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ORIGINAL CONTRIBUTIONS

Comparison of Short-Term Effectiveness and Postoperative Complications: Laparoscopic Gastric Plication vs Laparoscopic Sleeve Gastrectomy

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Abstract
Introduction Bariatric surgeries are the only effective long-term treatment in obese patients. The innovation of laparoscopic gastric plication (LGP) raised some questions about its effectiveness compared to traditionally used techniques such as laparoscopic sleeve gastrectomy (LSG). We tried to answer some of these questions.
Materials and Methods We investigated 70 patients in a randomized clinical trial (IRCT2013123012294N5) from 2012 to 2015. Thirty-five patients were randomly assigned to each LSG or LGP group, using sealed envelope method. The body mass index (BMI) reduction and the percentage of excess weight loss (%EWL) along with %total body weight loss (%TWL) were primary endpoint and were assessed at follow-up periods. We recorded postoperative complications, as well.
Results Two-year follow-up rate was 100%. There were no statistically significant differences between the two groups in means of preoperative BMI. Also, postoperative follow-ups were not suggestive for a significant difference in BMI (all p values > 0.05). The mean %EWL at follow-ups showed no significant difference at any point, except for 3 and 6 months after surgery (p value = 0.002 and 0.017, respectively). This finding was confirmed by %TWL trend in 12 months after surgery. LSG patients were readmitted more than LGP patients (seven cases vs one case, p value = 0.024). Postoperative complications such as nausea and vomiting, hair loss, iron deficiency, vitamin D deficiency, and cholelithiasis were not different between the two groups. There was one death in the LGP group due to pulmonary thromboembolism.
Conclusions LGP showed to be efficient regarding %EWL and %TWL reduction in short-term follow-ups with comparable postoperative complications to LSG.

Keywords Laparoscopic sleeve gastrectomy · Laparoscopic gastric plication · Short-term follow-up · Excess weight loss · Postoperative complication

Introduction

Obesity has become a major health problem in both developing and developed countries reducing life expectancy [1, 2]. Since 1997, World Health Organization mentioned obesity as a global epidemic and over 1.7 billion people are affected [3]. Growing interest in bariatric surgery has been developed as conservative approaches (diet, exercise, and medication) failed to achieve clinically significant results [4].

Surgical methods for obesity treatment are possibly effective in three main mechanisms: reduction in intestinal absorption (malabsorptive), mechanical restriction in gastric volume and subsequent hormonal change (restrictive), and the combination of these two [5, 6]. Laparoscopic sleeve gastrectomy (LSG) has become the most popular bariatric surgery designed to reach sustainable, significant weight loss with reasonable complication rates [7, 8]. In a systematic review study by Colquitt et al. [9], 20 randomized clinical trials which compared different bariatric surgeries were reevaluated. In this study, LSG was claimed to be superior to LAGB as it showed more weight loss and comparable outcomes to gastric bypass [9, 10]. Laparoscopic gastric plication (LGP) is a novel

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technique which was firstly innovated in the animal study by Tretbar et al. in 1976 [11].The improved and modified technique has been used since 2000 and then it was introduced as a new standard method in the human study by Talebpour in 2006 [12]. LGP and LSG are notably similar regarding anatomical appearance, as both techniques result in gastric tube formation and elimination of the greater curvature. The advantageous feature of LGP is its reversibility and the fact that there is no resection needed compared to LSG. However, the short-term efficacy of LGP in comparison to LSG is not clearly defined, and there are very few studies addressing this field [5, 13–15]. Thus, the aim of the present study was to compare the short-term outcomes in weight loss indices and postoperative complications between LGP and LSG.

