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Laparoscopic gastric plicature: five year follow-up results in Mexican patients

Plicatura gástrica laparoscópica: resultados a cinco años de seguimiento en pacientes mexicanos

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ABSTRACT

Introduction: Laparoscopic gastric plicature (LGP) is an emerging bariatric procedure considered effective and safe for weight loss. **Objective:** To determine the percentage of excess of weight loss (%EWL), BMI, percentage of excess of BMI loss (%EBMI), and postoperative morbidity and mortality in a five-year follow-up of patients submitted to LGP. **Material and methods:** Analytical study based on the data of case files of patients who underwent LGP during 2012, with a five-year follow-up, and evaluations at three, six, 12, 36 and 60 postoperative months. **Results:** A total of 40 patients were included, with a mean age of 36.2 ± 8.2 years; preoperative weight and BMI were 105.8 ± 18.9 kg and 39.2 ± 5.5 kg/m^2, respectively. The %EWL was of 60.3% after one year, and 51.8% after 60 postoperative months. Weight, BMI, %EWL, and loss of excess BMI (% EBMI) were statistically significant in contrast to preoperative measures ($p < 0.001$). No changes were observed from 12 to 36 postoperative months. A significant regain of weight was observed from 36 to 60 postoperative months. Three reinterventions were required because of internal bleeding, and two conversions to Roux-en-Y gastric bypass. **Conclusion:** LGP is an effective bariatric procedure for weight loss, with an important % EWL observed after five years post-surgery.

RESUMEN

Introducción: *La plicatura gástrica laparoscópica (LGP) es una cirugía bariátrica reciente que es considerada segura y efectiva para la pérdida de peso del paciente con obesidad.* ***Objetivo:*** *Determinar el porcentaje de pérdida del exceso de peso (%EWL), IMC, porcentaje de pérdida del exceso de IMC (%LEBMI), morbilidad y mortalidad postoperatorias en pacientes operados de LGP con cinco años de seguimiento.* ***Material y métodos:*** *Estudio observacional analítico realizado mediante captura de datos de los expedientes de pacientes sometidos a LGP durante el año 2012, con su evolución a cinco años postoperatorios, con revisiones a los tres, seis, 12, 36 y 60 meses postoperatorios.* ***Resultados:*** *Se revisó la historia clínica de 40 pacientes con edad promedio de 36.2 ± 8.2 años, peso e IMC preoperatorios de 105.8 ± 18.9 kg y 39.2 ± 5.5 kg/m^2, respectivamente. El %EWL fue de 60.3% en un año y de 51.8% en cinco años. El peso, IMC, %EWL y pérdida del exceso de IMC (%LEBMI) tuvieron cambios estadísticamente significativos respecto a los valores preoperatorios ($p < 0.001$); no hubo cambio significativo del peso de los 12 a los 36 meses postoperatorios. Se observó un incremento de peso significativo de los 36 a los 60 meses postquirúrgicos. Fueron requeridas tres reintervenciones por hemorragia y dos conversiones a derivación gástrica en Y de Roux.* ***Conclusión:*** *La LGP es efectiva para la pérdida de peso en pacientes con obesidad a cinco años postquirúrgicos.*

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INTRODUCTION

Obesity is globally a major health problem that affects nearly 300 million people[1-3] and represents a significant economic burden on health care systems.[4-6] By 2050, the proportion of Mexicans with normal weight will decrease 12% in men and 9% in women. There will be more obese, than overweight people. For that year, it is projected that there will be around 12 million cases of cumulative incidence of diabetes mellitus, and about eight million accumulated cases of heart disease.[7]

Bariatric surgery is currently the most effective treatment for obesity, allowing significant and sustained weight loss that solves and improves many of the associated comorbidities, which in turn improves the quality of life of the obese patient in a substantial way.[8,9] Multiple studies and meta-analyses confirm a considerable reduction of the percentage of excess weight loss (%EWL) after laparoscopic gastric plication (LGP).[2,10-18]

Both, the gastric sleeve (GS) and the Roux-en-Y gastric bypass (RYGB) are the procedures for the management of obesity regularly performed with a greater frequency. With them, %EWL of up to 65% to 70% are observed.[12,19] However, these surgical procedures are associated with considerable morbidity.[4,12] Among the postoperative complications of these procedures, wound infection stands out in the RYGB (3%), anastomotic leakage (0.1 to 8.3%), and, in the long term, anastomotic stenosis (4.7%), as well as internal hernia (1.1%).[18] As for major complications, these occur in up to 5% of cases.[19,20] and include reoperation in up to 12.6% of them.[1] The mortality rate is around 0.2% for laparoscopic surgery and 0.9% for open surgery. On the other hand, GS is an increasingly used bariatric technique, also with a significant risk of leakage of up to 1.4-7%. Bleeding occurs in approximately 3.5% of cases.[21,22]

