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CLINICAL REPORT





# Short-Term Outcomes of Laparoscopic Gastric Plication in Morbidly Obese Patients: Importance of Postoperative Follow-up

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Abstract Demand for feasible, safe, and preferably lowcost methods of weight reduction is rising every day. The present study reports findings from laparoscopic gastric plication (LGP), which is a new restrictive bariatric technique, combined with a postoperative follow-up program. A 2-year prospective study was performed following LGP in 53 female morbidly obese patients from Gorgan, Iran, with a mean age of 36.3 years and mean body mass index (BMI) of 42.6 kg/m<sup>2</sup> (35.3–62.4). Through a four-port approach, the greater omentum and short gastric vessels were transected and the greater curvature was imbricated into the body of the stomach with two rows of nonabsorbable sutures. After surgery, all patients were scheduled to attend a weekly group meeting for behavioral modification and psychotherapy. The mean operative time and hospital stay was 95 min and 72 h, respectively. No intraoperative complications occurred. Mean percentages of excess weight loss (%EWL)

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Student Research Committee, Deputy for Research and Technology, Golestan University of Medical Sciences, Falsafi Educational Campus, Shaskalate, 5th km Gorgan, Tehran Rd., Gorgan, Iran e-mail: ali.r.maleki@gmail.com were 25.6 %, 54.2 %, 70.2 %, and 74.4 % after 1, 6, 12, and 24 months, respectively. Six patients lost >84 % of their excess weight after 24 months. Patients who did not participate in the group meetings had a lower %EWL after 12 (79.5 % vs. 55.6 %) and 24 months (90 % vs. 43.4 %) compared with the patients who regularly participated in the group meetings (P<0.005). LGP is a feasible, safe, and effective surgical method for weight loss for at least 24 months when performed on morbidly obese patients. Postoperative group meetings (POGM) for psychotherapy and behavioral modification helped patients to achieve better results.

**Keywords** Morbid obesity · Gastric plication · Bariatric surgery · Postoperative follow-up

## Introduction

The prevalence of obesity is increasing worldwide, and the demand for feasible, safe, and preferably low-cost methods of weight reduction is rising every day [1]. There are several reports of long-term feasibility and cost effectiveness of different bariatric procedures for weight reduction and elimination of obesity-related comorbidities such as metabolic syndrome and type 2 diabetes [2, 3].

During the last decade, different methods of minimally invasive surgery have been developed to achieve sustainable, significant weight loss with minimal invasion and complications [4, 5]. There has been a recent massive trend in common restrictive procedures such as laparoscopic adjustable gastric banding (LAGB) and sleeve gastrectomy (SG) between surgeons and the obese population [6–8]. Although these procedures have had acceptable results in some patients, there are issues concerning the complications and cost efficiency of these approaches. For example, LAGB has been shown to be less effective among common bariatric procedures, and there is a need for frequent postoperative adjustments and risk of band slippage and band erosion [3, 6, 9]. In addition, SG is an invasive, irreversible operation that has occasionally led to major adverse events following surgery, such as gastric leakage [3, 6, 10]. SG is also very expensive because of the application of a long staple line.

Gastric plication is a new restrictive bariatric procedure initially proposed by Tretbar et al. in 1976 [11] and Wilkinson et al. in 1981 [12]. Laparoscopic gastric plication (LGP) was subsequently developed and introduced by Talebpour in 2006 [13]. LGP was first used in a large group of morbidly obese patients in Iran (by Talebpour) and is currently applied in several countries worldwide to treat morbid obesity. We have been involved in the evolution of this new procedure since 2003. During this period, we have frequently witnessed excellent weight loss in patients who had good postoperative follow-up and compliance. At the same time, some patients in a group with poor postoperative follow-up did not lose weight very well. Thus, we decided to evaluate the effect of a postoperative follow-up program (pilot study) on weight loss after surgery, and we herein present the initial results. We also investigated the safety, feasibility, and efficacy of LGP for treatment of morbid obesity in our population.

