



# The Effect of Anti-Reflux Suture on Reflux Incidence After Laparoscopic Gastric Plication

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## Abstract

**Introduction:** The focus of this research is to evaluate the effects of Laparoscopic Gastric Plication (LGP) associated with anti-reflux sutures on postoperative incidence, worsening or improving Gastroesophageal Reflux Disease (GERD) symptoms in obese patients.

**Methods:** This was a prospective study, assessing the efficacy of LGP with anti-reflux sutures in the prevention or improvement of GERD symptoms in obese patients. All of the patients followed at the first and 6th months after surgery in terms of GERD symptoms (incidence, improving or worsening).

**Results:** Among the 210 included patients, 105 were in group A (case group or with anti-reflux suture) and 105 in group B (control group or without anti-reflux suture). The incidence of GERD in both groups was similar during the first postoperative month ( $P=0.067$ ), whereas in the 6th month of follow-up, the incidence of GERD was significantly lower in the intervention group compared to another group ( $P=0.001$ ).

**Conclusion:** It seems that LGP associated with the anti-reflux suture is generally effective and safe in reducing the risk of incidence or worsening of GERD and weight loss.

**Keywords:** Gastroesophageal reflux disease (GERD); Laparoscopic Gastric Plication (LGP); Anti-reflux suture; Bariatric surgery; Morbid obese

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## Introduction

According to the World Health Organization (WHO) declaration, obesity is a major health problem associated with different complications [1,2]. For instance, it can result in serious conditions such as hypertension, metabolic syndrome, cardiovascular disease, GERD, and diabetes mellitus which considerably affect patients' Quality of Life (QOL) [2]. Thus, various bariatric surgery procedures were introduced by surgeons to resolve the prior problem. There are various surgical obesity methods with different effects on obesity that can be associated with major or minor complications. One of the most complications following restrictive bariatric surgery is GERD [3]. Laparoscopic Sleeve Gastrectomy (LSG) and LGP are common restrictive procedures. These procedures increase GERD prevalence due to increased intragastric pressure, Lower Esophageal Sphincter (LES) dysfunction, and anatomic changes such as hiatal herniation [2,4-7].

Each method has its advantages and disadvantages, depending on the patient's conditions and the surgeon's expertise [8]. For example, LSG is a simple, invasive, expensive method that is believed to be associated with an increased risk of Barrett's esophagus and cancer in the long-term follow-up [5,7], just like LGP which is a new restrictive bariatric method introduced in 2006 by Talebpour et al. [9]. Despite inexpensiveness, LGP requires skill and experience [10,11]. Also, LGP does not affect the body's physiology because no part of the stomach is removed [1]. On the other hand, LGP alone positively affects weight loss without obvious benefit to GERD [1,12]. A small change in LGP can reduce the risk of GERD.

Accordingly, this study aimed to evaluate the treatment outcome of the anti-reflux suture to prevent or control GERD after LGP.

## Methods

### Study design & Population

We conducted a prospective study at the Department of Surgery of Tehran university Hospital,

Tehran, Iran, from April 2013 to December 2018. Participants were assigned to groups A (case group or with anti-reflux sutures) and B (control group or without anti-reflux sutures).

This study was approved by the Medical Ethics committee of Tehran University of Medical Sciences. The ethical code is IR.TUMS.MEDICINE.REC.1398.083.

The eligibility criteria included the following: 1) Patients undergoing LGP surgery with a BMI over 40 or 35 with comorbidity and without a history of reflux or with a history of first or second-degree reflux disease.

The exclusion criteria were as follows: 1) Patients with a history of higher second-degree reflux; 2) Patients with a history of anti-reflux surgery; 3) Patients with a history of repaired hiatal hernia; 5) Patients dissatisfaction.

### Procedures

All patients underwent LGP surgery following an anti-reflux suture in group A. The surgical procedure was performed through laparoscopy by an expert surgeon and his team.

### Surgical technique

First, the patient was placed in a supine reverse Trendelenburg position and the surgeon was on the patient's left side. Three 5 mm trocars and one 10 mm trocar were inserted in the right position. The dissection of the greater curvature was started from 3 cm before the pylorus up to the esophagus by Liga Sure TM.

**Anti-reflux suture:** All attachments of the fundus to the diaphragm and esophagus, including the angle of Hiss, are made free. After the attachments between the esophagus and stomach have been released, the anterior zone of attachment is about 1 cm lower than the posterior zone. The first suture is stitched anterior to the stomach at the junction of the esophagus and stomach. The suturing continues above the first suture, above it to close the stomach on the lateral sides to perform an anterior wrap around the 1 cm distal part of the esophagus. (anti-reflux suture) Purse string suture below the esophagus, somehow the inverted stomach gets a fix at a place without risk of displacement, risk of vomiting decreased dramatically (Figure 1).