Materials and Methods

This study was held as a randomized clinical trial (IRCT2013123012294N5) on morbidly obese patients referring to Sina Hospital, Tehran University of Medical Sciences, Tehran, Iran, between 2012 and 2015. The institutional review board and the ethics committee of Tehran University of Medical Sciences approved the study protocol. Morbidly obese patients are candidates to undergo bariatric surgery based on the National Institutes of Health criteria. The patients were enrolled in the survey if they had the following criteria: morbid obesity (body mass index (BMI) > 40 kg/m^2 or > 35 kg/ m^2 in patients with comorbidities), previous unsuccessful nonsurgical weight loss attempts, and high motivation for weight loss. Patients with the following criteria were excluded from the study: prior history of any bariatric surgery, previous gastric or anti-reflux surgeries, history of debilitating diseases such as any cancer, tuberculosis, and acquired immune deficiency syndrome (AIDS), known cases of psychiatric illness, and refusal to participate in the study. Patients were informed about their operation and participation in the study, and written consent was signed by them.

All patients were evaluated by a psychiatrist, an endocrinologist, and a nutritionist before the surgical procedure. Routine metabolic, electrolyte, and hormonal laboratory tests were performed in all cases. Endoscopic evaluation of upper gastrointestinal track was performed to assess hiatal hernia, and no patient needed surgical intervention for hiatal hernia.

The primary endpoint of the study was to compare weight reduction property of two techniques based on BMI, %EWL, and %TWL. The secondary endpoint was to assess complication rates in each technique. The null hypothesis in this study was that LGP cause weight reduction at 2-year follow-up that is less than 5% different from LSG. We calculated the sample size setting $\alpha = 0.05$ and $\beta = 0.2$ in accordance to null hypothesis based on primary endpoint. The patients were assigned to undergo either LGP or LSG randomly using sealed envelope method.

The height and weight of the patients were measured before the surgery and at each visit during the follow-up periods. Body mass index (BMI) was calculated, as well. The percentage of excess weight loss (%EWL) was defined as the difference between ideal weight and current weight divided by the surplus weight calculated in the first visit and was assessed in follow-up meetings. Also, the percentage of total body weight loss (% TWL) was calculated using following formula: ((baseline weight − weight at each follow-up)/baseline weight) × 100. The presence of the following factors was recorded for each patient at the follow-up periods: nausea and vomiting, hair loss, iron deficiency, vitamin D deficiency, diarrhea, cholelithiasis, the need for readmission or reversal surgery, and the presence of serious conditions such as leakage or collection formation.

All patients received prophylactic heparin and a single dose of antibiotic preoperatively. Proton pump inhibitors were administered for less than 1 week during the postoperative period.

Under general anesthesia, two-row LGP procedures were performed as described previously by Talebpour et al. [16]. A single surgical team performed all surgeries during the 3-year period. The patients were visited in 3, 6, 12, 18, and 24 months after surgery.

Categorical variables are shown as frequency, and relative frequency and continuous variables are shown as mean (standard deviation). Collected data for categorical variables were compared using the chi-squared test. An independent Student *t* test was used to compare means between the two groups at each follow-up visit and baseline, whenever indicated. All analyses were performed by the two-sided method using Statistical Package of Social Science software (SPSS version 22; SPSS, Inc., Chicago, IL), and the p value of < 0.05 was set as statistically significant.

Results

Thirty-five patients participated in each group of either LGP or LSG surgery. All patients were followed for at least 2 years, and 2-year follow-up rate was 100%. There were no statistically significant differences in patients' demographics between two groups (Table 1).

The most common underlying disease at preoperative assessment in both groups was gastroesophageal reflux disease (14 and 11 in LSG and LGP patients, respectively) and the least common was depression (4 and 1 in LSG and LGP patients, respectively, Fig. 1). Postoperative assessment of GERD based on the clinical symptoms, patients' complaints, and the need for taking proton pump inhibitor or H2 blocker more than preoperative period revealed that 11 patients in

Table 1 Patients' demographics in study groups

Characteristic		LSG group	LGP group	*p* value
Age (mean ± SD)		38.60 ± 10.27	35.34 ± 10.08	0.185
Gender *n* (%)	Male	6(17.1)	8(22.9%)	0.550
	Female	29(82.9)	27(77.1%)	
Height (mean ± SD)		160.11 ± 7.09	161.54 ± 6.81	0.393
Weight (mean ± SD)		124.68 ± 19.81	116.68 ± 9.49	0.126
BMI		44.60 ± 3.50	48.39 ± 4.89	0.09

LSG laparoscopic sleeve gastrectomy, *LGP* laparoscopic gastric plication, *SD* standard deviation

LSG and all patients in LGP had improvement in GERD. Changes in metabolic disorders and other preoperative disease were not the purpose of current study but have been discussed in other study [17].