# **Material and Methods**

#### Patients and Study Design

The present study was a prospective case series that aimed to evaluate the initial outcomes of LGP in morbidly obese patients. Beginning in December 2009, morbidly obese subjects referred to our bariatric surgery clinic were offered different options of bariatric procedures (i.e., gastric bypass, LAGB, and SG) that were performed in our center. After a description of all surgical options, the patients who expressed interest in LGP and met the inclusion criteria were invited to participate in this study. The US National Institute of Health criteria for bariatric surgery were used for patient selection [14]; patients required a body mass index (BMI) of  $>40 \text{ kg/m}^2$ or  $>35 \text{ kg/m}^2$  with at least one comorbidity and an absence of psychological conditions that influence his/her perception of the study protocol and postoperative evaluations and recommendations. All recruited patients underwent a presurgical evaluation, including consultations with a cardiologist, psychologist, and nutritionist plus routine laboratory tests. All procedures were performed by the same surgeon (M.N.) at Kapri Surgical Center and Falsafi Hospital in Gorgan, north of Iran. All participants signed informed consent forms. The ethics committee of Golestan University of Medical Sciences approved the study protocol.

#### Surgical Procedure

All patients were placed in the supine, 30° reverse Trendelenburg position. Pneumoperitoneum was established by midaxillary, left subcostal insertion of a Veress needle. The first trocar was placed at the left paramedian line 20 cm below the xyphoid angle. The left and right hands of the surgeon's trocars were inserted based on ergonomic assessment at this stage (left middle axillary subcostal line and right midclavicular line 5 cm above the first trocar). The surgeon's assistant's trocar was inserted at the right anterior axillary line. Three 5-mm and one 10-mm trocar were almost always used.

Dissection started at the greater curvature of the stomach from the middle of the antrum and continued until 2 cm distal to the angle of His, preserving the anatomy of the angle and the left and right gastroepiploic artery. Communicating vessels were ligated by intracorporeal suturing, coagulation, LigaSure, or clips. Continuous suturing from the fundus through the antrum was performed in this stage, making one and then two layers of plicated stomach from the anterior wall of the stomach to the posterior wall. For suturing, 2-0 prolene or nylon was used, and the bulk of each stitch was 2 cm with a 2-cm interval and a 2-cm distance from the lesser curvature. Sutures were extramucosal, preventing absorption by gastric acid.

The volume of stomach in this condition is approximately 100 mL. The volume is calculated by transient occlusion of the pylorus with an atraumatic grasper and infusion of liquid into the stomach via a nasogastric tube without any force (the stomach in this condition is relaxed and dilated).

## Postoperative Follow-up

Patients were discharged after complete resolution of nausea and vomiting and compliance with a liquid diet. Proton pump inhibitors and prokinetic and antispasmodic agents were prescribed if needed. The postoperative diet was as follows: in the first 2 weeks after discharge, patients drank only clear liquids such as water or fruit juice. During the next 4 weeks, concentration of foods gradually increased, and patients were allowed to consume liquids with small particles and softened foods. After that, they started a regular diet in a limited amount according to the nutritionist's recommendation.

Data concerning hospital stay, intra- and postoperative adverse events, and other demographic information were collected by proper checklists. The mean changes in different parameters related to obesity in a period of 2 years were monitored.

## Postoperative Group Meeting

We run a regular postoperative group meeting (POGM) in our clinic and invited all patients to participate immediately after the operation. In this group meeting, which was started early after the operation and lasted for at least 12 months for each patient, lifestyle modification was the main purpose. We asked patients to omit junk food and high-calorie diets and encouraged them to participate in a regular exercise program. We also created a friendly environment in which the patients could discuss their problems and share experiences and information to help one another in losing weight.

## Weight Loss

The main study objective was to assess the weight loss after LGP. The weight loss assessments included absolute weight loss (AWL), percentage of total weight loss (%TWL), percentage of excess weight loss (%EWL), and changes in BMI. Percentage of EWL was calculated using ideal body weight according to the middle of the 1983 Metropolitan Life Insurance tables for median frame. The weight was measured by electronic scales on the day of surgery and at 1, 3, 6, 12, 18, and 24 months after surgery.

#### Quality of Life Assessment

The effect of surgery on quality of life was assessed by a standard quality of life survey before and during the study period. The Impact of Weight on Quality of Life-Lite (IWQOL-Lite) was administered at the preoperative evaluation and 12 months postoperatively. The IWQOL-Lite (31 questions) is a shorter version of the IWOOL (74 questions), which is designed to assess the effects of obesity on the quality of life of those seeking weight loss treatment options [15]. The questionnaire contains five domains: physical function (11 items), self-esteem (seven items), sexual life (four items), public distress (five items), and work (four items). Each item has five response options with a scoring range from 1 to 5. The subjects' IWQOL-Lite total scores were considered to show meaningful improvement from baseline to 1 year after treatment if the scores had increased by seven to 12 points, depending on the baseline severity compared with the normative mean.

