from the individuals. The patients in the age range of 18 to 65 with the BMI of at least 40 kg/m² or 35 kg/m² in the case of comorbidities and who had never undergone an upper gastrointestinal surgery before were included in the study while those with Severe mental illnesses or having a history of drug or alcohol use were excluded.

Surgical Procedure

The patient was placed in the French position and given general anesthesia. The patient's weight determined where and how many of the five ports were positioned. 15 cm distal to the xiphoid process was where the first camera port (10 mm) was positioned. The surgeon's port (12 mm) was positioned 7 cm lateral to the camera port at the midclavicular line. The surgeon's port was positioned 7 cm above and laterally to the fourth port, an assistant port measuring 5 mm. Furthermore, a 5 mm nathanson liver retractor port was placed at the xiphoid process. Initially, a diagnostic laparoscopy was conducted.The last stappler's gastroesophygeal junction was then dissected. In some cases, a large pouch 6 cm (100 cc) distal to the gastroesophageal junction was formed, while in another, a small pouch 4 cm distal to the gastroesophageal junction generated a 60 cc pouch. A gastro-jejunastomy and jejeno-jejunostomy were carried out, and a 100-centimeter biliopancreatic limb was also removed.

Follow-up and Data Collection

Post operatively, the patients were examined on six and twelve months. Clinical evaluations were conducted at each appointment, and the following information was gathered:
• Demographic details: comorbidities, age, gender, and BMI.
• Surgical specifics: Intraoperative complications, size of pouch.
• Postoperative outcomes including the likelihood of marginal ulceration, ulceration symptoms such as nausea, vomiting, and epigastric discomfort), endoscopic findings, and the need for therapy. Based on clinical symptoms, an upper gastrointestinal endoscopy was used to confirm the diagnosis of marginal ulceration.

Statistical Analysis

Data analysis was conducted using SPSS Version 25.0. Continuous variables were expressed using the mean ± standard deviation, whereas categorical variables were expressed using frequencies and percentages.Using chi-square test, the incidence of marginal ulceration was compared between the small pouch and large pouch groups. P-values less than 0.05 were considered statistically significant.

Results:

Demographic/Patient Characteristics and Baseline Values

A total of 135 patients performed Roux-en-Y gastric bypass surgery within the course of a year. The patients ranged in age from 22 to 65 years old, with a mean age of 42.3 ± 10.5 years. The sample was comprised of 55 male (41%), and 80 females (59%). The mean BMI reported was 44.2 ± 5.8 kg/m². Comorbidities associated were: Type 2 diabetes mellitus in 51(38%) patients, hypertension 61(45%), and acid reflux disease 34(25%).The participants with current smoking status were 41(30%).Table 1 summarizes the patients' baseline values and demographic information

Table 1: Demographic and Patient Characteristics:

Variables	Frequency/Percentages/Mean
Total Patients undergoing RYGB	135
Small Pouch (<4cm)	84(62%)
Large Pouch (>4cm)	51(38%)
Mean Age (years)	42.3 ± 10.5
Age Range (years)	22-65
Gender	Male:55(41%) Female:80 (59%)
BMI (kg/m²)	44.2 ± 5.8
Comorbidities:	
Hypertension (%)	61(45%)
Type 2 Diabetes Mellitus (%)	51(38%)
Gastroesophageal Reflux Disease (%)	34(25%)
Smoking Status (Current Smokers)	41(30%)

Pouch Size used in RYGB procedure:

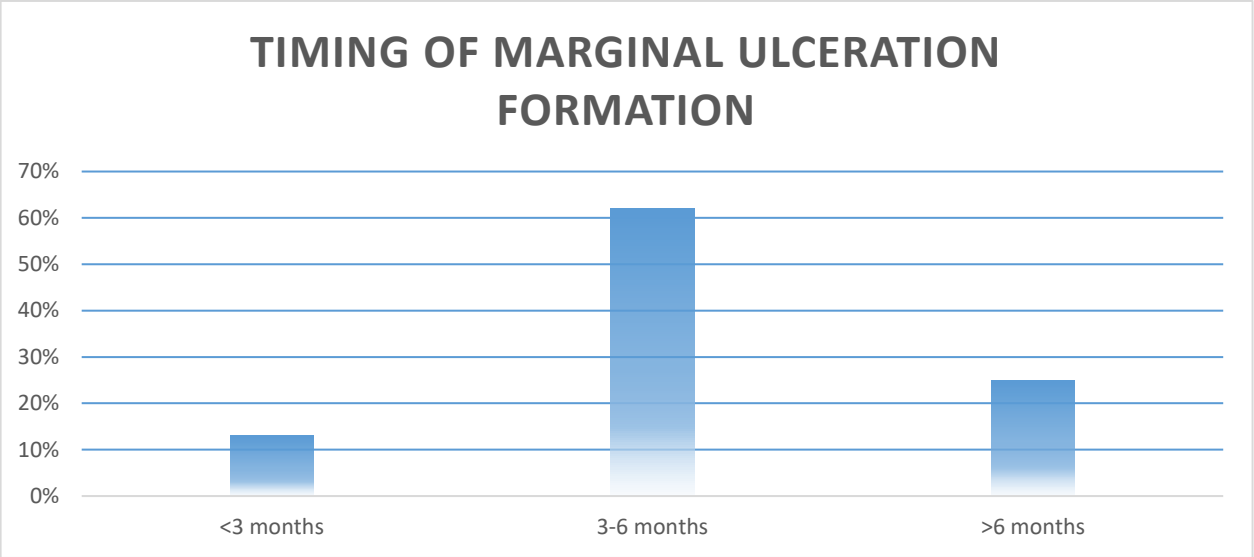
While undergoing RYGB procedure the mean pouch size was 6. The patients were divided into two groups according to the size of the pouch: 51 (38%) had a large pouch operation (more than 4 cm), whereas 84 (62%) had a small pouch operation (less than 4 cm).

Table 2: Pouch Size used in RYGB Procedure

Pouch Size (cm)	Frequency (Percentage)
Small pouch (<4cm)	84(62%)
Large pouch (>4cm)	51(38%)

Incidence of Marginal Ulceration:
A total of 8 patients experienced marginal ulcer development over the one-year follow-up period; as a result, the study cohort's total incidence rate was 6%. The incidence of ulcers varied in terms of timing of their development: 1 (13%) were found during the first three months following surgery, 5 (62%) occurred between three and six months, while 2 (25%) occurred beyond six months. Ulcers were primarily located at gastro-jejunal anastomosis site representing 5(65%) of total patients.

Table 3: Incidence and Timing of Marginal Ulceration



Pouch Size and development of Ulcers:
The statistical analysis showed that pouch size and the emergence of marginal ulcers were not significantly associated ($p > 0.05$) in our cohort of patients. Although, patients with larger pouch size developed more ulcers 5(4 %) as compared to smaller pouch size 3(2%).

Table 4: Pouch size and ulcer formation

Pouch Size	Frequency/Percentage of ulcers	P Value
Small (0-4cm)	3 (37%)	
Large (>4cm)	5 (63%)	0.07

Association between ulcer development and other variables:
Age ($p = 0.04$), smoking status ($p=0.015$]), and NSAID use after surgery ($p = 0.02$) were statistically associated with an elevated risk of ulcer formation. As a higher frequency of ulcers was found to be associated with older age, in current smokers and patients who used NSAIDs after surgery. In this study, there was no statistically significant correlation found between the development of ulcers and gender ($p = 0.15$) or diabetes ($p = 0.74$).

Discussion:
This prospective study aimed to examine the impact of gastric pouch size on the incidence of marginal ulceration (MU) after Roux-en-Y Gastric Bypass (RYGB) surgery. Our findings demonstrated no statistically significant association between pouch size and the development of MU during the first postoperative year, however patients with bigger pouches had a higher prevalence of ulcers.
In our study, the incidence of marginal ulcers (MU) after Roux-en-Y Gastric Bypass (RYGB) was 6% over a one-year period. This incidence rate is rather higher when compared to the study by Sacks et al., which found a 2.6% (28 out of 1,095) when non-absorbable suture was employed [16].

Conversely, our findings are more in line with those of Rasmussen et al. (2007), who observed a 7% incidence of MU following laparoscopic gastric bypass [17]. Variations in MU incidence across studies could be attributed to differences in postoperative care, such as the use of PPIs, as well as patient characteristics, including comorbidities and adherence to lifestyle changes. These variations highlight the significance of complete postoperative care in lowering the risk of MU.