The patients' mean BMI was 44.60 ± 3.50 and 48.39 ± 4.89 before surgery in LGP and LSG group, respectively, which showed no statistically significant difference (p value = 0.09). After surgery, periodical BMI measurements were performed for the participants of the two groups and the mean BMI was compared to the baseline which showed significantly lower BMI at all follow-ups in both techniques (All p values < 0.05). As it can be seen in the Table 2, the comparison of this variable between the two groups was not statistically significant at any point of follow-ups.

The mean %EWL was compared between the two groups which showed no significant difference at any point, except for 3- and 6-month follow-ups (Table 2).

Table 3 compares postoperative %TWL between two groups. It demonstrated significant difference lasting for 12 months.

Postoperative complications were compared between two study arms. There were no statistically significant differences between two groups, except for occurrence of diarrhea and readmission (Table 4). Nausea and vomiting were the most common complications in both groups. No patient needed reversal surgery, but there were seven patients in LSG and one in LGP who needed readministration to the hospital (p value = 0.024). Readmissions in the LSG group were due to two cases of leakage, one case of a suppurative abscess, two cases of cholecystectomy, and two patients developed acute coronary syndrome (ACS). In LGP group, one patient was readmitted to perform an abdominoplasty. Also, diarrhea was more frequent in the LGP group (6 vs 1, p value = 0.046). Serious conditions were more common in the LSG group including two cases of leakage and one case of suppurative abscess formation, whereas in the LGP group, one patient developed pulmonary thromboembolism and unfortunately passed away.

Hospital stay was 6.06 ± 1.53 days in the LGP group and 7.46 ± 1.93 days in the LSG group which showed a significant difference (p = 0.001).

Discussion

The recent bariatric surgery perspective has been associated with high success rate in weight loss and improvement of comorbidities [18]. One of the traditional strategies to achieve weight loss is to reduce the stomach capacity by restrictive surgical techniques [19]. Gastric plication has unique advantages as this method does not include any gastric resection nor does it leave a staple line behind, thus the risks of resection and staple line-related complications are reduced [20]. The principal advantage of this technique is the potential to reverse the procedure which was demonstrated by many authors to be simple and feasible [12, 21–23]. In gastric plication, there is neither resection procedure as used in LSG nor the need for adjustment as in gastric banding. Therefore, further problems of having foreign body along with the psychological

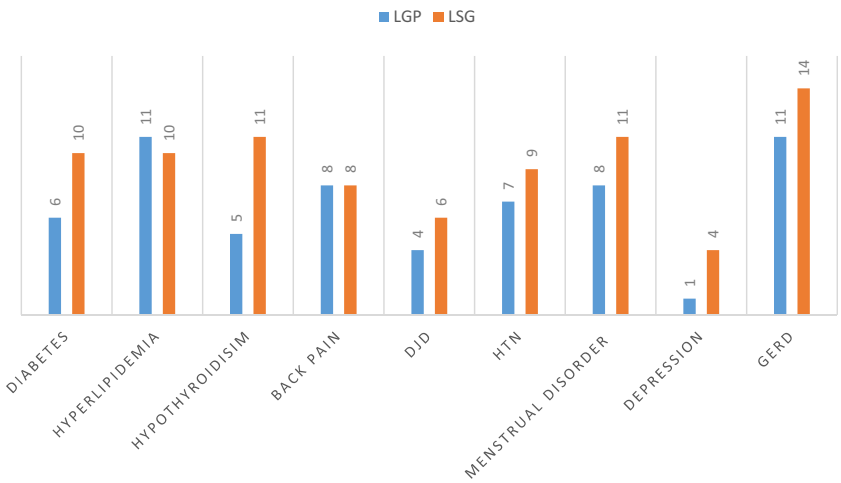

Fig. 1 Patients' preoperative underlying diseases. DJD degenerative joint disease, HTN blood hypertension, GERD gastro-esophageal reflux disease, LSG laparoscopic sleeve gastrectomy, LGP laparoscopic gastric plication

