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NEW CONCEPTS

Laparoscopic Greater Curvature Plication: Initial Results of an Alternative Restrictive Bariatric Procedure

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Abstract
Background Vertical sleeve gastrectomy (VSG) is a surgical technique that involves resection of a significant portion of the stomach. This surgery is sometimes associated with gastric leaks, which can be difficult to treat. The present study reports findings from laparoscopic greater curvature plication (LGCP), which is an alternative bariatric procedure similar to VSG but without the need for gastric resection.
Methods A prospective study was carried out, following LGCP in 42 morbidly obese patients (30 female/12 male) with a mean age of 33.5 years (23 to 48) and mean BMI of 41 kg/m² (35 to 46). Through a five-port approach, the stomach was reduced by dissecting the greater omentum and short gastric vessels, as in VSG, and the greater curvature was then invaginated using multiple rows of non-absorbable suture performed over a 32-Fr bougie to ensure a patent lumen.
Results All procedures were completed laparoscopically. Mean operative time was 50 min (40 to 100 min) and mean hospital stay was 36 h (24 to 96). Patients returned to their regular activities at an average of 7 days (4 to 13) following surgery. No intra-operative complications occurred. All patients experienced excess weight loss (EWL) of at least 20% after 1 month. Mean EWL was 62% (45% to 77%) in nine patients after 18 months. There has been no record of weight regain in any patient to date.
Conclusions LGCP is feasible, safe, and effective for at least 18 months when performed on morbidly obese patients. Longer follow-up and prospective comparative trials are needed.

Keywords Laparoscopic bariatric surgery · Greater curvature plication · Morbid obesity · Vertical sleeve gastrectomy · Restrictive procedure

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Introduction

Morbid obesity is a growing health problem worldwide [1]. Clinical treatment with diet, exercise, and/or medication has not demonstrated sustainable clinically significant results [2]. There is substantial evidence in the literature on the long-term positive impact of bariatric surgery as a primary therapy for the treatment of obesity and its comorbidities. Significant debate remains as to which patients are optimal candidates for which procedures [3].

Traditionally, the primary mechanisms through which bariatric surgery achieves its outcomes are believed to be the mechanical restriction of food intake, reduction in the absorption of ingested foods, or a combination of both [4]. Adjustable gastric banding (AGB) and vertical sleeve gastrectomy (VSG) are restrictive approaches commonly used in bariatric practice. Although these procedures have proven to be good therapeutic options for some patients, they are not without significant complications, such as erosion or slippage of the gastric band or gastric leaks in VSG. Leaks in VSG pose a particularly difficult challenge when they occur near the Angle of His, potentially generating severe clinical conditions that require reoperation and may even cause death [5, 6].

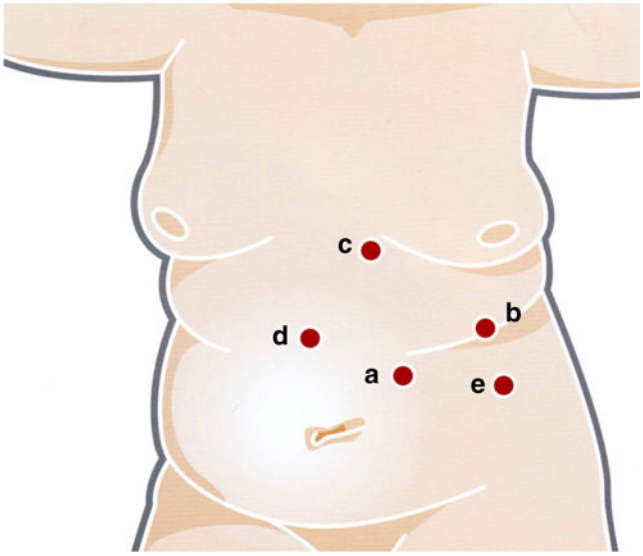

Fig. 1 Trocar position: a. 10mm above the umbilicus slightly to the right; b. 10mm in URQ; c. 5mm below xiphoid's appendices; d. 5mm in the ULQ; e. 5mm on the URQ at the axilary line

The aim of the present study was to investigate laparoscopic greater curvature plication (LGCP), which is a new restrictive bariatric surgical technique that has the potential to eliminate the complications associated with AGB and VSG by creating a restriction without the use of an implant and without performing gastric resection. Variations of this technique have recently been described by a few surgical groups [7–9].