Laparoscopic gastric plication (LGP) is a recent, restrictive and reversible bariatric technique performed worldwide.[10] Multiple meta-analyses show that it is effective in a sustained weight loss[6-12] and consider it a safe procedure that achieves a %EWL 40 to 70%, with a low prevalence of postsurgical complications compared to other bariatric procedures[1,8,10,11,13-16] and a shorter hospital stay.[1,9,11]

This surgical technique consists in creating a gastric restriction without the use of implants or gastric resections,[10,14,15] it is potentially reversible and minimally invasive. The use of mechanical sutures and cuts is not required; therefore, the risks of fistulas, leakage, hemorrhage and nutritional deficiency are minimized, with a lower morbidity and mortality rate.[2,3,15,16] Recent reports have found that LGP is effective in promoting remission of type 2 diabetes mellitus and high blood pressure after one year of surgery. There are also favorable changes in the lipid profiles of patients.[2] Furthermore, studies indicate that the total cost of this procedure is almost half that of a RYGB or GS.[17]

This surgical technique has been published with certain variations by multiple surgical groups, which report the development of a gastric tube by means of an invagination or plication of the greater curvature of the stomach, using stitches that span from the fundus to the pylorus.[14,15]

This technique can provide an attractive, less invasive and significantly less expensive alternative for a wide group of potential candidates.[3] However, there are very few long-term follow-up reports, even in the Mexican population.

Study objective: To evaluate the percentage of loss of excess BMI (%LEBMI), as well as %EWL in Mexican patients undergoing LGP with a follow-up of five years of evolution.

MATERIAL AND METHODS

An analytical study was carried out from records of patients undergoing LGP during 2012. The demographic variables analyzed included sex, weight, BMI, %EWL, %LEBMI and evolution at five postoperative years, with evaluations at three, six, 12, 36 and 60 postoperative months. The inclusion criteria

were a BMI greater than or equal to 40, or from 30 to 39.9 kg/m^2 with one or more comorbidities, an age of 18-55 years, and previous unsuccessful weight loss attempts. Participants were required to sign an informed consent form prior to surgery.

Laparoscopic gastric plication technique

Under general anesthesia, patients were placed in the English position and a laparoscopic approach with placement of three ports was performed. The greater curvature of the stomach was liberated, from a 3 centimeter distance proximal from the pylorus, to the esophagogastric (EG) junction and adhesions were released. The greater curvature was invaginated upon itself, by placing simple stitches with 2-0 polyester for the foreground, and 0-0 polypropylene (Prolene®) for the background. The first stitch was placed one centimeter below the EG junction in the posterior fundus, with a two centimeter space between each stitch: Then, intermediate stitches were placed over the invaginated tissue, with a second line of non-absorbable suture, reinforcing the plicature. At the points closest to the pylorus, the invagination was attenuated, to avoid impacting the invaginated tissue on the pylorus; the plicature is finished five centimeters above the pylorus. Hemostasis is verified and the trocars are removed. Aponeurosis and skin were closed.

Postoperative care and follow-up

Once clear liquids were tolerated, the patients were discharged. Clear liquid diet was indicated for the first week and complete liquids for another week, continuing with porridge and a soft diet. Each patient was summoned every two weeks during the first month, and monthly during the first year. Subsequently, they were summoned every six months, until completing the five-year follow-up. Body composition was evaluated by bioimpedance measurement system by means of a low-frequency signal, using a Tanita BC-543® scale. Also, a food tolerance and medical and nutritional follow-up laboratory tests such as blood count (red blood cells, hemoglobin, hematocrit, mean corpuscular volume, mean hemoglobin concentration, leukocytes and lymphocytes, etc.), blood chemistry (glucose, urea, creatinine, uric acid), electrolytes (sodium, potassium, chlorine, magnesium), profile lipid (cholesterol and triglycerides) and vitamins were measured as required.

Statistical analysis

Descriptive statistics with frequencies, percentages, mean and standard deviation were used. Student's t-test and ANOVA were used for repeated measures on quantitative variables and χ^2 test or Fisher's exact test for qualitative variables. A value of $p < 0.05$ was considered statistically significant. Statistical Package of Social Science (SPSS version 20; IBM Company, New York, NY, USA) was used for statistical analysis.