#### Results

A total of 53 patients underwent operations from December 2009 to January 2012. Their initial mean age and mean weight were 36.3 years and 115.2 kg, respectively. The mean BMI was 42.61 kg/m<sup>2</sup> (range, 35.3–62.4), including eight patients with a BMI of >50 kg/m<sup>2</sup>. The mean procedure duration was 95 min (range, 82–120). All operations were performed laparoscopically without any need for

conversions. All LGPs were performed with two rows of sutures.

The mean hospital stay was 72 h (range, 24–120 h). A total of 41 patients passed a >6-month postoperative followup (other patients underwent operations in the last 5 months of the study period and were not eligible for analysis), while 26 of them participated in weekly group meetings in our clinic for at least 6 months postoperatively. Fifteen patients did not participate because ten came from different cities and could not come to our clinic regularly and five refused to participate in group meetings. However, these patients have been followed individually at different intervals.

#### Weight Loss

The data regarding weight loss during the 2-year follow-up are listed in Table 1. Ten patients achieved a mean %EWL of 74.4 % after 24 months postoperatively, while six lost >84 % (including two who lost >100 %) of their excess weight during this period. Our data indicate that patients who did not participate in group meetings had a significantly lower %EWL after 6, 12, 18, and 24 months postoperatively (P<0.01, analyzed using an independent samples *t* test ) compared with the patients who regularly participated in our group meetings (Table 2).

## Quality of Life

The overall IWQOL-Lite had improved significantly (P=0.000, analyzed using a paired samples t test) after 12 months in all 20 patients who passed >12 months from surgery. There were significant improvements in all domains as well. There was more statistically significant improvement in all domains among the patients who participated in weekly meetings (n=30) compared with the scores of patients who did not participate in the meetings, especially in the public distress domain (P=0.000 vs. P=0.026, respectively; analyzed using a paired samples t test).

#### Complications

No intraoperative complications occurred. Two patients (3.8 %) required reoperation due to severe nausea and vomiting following acute gastric obstruction, resulting in prolonged hospitalization up to 7 days. Both underwent a second operation 5 days after the first LGP. Nausea, vomiting, and gastroesophageal reflux occurred in six (11.3 %) patients, and five (9.4 %) experienced epigastric pain in the first postoperative month that resolved by metoclopramide and omeprazole without any residual symptoms. No long-term complications related to the procedure and no weight regain were reported until now in our study population.

Parameter	1 m ( <i>n</i> =53)	3 m ( <i>n</i> =48)	6 m ( <i>n</i> =41)	12 m ( <i>n</i> =30)	18 m ( <i>n</i> =19)	24 m ( <i>n</i> =10)		
%EWL	25.6±7	40.7±8.9	54.2±11.9	$70.2 \pm 18.6$	71.7±21.8	74.4±24.8		
%TWL	$11.3 \pm 2.5$	$18.3 \pm 3.1$	25.2±5.1	32.7±8.1	32.3±8.9	$34.4{\pm}10$		
AWL	$12.9 \pm 3.5$	21.3±6.1	$30 {\pm} 8.9$	38.9±12.4	38.8±12.9	42.2±14.7		
BMI	37.5±6.1	35±5.6	32.5±4.4	29.3±4.8	28.6±5.7	28.9±6.7		

Table 1 Detailed weight loss results after LGP in a period of 24 months

%EWL percentage of excess weight loss ([(weight at baseline-weight at each visit) / (weight at baseline-ideal body weight)]×100), %TWL percentage of total weight loss ([(weight at baseline-weight at each visit) / weight at baseline]×100), AWL absolute weight loss (weight at baseline-weight at each visit) / weight at each visit)

## Discussion

We herein present the 2-year outcome of LGP in morbidly obese patients from Golestan province in the north of Iran. LGP already been used in bariatric surgery for more than 10 years after first application by Talebpour in Iran in 2000 [16], but there are no data concerning the exact mechanism of weight loss with this method. Similar to the report by Brethauer et al. [17], we saw a noticeable decrease in appetite and good hunger control in our study population. At the same time, most patients experienced epigastric pain or nausea and vomiting with large meals and gastroesophageal reflux after consumption of foods that were not recommended. This compulsory dietary restriction, subsequent conditioning to the reduced food intake, and finally, metabolic conversion to fat catabolism seem to be the main mechanisms of weight loss after this simple procedure [13].