Methods

The inclusion criteria followed the USA NIH criteria for bariatric surgery: patients needed to have a BMI over 40 kg/m² or BMI over 35 kg/m² with at least one comorbidity [10]. All patients underwent a multidisciplinary evaluation (endocrinologist, cardiologist, psychologist, and nutritionist). Blood tests, abdominal ultrasonography, and upper endoscopy were performed preoperatively to establish a baseline. The study design was a prospective non-comparative case series that received approval from the local ethics committee. All patients signed terms of informed consent.

From January 2007 to February 2009, 42 subjects (30 female and 12 males) were enrolled in the trial. Mean age was 33.5 years (ranging from 23 to 48 years) and mean BMI was 41 kg/m² (ranging from 35 to 46 kg/m²).

Surgical Procedure

All surgical procedures took place under general anesthesia with the patient in supine position (legs open). Closed pneumo-peritoneum was achieved using a five-trocar port technique similar to that employed in laparoscopic Nissen fundoplication. Trocar placement

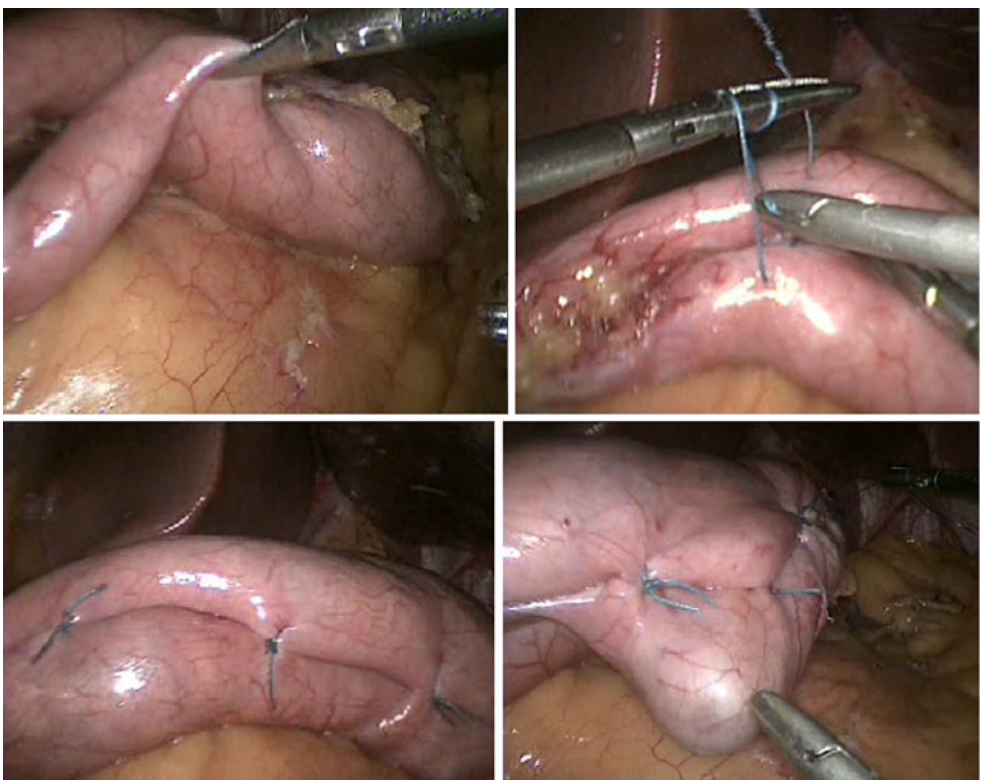

Fig. 2 Sequence of intra-operative pictures of initial suture line with interrupted non-absorbable suture

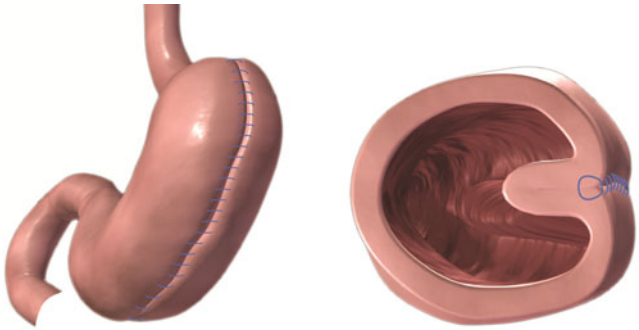

Fig. 3 Computerized drawing of the initial fold generated by first initial suture line

was as follows: one 10-mm trocar above and slightly to the right of the umbilicus for the 30° laparoscope; one 10-mm trocar in the upper right quadrant (URQ) for passing the needle, for suturing, and for the surgeon's right hand; one 5-mm trocar also in the URQ below the 10-mm trocar at the axillary line for the surgeon's assistant; one 5-mm trocar below the xiphoid appendices for liver retraction; and one 5-mm trocar in the upper left quadrant (ULQ) for the surgeon's left hand (Fig. 1)