Ethical considerations

The study was carried out under the guidelines established in the Declaration of Helsinki of the World Medical Association (WMA) and with the provisions established in the General Health Law of Mexico, Title Five, and the Regulation of the General Health Law in Research Matters for Health, as well as the Official Mexican Standard (*Norma Oficial Mexicana, NOM*) NOM-012-SSA3-2012. The protocol was registered at ClinicalTrials.gov: NCT03210207 and approved by the Ethics Committee of Puerta de Hierro Medical Center, Guadalajara, Jalisco. There are no conflicts of interest.

RESULTS

A total of 40 patients were included, 15% male (n = 6) and 85% female (n = 34). The mean age was 36.2 ± 8.2 years, with a minimum of 24 and a maximum of 55 years. Preoperative weight and BMI were 105.8 ± 18.9 kg and 39.2 ± 5.5 kg/m^2, respectively.

The results of the analysis of variance (ANOVA) of anthropometric variables *(Table 1)* at three, six, 12, 36 and 60 months of follow-up in weight, BMI, %EWL and %LEBMI showed

Table 1: Results of anthropometric variables over time.

	Preoperative values	3 months	6 months	12 months	36 months	60 months	p value (ANOVA)
Weight (kg)	105.8 ± 18.7	91.9 ± 17.5	85.7 ± 17	81.4 ± 19	81.5 ± 19.4	84.6 ± 19.6	0.001
*BMI (kg/m^2)	39.2 ± 5.4	34.1 ± 5.4	31.8 ± 5.4	30.23 ± 6.01	30.2 ± 5.8	31.3 ± 6.02	0.001
**%EWL	---	34.7 ± 16.2	49.5 ± 20.8	60.3 ± 24.7	59.4 ± 24.9	51.8 ± 26.1	0.001
***%LEBMI	---	41.1 ± 21.2	58.5 ± 27	70.9 ± 30.5	69.7 ± 30.3	60.8 ± 31.3	0.001

*BMI = body mass index, **Percentage of excess weight loss, ***Percentage of loss of excess BMI.

a total change from start to end which was statistically significant (p = 0.001).

Within the weight loss observed for each interval *(Figure 1)*, it can be seen that it was statistically significant during the first postoperative year, 81.4 ± 19 kg (p = 0.001). This value, though, was maintained without significant changes from months 12 to 36 (p = 0.912). At the end of five-year period, a significant increase in average weight of four kilograms was observed (p = 0.002).

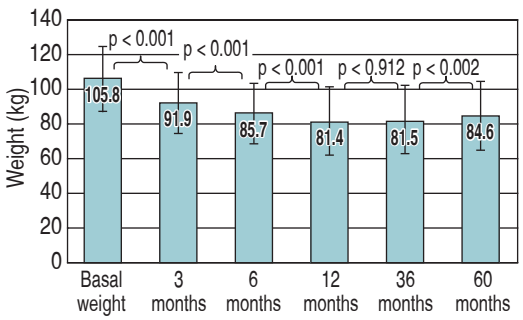

Figure 1: *Variability in weight during postoperative follow-up.*

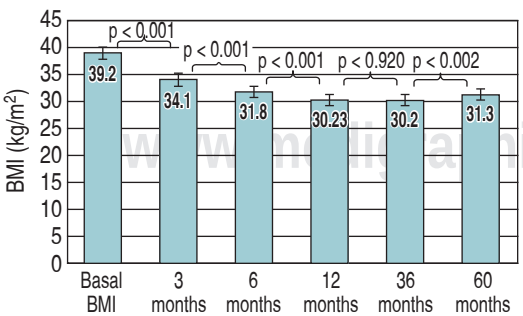

Figure 2: *Variability in the body mass index during the postoperative follow-up.*

BMI behaved in the same way as weight, with a constant significant reduction up until the first year (p = 0.001), with no significant changes observed at three-year follow-up. After five years, an average gain of 1 kg/m^2 was observed *(Figure 2)*, this increase being statistically significant (p = 0.002).

The increase in %EWL was 60.3% in one year and 51.8% in five years *(Figure 3)*, and the %LEBMI *(Figure 4)* was statistically significant (p = 0.001) until the first follow-up year, remaining stable at 36 months, without significant changes. On the other hand, a significant decrease in the reduction was observed in both values analyzed at the five-year follow-up for %EWL (p = 0.006) and %LEBMI (p = 0.001).

Regarding postsurgical complications, three early surgical reoperations (7.5%) were reported due to intra-abdominal hemorrhage from the gastro-plicature, without significant difference. Likewise, two patients were converted to RYGB due to failure in losing weight (5%). No mortality was observed in the is series of patients.