### Postoperative follow-up

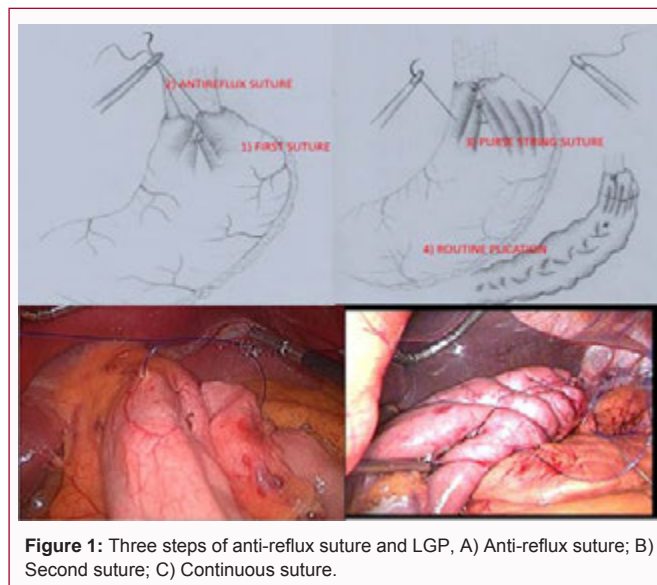
Participants were followed at the first and sixth months postoperatively regarding the incidence or worsening of reflux disease. Follow-up was performed according to the standard GERD-HRQL questionnaire [13]. This questionnaire contains nine questions with a score from 0 to 5. Patients with scores higher than 15 are considered to have reflux disease.

### Data collection

Extracted demographic data were age, gender, and initial Body Mass Index (BMI). In total, 210 obese patients that underwent LGP surgery were included in this study. All patients were evaluated at the first and sixth months postoperatively in an outpatient setting. Patients were assessed for GERD by the surgeons. All the patients were evaluated for postoperative GERD in two groups based on mentioned items, also subjectively according to the treating surgeon's opinion.

### Statistical analysis

All statistical analyses were performed using IBM SPSS Statistics for Windows, version 22. Quantitative data with normal distribution



**Figure 1:** Three steps of anti-reflux suture and LGP, A) Anti-reflux suture; B) Second suture; C) Continuous suture.

were tested by the t-test. Qualitative data were tested with Chi-square. A p-value below 0.05 was considered as the threshold of significant difference.

### Results

A total number of 210 obese patients who underwent operation from April 2013 to December 2018 were divided into two equal groups. All of the patients were followed for one month and six months. The follow-up rate was 100%.

### Demographic data of patients

Of the 210 patients, 60 (28.6%) were male, and 150 (71.4%) were female, who were similarly distributed in the two groups (Table 1). Their mean (SD) age and mean (SD) perioperative BMI were 36.43 (11.10) years and 40.26 (4.72) kg, respectively (Table 1).

### Comparison of EWL between two groups according to the following time

The EWL rate had significantly lower values in the intervention group in follow-up ( $P < 0.001$ ). The mean EWL in the intervention group was  $19.01 \pm 67.12$ , and  $60.07 \pm 13.05$ , while in the other group, the values were  $12.22 \pm 5.03$ , and  $61.04 \pm 13.14$  in the first and sixth months after surgery, respectively (Table 2).

### The effect of anti-reflux suture on reducing GERD

Of 105 patients in the control group, 23 patients (21%) demonstrated symptoms of GERD. Whereas, from 105 patients who had anti-reflux sutures, only 13 patients (12%) showed GERD in the first postoperative month. Thus, the incidence of GERD in group A was similar to the other group ( $P = 0.067$ ) (Table 3).

In the sixth month of follow-up, 6 patients (5%) from group A displayed GERD symptoms, while 23 patients (21%) from the other group showed reflux symptoms. Consequently, the incidence of GERD was significantly lower in group A than in the other group ( $P = 0.001$ ). The related data is summarized in Table 3.