The procedure began with the dissection of the Angle of His and the removal of the fat pad in this location, followed by careful dissection of the gastric greater curvature using the Harmonic™ scalpel (Ethicon Endo-Surgery, Inc., Cincinnati, Ohio) and opening the greater omentum at the transition between the gastric antrum and gastric body. Once access to the posterior wall was achieved, the greater curvature vessels were dissected distally up to the pylorus and proximally up to the Angle of His. Occasionally, posterior gastric adhesions were also dissected to allow optimal freedom for creating and sizing the invagination properly.

The next step was to initiate gastric plication by imbricating the greater curvature over a 32-Fr bougie and applying a first row of extra-mucosal interrupted stitches of 2-0 Ethibond™ (Ethicon, Inc., Somerville, NJ, USA) sutures (Fig. 2). This row (Fig. 3) guided two subsequent rows (Fig. 4) created with extra-mucosal running suture lines of 2-0 Prolene™ (Ethicon, Inc., Somerville, NJ, USA). The reduction resulted in a stomach shaped like a large sleeve gastrectomy (Fig. 5). Leak tests were performed with methylene blue in all cases. No drains were placed.

In the postoperative period, patients were discharged as soon as they accepted a liquid diet without vomiting and received a prescription of a daily proton-pump inhibitor (PPI; single dose) for 60 days. Ondasentron and the anti-spasmodic hyoscine were prescribed for 7 days. The postoperative diet was prescribed as follows: a customized liquid diet for 2 weeks, followed by a progressive return to solid foods in a stepwise fashion, with the dietary restrictions removed at 4 to 6 weeks, depending on patient acceptance.

Follow-up visits for the assessment of safety and weight loss were scheduled for 1 week and at 1, 3, 6, 12, 18, and 24 months in the postoperative period. Endoscopic evaluations were scheduled for 1, 6, and 12 months.

Results

All procedures were performed laparoscopically without conversions. Mean operative time was 50 min (40 to 100 min). Mean hospital stay was 36 h (24 to 96 h). On average, patients returned to normal activities 7 days (4 to 13 days) following surgery. Mean total weight loss (TWL) (Fig. 6) was calculated to be 10%TWL at 1 month (42 patients, 8% to 13%), 15%TWL at 3 months (33 patients, 10% to 17%), 22%TWL at 6 months (20 patients, 17% to 29%), 28%TWL at 12 months (15 patients, 23% to 32%), and 30%TWL at 18 months (nine patients, 25% to 36%). Mean percentage of excess weight loss (%EWL) (Fig. 7) was calculated to be 20%EWL at 1 month (42 patients, 20% to 29%), 32%EWL at 3 months (33 patients, 25% to 42%), 48%EWL at 6 months (20 patients, 31% to 56%), 60%EWL at 12 months (15 patients, 42% to 68%), and 62%EWL at 18 months (nine patients, 45% to 77%).

No intra-operative complications were documented. In the first postoperative week, however, nausea, vomiting, and sialoreia occurred in 20%, 16%, and 35% of patients, respectively. In all cases, these symptoms were resolved in no more than 2 weeks. There has been no record of weight regain in any patient to date.

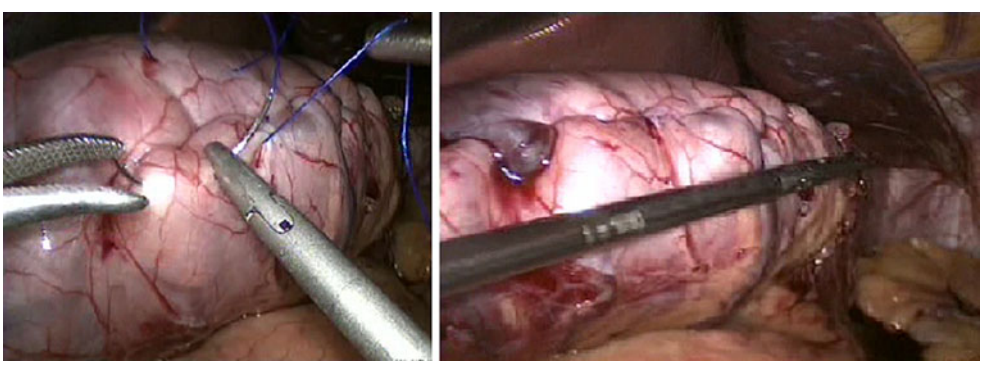

Fig. 4 Intra-operative pictures of the final suture line with running non-absorbable suture