Table 2 Postoperative BMI and %EWL and in study groups

Postoperative BMI and EWL% (mean ± SD)		LSG group	LGP group	*p* value
3 months after surgery	BMI	48.39 ± 4.89	44.60 ± 3.50	0.09
	%EWL	29.23 ± 10.72	21.76 ± 8.47	0.002*
6 months after surgery	BMI	41.10 ± 4.41	40.11 ± 3.43	0.301
	%EWL	49.65 ± 16.02	41.39 ± 12.03	0.017*
12 months after surgery	BMI	36.09 ± 4.82	35.90 ± 3.24	0.850
	%EWL	65.45 ± 16.52	59.34 ± 12.35	0.084
18 months after surgery	BMI	32.20 ± 4.52	32.14 ± 2.74	0.949
	%EWL	73.34 ± 15.82	68.99 ± 12.76	0.245
24 months after surgery	BMI	30.48 ± 4.29	30.13 ± 2.76	0.701
	%EWL	72.26 ± 11.91	72.87 ± 12.60	0.872

LSG laparoscopic sleeve gastrectomy, LGP laparoscopic gastric plication, SD standard deviation, BMI body mass index, %EWL percentage of excess weight loss (%EWL)

*p value < 0.05 is significant

discomfort of having foreign body placed in the patient's body are resolved.

In our study, we find impressive results regarding weight loss among LGP and LSG at different follow-up periods. Although patients undergoing LGP had lower means of %EWL compared to LSG at various follow-up visits but the data was not statistically significant, except for first (month 3) and second (month 6) follow-up periods; the higher mean of %EWL detected in LSG group, lasted only for 18 months of follow-up (irrespective to statistical significance), and this trend was changed at 24 months follow-up. This trend has been found in %TWL as well. These findings are in agreement with Verdi et al. who reported greater results regarding weight loss among LSG than LGP patients at 6-month follow-up. They were unable to provide weight loss data at 12 and 24 months in gastric plication patients, but they believed longer follow-ups would result in the detection of greater differences between LGP and LSG regarding weight loss [19].

Other researchers reported a significant percentage of EWL with gastric plication that was comparable to sleeve gastrectomy. Ramos et al. followed 15 patients for 2 years. They demonstrated an excess weight loss of 60% in the second year, and nine patients continued their weight loss to 62% %EWL at 1.5 years postoperatively [6]. Also, Brethauer et al. reported a significant weight loss by gastric plication with a median of 53.4% at 1 year in six patients who had undergone LGP and only 23.3% with anterior plication in five patients [24]. Recently, Skrekas and Antiochos published a large series of 135 patients who underwent LGP and were followed for a mean of 22.59 months [23]. They had a slightly higher mean %EWL of 67.1% at 1 year than previous reports. However, they reported inadequate excess weight loss (<%EWL 50%) in 29/135 (21.48%) and failure (<%EWL 30%) of weight loss in 8/135 (5.9%). They argued that the following results are due to either inadequate gastric volume reduction or failure of gastric walls bonding.

Nausea and vomiting ranging from mild to moderate is the most common complication almost seen in all patients in every study [6, 12, 21, 22, 24]. It is usually resolved within 1 to 2 weeks, but reports are stating that it might last for as long as 23 days [12]. Despite high incidence, in most cases, it did not require readmission and was managed using antiemetics and prokinetics.

In a systematic review by Abdelbaki et al., seven different studies including 307 patients were extracted [18]. These studies included five prospective studies and two case reports. The patients' age ranged from 23 to 59 years old. The three highest excess weight loss was reported at 54, 51.7, and 28.4% by Talebpour and Amoli [12], Skrekas and Antiochos [23], and

Table 3 Postoperative %TWL in different follow-up periods

Postoperative %TWL (mean ± SD)	LSG group	LGP group	*p* value
3 months after surgery	14.94 ± 5.61	10.05 ± 3.41	0.033*
6 months after surgery	25.29 ± 8.00	19.36 ± 5.92	0.001*
12 months after surgery	33.32 ± 7.91	27.72 ± 5.88	0.038*
18 months after surgery	37.73 ± 7.55	32.24 ± 6.08	0.229
24 months after surgery	37.94 ± 6.96	33.99 ± 6.14	0.619