### The assessment of GERD in following based on gender, age, and BMI

We observed that GERD incidence was lower in group A only in patients with an age of more than 30 years, while six months after surgery, it was lower in the anti-reflux suture group in all age groups

**Table 1:** Demographic data.

		Control group	Intervention group	P-value
Age (mean ± SD)		38.07 ± 11.12	34.18 ± 10.05	0.032
Gender (number)	Female: 150	75 (71.42)	75 (71.42)	>0.05
	Male: 60	30 (28.6)	30 (28.6)	
Initial BMI (mean ± SD)		41.02 ± 5.07	39.10 ± 4.08	0.001

SD: Standard Deviation; BMI: Body Mass Index

**Table 2:** Comparison of EWL between two groups according to the following time.

		Control group	Intervention group	P-value
EWL	First month	19.01 ± 67.12	12.22 ± 5.03	<0.001
	Sixth month	60.07 ± 13.05	61.09 ± 13.14	<0.001

EWL: Excessive Weight Loss

**Table 3:** The effect of anti-reflux suture on reducing GERD in following time.

		Control group (Number)	Intervention group (Number)	P-value
GERD-first month	Positive	23 (21%)	13 (12%)	0.067
	Negative	82 (78.1%)	92 (87.0%)	
GERD-sixth month	Positive	22 (20.0%)	6 (5.0%)	0.001
	Negative	83 (79.0%)	99 (95.0%)	

GERD: Gastroesophageal Reflux Disease

**Table 4:** The assessment of GERD in following based on gender, age, and BMI.

		Control group	Intervention group after first month	Control group after sixth month	Intervention group after sixth month
Age	<20	2 (8%)	2 (15.0%)	2 (9.0%)	0
	20-29	4 (17%)	4(30.0%)	4 (18.0%)	1 (16.0%)
	30-39	7 (30%)	4 (60.0%)	7 (31.0%)	4 (66.0%)
	40-49	5 (21.0%)	1 (7.0%)	4 (18.0%)	0
	50-59	5 (21.0%)	2 (15.0%)	5 (22.0%)	1 (16.0%)
	>60	0	0	0	0
Gender	Female	18 (78%)	10 (76%)	17 (77%)	5 (83%)
	Male	5 (21%)	3 (23%)	5 (22%)	1 (16%)
BMI		14 (60%)	12 (100%)	13 (59.1%)	6 (100%)
		9 (39%)	0	9 (40%)	0

(Table 4).

The evaluation of GERD based on gender showed that the incidence of reflux was lower in group A in both first- and sixth-months follow-ups after surgery (Table 4). Also, the assessment of GERD according to the BMI showed similar results regarding gender (Table 4).

## Discussion

This study demonstrated that LGP associated with the anti-reflux suture is effective in preventing or improving GERD symptoms in morbidly obese patients.

The overall results of this retrospective research comprised the following GERD incidence was significantly lower in the sixth month after surgery in the anti-reflux group. No significant difference was found between the two groups in terms of perioperative BMI, sex, and the incidence of reflux one month after surgery. Moreover, the presence of BMI-related reflux at one and six months after surgery was lower in the anti-reflux group.

Studies have shown that bariatric surgery effectively treats obese patients; however restrictive procedures such as LGP and LSG

increase the risk of GERD and Barrett's esophagus and can worsen GERD symptoms, hiatal hernia, and erosive esophagitis [14-16]. Nevertheless, based on a study by Chi-Ming Tie et al. [6], these methods (LSG and LGP) do not increase GERD symptoms in the absence of a hiatal hernia. Therefore, different measures have been taken by bariatric surgeons for resolving this issue through changes in LSG and LGP. For instance, studies by Stephano et al. [17] and Mariano et al. [18] showed that LSG accompanied by anti-reflux fundoplication is associated with decreased weight and improvement of GERD symptoms. Also, Juan Pablo et al. [19] assessed the efficacy of LSG with anti-reflux fundoplication in obese patients with GERD symptoms and achieved good results in the short term, but 53.3% of patients needed revision surgery. Another study showed that LGP with fundoplication has similar results in the short term but recommended further studies to assess the long-term durability of this procedure [20].

Our study implied that LGP alone increased the risk of GERD but can be effective in weight loss and control or preventing GERD by using anti-reflux sutures.

One of the strengths of our study was the novelty of the study. To the best of our knowledge, the current study was the first to examine

the efficacy of anti-reflux sutures in morbidly obese patients with GERD. Indeed, the main point of our research was the introduction of a new method that is cost-beneficial, and also improves patients' QOL.

However, we are aware that this research had some limitations. This study is not a randomized design. Future prospective studies are thus needed to determine the efficacy of this new method. The other limitation of the study is that patient evaluation was purely clinical and subjective, and we did not use either invasive or non-invasive paraclinical methods.

## Conclusion

In summary, it seems that LGP associated with the anti-reflux suture is generally effective and safe in reducing the risk of incidence or worsening of GERD and improving weight loss.

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