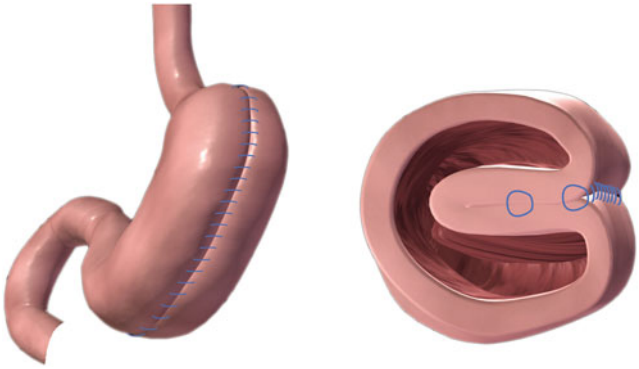

Fig. 5 Computerized drawing of the final aspect of LGCP procedure

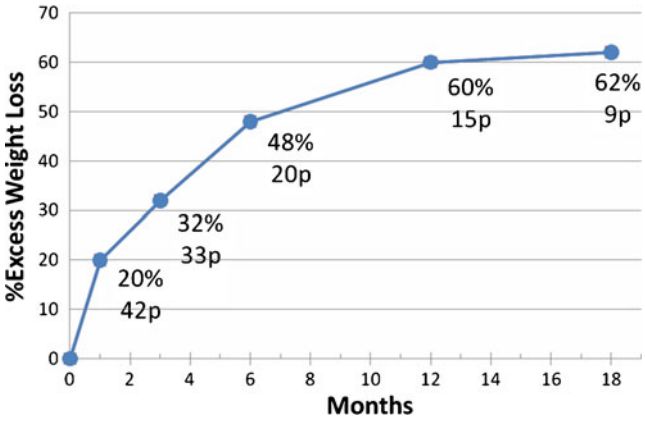

Fig. 7 Mean percentage of excess weight loss expressed in %EWL with the LGCP procedure at 1, 3, 6, 12, and 18 months

Postoperative upper endoscopy and radiologic evaluation were preformed on 12 patients at 1 and 6 months and in seven patients at up to 12 months. Qualitatively, the upper endoscopies suggest that the initial greater curvature fold is smaller at 6 months when compared with the initial fold size at 1 month but appears unchanged at 12 months. Mild esophagitis (Grade A of Los Angeles classification) occurred in three of the 12 patients at 1 month; these patients were symptomatic (nausea, vomiting, and sialoreia) and were kept on PPI, following the standard protocol. The 6-month endoscopic evaluation identified no lesions or symptoms. Lumen size appeared stable (e.g., no dilation) based on upper GI radiologic series performed on these patients at 1 and 6 months (Fig. 8).

Discussion

Reducing stomach capacity to promote mechanical restriction to food intake is one of the traditionally accepted mechanisms used in bariatric procedures to promote weight loss. There are at least two surgical procedures that appear to rely on this principle in current clinical practice, AGB and VSG [4]. AGB has been used for many years and offers surgical ease, adjustability, reversibility as well as low immediate mortality and morbidity rates [11]. In terms of weight loss, AGB achieves around 50%EWL, but unsatisfactory weight loss occurs in more than 20% of patients [3, 12]. AGB also has the disadvantage of requiring a long-term implant, which has been shown to dislodge and/or erode in the stomach in up to 11% of patients [13, 14]. This suggests a failure rate requiring surgical revision in up to 25% of patients [19]. These secondary procedures can be challenging and difficult [15].

VSG is a procedure initially used as the first stage of a definitive bariatric treatment known as the duodenal switch [16]. Vertical gastrectomy of the greater curvature is performed, resulting in a tubular stomach with the purpose of restricting food intake. As a primary bariatric procedure, medium-term results have been shown to be adequate