However, long-term preservation of weight reduction is a challenge in these patients. There is only one report regarding long-term outcome of LGP that reported weight regain of 15 % (n=11 of 75), 30 % (n=10 of 35), and 50 % (n=5 of 10) after 3, 7, and 10 years, respectively [16]. This report demonstrates the risk of huge weight regain in LGP patients. In the present study, we assessed the effect of adding a POGM to a formerly established method of LGP to overcome this problem. Our study demonstrates that scheduling a POGM can result in more satisfactory excess weight loss and maintenance of weight reduction in LGP patients. As shown in Table 2, there was a significant difference in the %EWL between patients who participated in meetings (POGM) and patients who did not (79.5 % vs. 55.6 % after 12 months and 90 % vs. 43.7 % after 24 months). The

weight reduction rate was always increasing in the participating patients during whole follow-up. The weight reduction rate was lower after 12 months postoperatively in the patients who did not participate (Fig. 1).

Our patients' weight loss rate after LGP was noticeably better than that in similar previously published reports. As shown in Fig. 1, the maximum %EWL and the durability and maintenance of overall %EWL in our population are markedly higher than those in other studies. We believe that our POGM program has had an important effect on weight loss and subsequent maintenance of reduced weight in our patients. However, nonrandomized allocation of patients in the POGM program affected the reliability of our results. No studies have addressed the effect of postsurgical follow-up on weight loss outcome in LGP patients. Saunders [18] and Ashton et al. [19] reported the positive effect of a cognitivebehavioral group therapy program for compulsive eaters who previously underwent a bariatric surgery. Ashton et al. performed a brief cognitive-behavioral group treatment for binge-eating behaviors in a total of 128 bariatric surgery candidates. In their study, the positive responders to a brief binge eating intervention had lost significantly more weight at 6 months (46 %EWL vs. 38 %EWL) and 12 months (59 %EWL vs. 50 %EWL) postoperatively [19]. Interestingly, another advantage of such group meetings is formation of a friendly and supportive connection among patients with the same problem and concern. The newly operated patients are more encouraged when meeting other patients who have lost a huge amount of weight and are motivated to follow the postoperative recommendations to achieve the best results.

Wilkinson et al. [12] attempted to reduce the capacity of the stomach by wrapping the greater curvature around the

Table 2 Comparison of percentage of excess weight loss (%EWL) based on participation in postoperative weekly group meetings

	6 m	12 m	18 m	24 m
Participated	59.8±10.4 ( <i>n</i> =26)	79.5±16.5 ( <i>n</i> =17)	90.6±8 (n=10)	90±7.5 ( <i>n</i> =6)
Not participated	45.5±8.6 ( <i>n</i> =15)	55.6±10.8 ( <i>n</i> =13)	52.9±10.7 ( <i>n</i> =9)	43.4±3.4 ( <i>n</i> =4)
P value <sup>*</sup>	0.002	0.004	0.000	0.001

Data were analyzed using an independent samples *t* test by means of SPSS 16.0 software (SPSS, Inc., Chicago, IL, USA)

\*P < 0.05 (statistical significance)

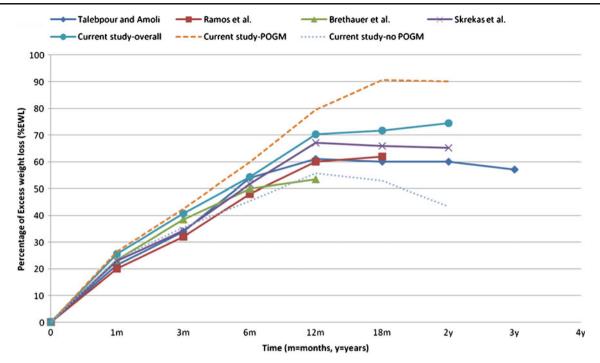


Fig. 1 Comparison of %EWL after LGP between the current study and previously published reports (POGM postoperative group meeting)