Our study demonstrated no statistically significant association between gastric pouch size and the incidence of marginal ulceration (MU) after Roux-en-Y Gastric Bypass (RYGB) surgery ($p > 0.05$). While patients with bigger pouches had a slightly greater rate of ulcers (4%) than those with smaller pouches (2%), the difference was not statistically significant. These findings are in contrast to findings of the study conducted by Sullivan A. Ayuso and colleagues (2022), who found a significant increase in MU incidence in individuals with larger pouches, attributed to increased acid production and exposure at the anastomotic site. The results of their study reported that the MU group exhibited a bigger gastric pouch than the non-MU group (34.1 ± 11.8 versus 20.1 ± 6.8 cm3). When evaluated for matched patient cohorts, this difference continued for the MU group, which included smokers and PPI users [18]. Another study which used length of stapler as a measure of pouch size reported that the length of the stapler on the pouch predicted the chance of developing a marginal ulcer at both time points. Each centimetre of stapler in the pouch increased the incidence of marginal ulcer by 14% (95% CI 9-20%) [6]. However, the findings of our study are consistent with a study which observed no significant difference in pouch size between individuals with and without MU, measured by the number of staples [9]. These findings add to the ongoing discussion over the impact of pouch size on postoperative complications, implying that, while pouch size may play a role, it is not the only determinant of MU risk. Other characteristics, like as age, smoking status, and postoperative NSAID use, were shown to be more strongly linked with MU, demonstrating the complex nature of ulcer formation.

It is difficult to fully understand the etiology of MU. Although the precise cause is uncertain, a number of potential processes have been put forth. When parietal-cell-rich stomach regions are included in Billroth operations, the development of gastrojejunostomy (GJ) ulcers has been linked to the presence of extremely acidic gastric secretions. [19]. Antral stimulation and gastrin release diminish after RYGB because food bypasses the antrum. Nonetheless, the stomach mucosa can respond to vagal and hormonal stimuli and hence maintain an acidic environment [20]. Additionally, it has been demonstrated that the formation of a gastro-gastric fistula during RYGB lowers the pH of the gastric pouch. This occurs when gastric residual acid enters the pouch through the fistula and aids in the development of MU [21].

In our study, marginal ulcer (MU) formation occurred at various time frame throughout the one-year follow-up period. Our results showed that 1 (13%) were formed during the first three months following surgery, 5 (62%) occurred between three and six months, while 2 (25%) occurred beyond six months. This pattern is comparable with the findings of Dittrich et al. (2016), [5] who reported that the majority of MUs normally emerge within the first six months after RYGB. Ulcer development is frequently related to an immediate inflammatory response and increased acid production during the initial healing period following surgery. Ulcers that occur later may be influenced by variables such as persistent Helicobacter pylori infection, continued NSAID use, or poor adherence to proton pump inhibitor (PPI) therapy.

Our study found significant association between marginal ulcer (MU) formation and a number of factors, including age ($p = 0.04$), smoking status ($p = 0.015$), and postoperative NSAID use ($p = 0.02$). The use of NSAIDs after surgery was also substantially related with an increase in ulcer risk, consistent with their known ability to suppress prostaglandin synthesis, lowering mucosal protection. The findings are consistent with a study conducted to determine the risk factors for development of marginal ulcers post RYGB which demonstrated that by using Multivariable regression model ,the current long-term NSAID use was the most significant risk factor for MU with $p < 0.0001$ [22]. The findings of a systematic review and meta-analysis undergoing 14 studies also aligns with our study as smoking status was also a significant factor for ulcer formation. The

results of the systematic review and meta-analysis illustrated smoking to be an ulcer-inducing factor, as did previous studies by Beran et al. and Coblijn et al [23,24] as tobacco use promotes ulcer progression and impairs epithelial cell healing capacity. Furthermore, nicotine may easily reduce stomach mucosal blood flow by creating a local vasoconstrictive environment. Heavy smokers were significantly more likely than nonsmokers to develop complications including bleeding and perforation [25]. Ulcers were more common in older individuals, which could be attributed to age-related declines in mucosal defence and healing capacity.

The study has certain limitations as the study was conducted at a single centre, which may limit the findings' applicability to different demographics and contexts. While the sample size is acceptable for preliminary analysis, it may not be sufficient to identify all potential factors and small changes across the groups. Furthermore, a one-year follow-up period may not capture all cases of marginal ulceration because some ulcers may occur after this time frame. Future research should involve multi-centre studies with larger, more diverse populations to improve the generalizability of the findings. Furthermore, longer follow-up periods are suggested to better understand the long-term incidence and factors impacting marginal ulcer development.

Conclusion:

This study concluded that although the patients with larger pouches had a higher frequency of marginal ulcers, but the association was not statistically significant. Certain factors such as age, smoking status, and postoperative NSAID use, are also associated with the development of ulcers demonstrating the complex nature of ulcer pathophysiology. The preoperative and postoperative management methods, including smoking cessation, optimum use of NSAIDs, and routine use of proton pump inhibitors, are imperative factors for decreasing the incidence of MU.

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