LSG laparoscopic sleeve gastrectomy, LGP laparoscopic gastric plication, %TWL percentage of total body weight loss

*p value < 0.05 is significant

Table 4 Postoperative complication in study groups

Postoperative complication	LSG group(n = 35)	LGP group(n = 35)	p value
Nausea and vomiting (after 1 month)	33(94.3%)	32(91.4%)	0.643
Nausea and vomiting(after 1 year)	13(37.1)	20(57.1)	0.094
Hair loss	28(80%)	28(80%)	1
Iron deficiency	7(20%)	3(8.6%)	0.172
Iron deficiency anemia	6(17.1%)	3(8.6%)	0.284
Vitamin D deficiency	1(2.9%)	0(0%)	0.314
Diarrhea	1(2.9%)	6(17.1%)	0.046*
Cholelitiasis	4(11.4%)	3(8.6%)	0.643
Readmission	7(20%)	1(2.9%)	0.024*
Serious conditions	3(8.6%)	1(2.9%)	0.303
Reversal surgery	0(0%)	0(0%)	1

LSG laparoscopic sleeve gastrectomy, LGP laparoscopic gastric plication, SD standard deviation

*p value < 0.05 is significant

Brethauer [24], respectively. Twenty patients (6.5%) were readmitted, of whom 14 (4.6%) patients required reoperation. Gastric obstruction was the most common reason for reoperation (8/14; 57%). Persistent vomiting [12], invaginated gastric fold, and intractable vomiting due to a gastro-gastric hernia [22] were the other complications leading to reoperation in these series [18].

There were other reports of acute gastric obstruction as in Skrekas and Antiochos study [23], three cases (of 138 patients) were reported, and Tsang [21]also reported a patient 2 weeks after surgery who was relieved by reversal of plication. Brethauer et al. [24] had to reoperate on the first patient in their series due to gastric obstruction 2 days after surgery. In the present study, we did not perform any surgical intervention in order to resolve obstruction.

In this study, the LGP group had significantly lower readmission. Unfortunately, there was one patient who passed away due to pulmonary thromboembolism, though he was under heparin treatment regimen. An autopsy was performed, and thromboemboli was confirmed. There was nothing wrong with plication surgery site.

Also, we found the significantly higher rate of diarrhea in patients underwent LGP. We assume this finding is due to the milk of magnesia prescribed orally for LGP patients to alleviate bloating. In five patients out of six who complaint of diarrhea in this group, diarrhea was resolved as they stopped taking milk of magnesia. Although all patients received PPIs routinely after surgery but milk of magnesia was used in these patients as the second line treatment. So we assume milk of magnesia is not needed to be added to routine postoperative medicine regimen

As it has resulted in other studies, hospital stay in patients who underwent LGP was significantly lower than LSG. This issue is confronted mainly because of the lack of suture or staple line in the first method that makes it possible to start nutrition earlier in postoperative days [10].

This study has few limitations. First, the sample size is small and is not sufficiently powered to assess postoperative complications, as we designed the study to assess weigh reduction. This might compromise the definite conclusion about advantages of LGP in terms of postoperative complications. Second, national regulations in health care system are different in our country and we believe this is the only reason for higher length of hospital stay reported in this study. Although we could manage to follow all patients for 2 years but studies with longer follow-ups are promised to fully address the difference between weigh reduction property of each LSG and LGP

Conclusion

LGP showed to be a promising bariatric procedure regarding %EWL reduction in short-term follow-ups with comparable outcomes with fewer complications than a standard restrictive surgical method like LSG.

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Compliance with Ethical Standards

Conflict of Interest All authors declare that they have no conflict of interest.

Statement of Informed Consent Informed consent was obtained from all the patients participated in the study (General note#2).

Statement of Human and Animal Rights/Ethical Approval The institutional review board and the ethic committee of Tehran University of Medical Sciences approved the study protocol for Human rights (General note#2).

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