lesser curvature using a monofilamented polypropylene mesh garment in 1981, which is different from the method of Talebpour. In 2006, Fusco et al. [20] described the efficacy of gastric greater curvature plication for weight reduction in an animal model. Furthermore, they reported higher effectiveness of greater curvature plication than anterior gastric wall plication for weight loss in animals [21]. The first attempts at application of the new procedure of gastric plication in an animal model (sheep) and then in human subjects were carried out by Talebpour in 2000 [16]. He first used anterior plication and then modified the technique three times to achieve the best results in weight loss (no published data). Talebpour and Amoli then reported the first results of LGP in a series of 100 patients in 2007 [13]. This report opened a new window in bariatric surgery.

There are already several reports on the short-term outcomes after LGP from different countries worldwide (Table 3). Further reports by Ramos et al. [6], Brethauer et al. [17], Skerekas et al. [22], and Gebelli et al. [23] demonstrate that LGP is a feasible and effective method of restrictive bariatric surgery with remarkable cost efficiency and patient safety (Table 3).

We experienced two patients with acute gastric obstruction who underwent a second operation 1 week after the

 Table 3 Available reports on short-term results of LGP in morbidly obese patients

Author (pub. year)	Country	No.	Mean follow-up duration (m)	Mean preop BMI (kg/m <sup>2</sup> )	Mean %EWL 6 months	Mean %EWL 12 months	Mean %EWL 24 months	Mean op time (min)	Major comp <sup>a</sup> (no)
Talebpour and Amoli [13] (2007)	Iran	100	24	46	55	61	60	98	4
Ramos et al. [6] (2010)	Brazil	42	18	41	48	60	NP	50	0
Brethauer et al. [17] (2011)	USA	6	12	43.3	49.9	53.4	NP	72	1
Skrekas et al. [22] (2011)	Greece	135	22.6	39.5	51.7	67.1	65.2	40–50	4
Gebelli et al. [23] (2011)	Spain	13	12	44.5	32	NP	NP	NP	2
Present study (2012)	Iran	53	13.1	42.61	54.2	70.2	74.4	95	2

pub. publication, No. number of patients, preop preoperation, comp complication, NP not provided, op operation

<sup>a</sup> Major complication rate refers to the postoperative complications that required reoperation

initial procedure. Brethauer et al. [17] (one case) and Skrekas et al. [22] (three cases) previously reported gastric obstruction after LGP. Brethauer et al. described a patient with severe nausea and liquid intolerance due to obliteration of the gastric lumen by edematous folds early after surgery. They managed the patient by removing the outer row of sutures and replacing it with a looser row [17]. Skrekas et al. presented a case of gastric obstruction 14 months after the initial operation caused by a partial prolapse of the gastric fundus between two distal fasteners of the suture line and two cases of obstruction caused by accumulation of serous fluid (seroma) within the cavity formed by the plicated gastric wall [22]. One of our cases was quite similar to that reported by Brethauer. The patient had a huge gastric body, which resulted in formation of a very large intragastric fold after greater curvature plication. Radiologic assessment revealed that the distal portion of the intragastric fold was kinked and protruded into the pylorus. Three days after the first surgery, the patient returned to the operation room because of prolonged liquid intolerance. We removed the primary continuous sutures and performed triple plication of the greater curvature with a row of stitches to achieve a shorter intragastric fold. Interrupted mattress sutures were placed on the second row. In the second case, after completion of the first row of continued sutures, we continued the second row about 4 cm away from the distal end proximally, which resulted in bending of the proximal portion over the pylorus. This patient was managed like the former.

## Conclusion

Our experience and that of previous reports demonstrates the feasibility and efficacy of LGP for treatment of morbid obesity. A review of the current state of this method revealed short-term LGP results comparable with those of other bariatric surgery methods such as gastric bypass and SG. Considering its lower invasiveness and cost, LGP will be more popular in the near future; thus, further randomized feasibility trials are recommended. Bearing in mind the limitations of our study, such as the simple study design, the nonrandomized assignment of patients to participation in POGM, and the unstructured POGM program, we suggest a close follow-up program and cognitive-behavioral support after any bariatric procedure to achieve better results. A randomized controlled trial with a structured cognitive-behavioral group therapy program is ongoing to establish the effect of this program on short-term outcomes of LGP in morbidly obese patients.

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Conflict of interest None.

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