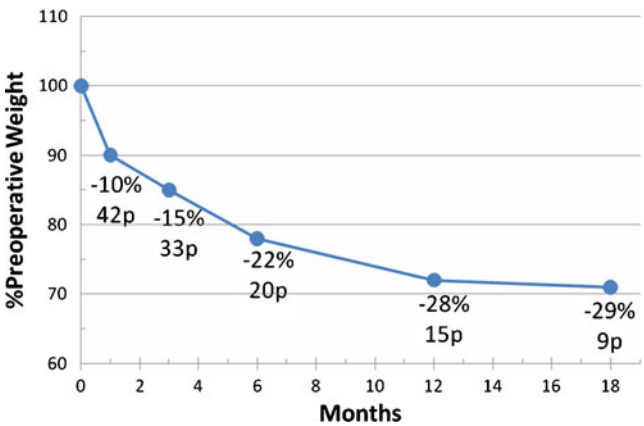

Fig. 6 Mean total body weight loss expressed in %TBW with the LGCP procedure at 1, 3, 6, 12, and 18 months

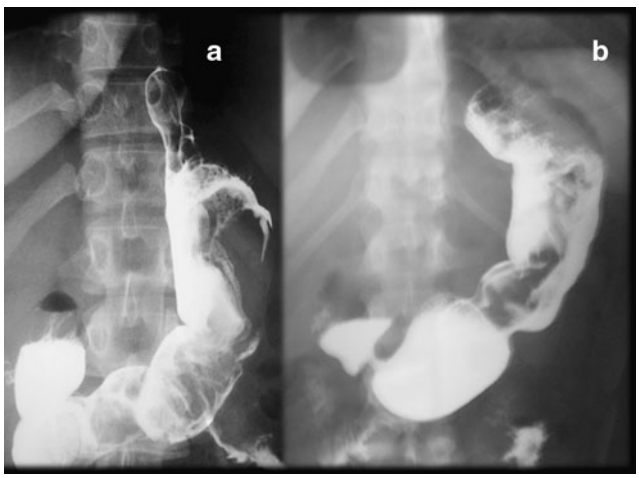

Fig. 8 Upper GI series of LGCP procedure at 1 month (A.) and 6 months (B.)

(greater than 60%EWL), with improvements in comorbidities such as type 2 diabetes, hypertension, and obstructive sleep apnea in more than 65% of cases [17]. These promising results are associated with some complications, however, such as esophagites, stenosis, fistulas, and gastric leaks near the Angle of His. These leaks and fistulas are reported in nearly 1% of cases and can be very difficult to treat [6, 16, 18].

Thus, a bariatric procedure that brings together the benefits of food restriction without the possible complications associated with a permanent implant while also minimizing the possibility of leaks from the rupture of staple lines is highly desirable and may be a preferred alternative restrictive procedure for some patients.

LGCP is notably similar to a VSG in that it generates a gastric tube by means of eliminating the greater curvature but does so without gastric resection. It is likely that LGCP greatly reduces the possibility for gastric leaks. Talebpour and Amoli report one case of a gastric leak associated with a more aggressive version of LGCP, which the authors attributed to excessive vomiting in the early postoperative period [7]. In two separate papers, Fusco et al. report efficacy in gastric plication procedures, as measured by changes in the weight progression of rats [20, 21]. In one paper, Fusco et al. report an increased effect from plication of the greater curvature when compared to plication of the anterior surface. These results are in agreement with initial clinical reports by Brethauer et al., who report an increased weight loss in patients receiving LGCP when compared to plication of the anterior surface [9].

In the present study, there were no conversions in a mean operative time of 50 min. This compares to findings reported in some series involving AGB, which has the lowest early complication rates among all bariatric procedures [3]. Moreover, there were no major complications to report in the present series. The adverse events described by patients were minor, such as nausea, vomiting, and hypersalivation, which were resolved quickly. These events may be related to the severity of the restriction induced by the invagination of the greater curvature and/or edema caused by venous stasis. A key difference between LGCP and VSG is the presence of the endolumenal fold. Qualitative endoscopic findings suggesting that the greater curvature fold gets smaller may be related with the resolution of the initial edema, although the radiological findings did not reveal significant dilation of the LGCP at 6 months

In terms of efficacy, there has been no weight regain and the EWL achieved a very satisfactory mark of 62% at 18 months in nine patients, with all patients achieving at least a 10% loss of initial weight. This can be favorably compared with results from VSG.

This study is not without significant limitations, such as the low number of patients, the simple study design, the lack of a control/comparative group, the non-inclusion of patients with a of BMI>50 kg/m², and the incomplete follow-up period. These limitations appropriately limit the broader acceptance of these results. However, the authors are currently carrying out new trials addressing some of the limitations of this initial study.

In conclusion, LGCP is a promising bariatric procedure and the present trial demonstrates it to be feasible, safe, and effective in the short term when applied to morbidly obese patients. Longer follow-up and prospective comparative trials are needed in order to broaden the acceptance of this promising procedure.

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