DISCUSSION

Obesity is currently a worldwide epidemic. During 2004 in Mexico, comorbidities related to obesity caused 75% of all deaths and 68% of disabilities adjusted to life years.[3,15,16]

Because the number of morbidly obese patients is increasing, more people require treatment, but access to health resources is

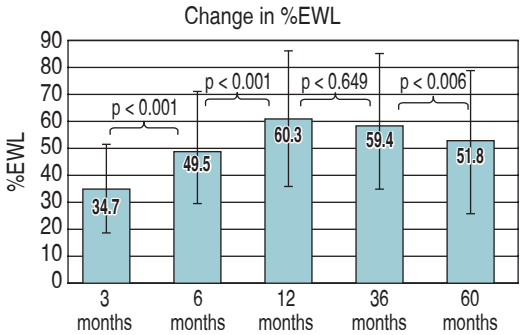

Figure 3: *Variability in the percentage of excess weight loss during the postoperative follow-up.*

limited.[5,6] In developing countries, bariatric surgery may be a limited option for the population due to its total cost. A more economic procedure can be attractive to patients, as they decide which procedure to undergo.

LGP is a restrictive procedure, similar to GS, but it does not have the malabsorption components or tissue resection, nor does it involve the placement of a foreign body. Multiple studies describe the use of LGP worldwide for the treatment of obesity, whether with short, medium or long-term follow-ups.[2,18,21] Ji and colleagues, in 2014, published a systematic review of a total of 1,407 patients undergoing LGP, where they described a %EWL of 31.8% at six months and 74.4% at 24 months after surgery.[12] Only Talebpour and his group achieved a 12-year postoperative follow-up of 800 patients. The %EWL observed at five years was 55%, and 42% at 10 postoperative years, with some postoperative technical complications (1%) and a low reoperation rate (1%).[18] Similar results were registered in the present study, a statistically significant %EWL of 51.8% at five years was found. Longer follow-up would yield stronger evidence in this regard, so it is still necessary to monitor this cohort of patients.

Both studies manage to show the reduction of more than 50% of excess weight in the long term by means of LGP. Furthermore, the effectiveness and complication rates are comparable to other bariatric surgeries, but at a lower cost, since it does not use surgical staplers or bands and installation of no device is required. This makes LGP a cheaper and more attractive procedure for obese patients.[18]

Our study aimed to describe the long-term evolution of LGP operated patients, up to five years. We found that the %EWL was 60.3% in one year and 51.8% in five years. This loss of excess weight is similar to that reported by many authors,[11,16] as well as in the study by Talebpour and colleagues, where the %EWL at five-year follow-up was up to 55%.[18]

The highest %EWL observed in our patients was obtained in the first postoperative year, also with the greatest reduction in %LEBMI (60.3 ± 24.7% and 70.9 ± 30.5%, respectively). The reduction obtained in the first six months after surgery was remarkable, since the desirable 50% EWL was reached, which shows LGP to be an effective bariatric surgery in this series of patients. Complications observed in the present study were present in only three patients, who required reoperation (7.5%) due to internal bleeding. On the other hand, due to failure in weight loss, LGP was converted to RYGB in two (5%). This number of complications and conversions to another bariatric procedure were greater than those observed in other series of patients, which reported a 1.6% of postoperative complications and only 1% of reoperation.[18]

On the other hand, a significant recovery of weight was observed at the fifth year of follow-up as compared to the third postoperative year. However, the total weight loss recorded from the preoperative period was statistically significant. Similarly, Talebpour

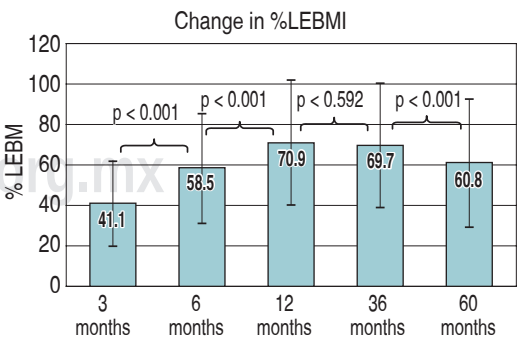

Figure 4: *Variability in the percentage of loss of excess BMI during postoperative follow-up.*

and his team observed weight gain at three, four, and five years after surgery, ranging from 70% of the %EWL obtained at 24 months, to 66% at three years, 62% at four years and 55% after five years of surgery.[18] Because of this, we must work closely with other factors that contribute to the patient's recovering of weight after surgery, such as rigorous monitoring of nutritional and psychological treatment. This, perhaps, will give patients more control over their eating habits.

CONCLUSION

We can affirm that LGP is a safe and feasible procedure for the treatment of morbid obesity. Longer follow-up and larger prospective comparative trials are needed to confirm the long-term results of this procedure. Although our study has significant limitations, such as the low number of patients and the simple design of the study, our results demonstrate that LGP is a feasible and safe bariatric procedure for short, medium and long-term weight loss in Mexican patients.

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