

Gastric plication for morbid obesity

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Abstract: Background: The field of bariatric surgery is continually evolving. Since the introduction of surgical procedures to induce weight loss, many different operations have been tried and discarded owing to the poor long-term weight loss and/or metabolic or mechanical complications. 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 from January 2010 to October 2013, following GCP in 30 morbidly obese patients (12 males/18 females) with a mean age of 33.5 years (23 to 60) 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 by open and laparoscopic surgery. Mean operative time was 50 min (40 to 100 min) and mean hospital stay was 2 days (2 to 5). 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. **Conclusions:** GCP is feasible, safe, and effective for at least 2 years when performed on morbidly obese patients. Longer follow-up and prospective comparative trials are needed.

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1. 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 co-morbidities. ^[3] Historically, many types of restrictive procedures have been performed to achieve weight loss. Most of these have been neglected owing to poor long-term weight loss, food intolerance, or severe gastro-esophageal reflux. These gastro-plastic procedures were designed to partition the proximal stomach horizontally or vertically, with a small outlet to achieve gastric restriction. ^[1] Vertical banded gastroplasty, in particular, has resulted in poor long-term outcomes, and a high percentage of vertical banded gastroplasty patients have required revision to Roux-en-Y gastric bypass to alleviate intolerable reflux symptoms and dysphagia or to achieve weight loss again. ^[2- 8] Currently, gastric restrictive procedures include laparoscopic adjustable gastric banding and sleeve gastrectomy. The placement of an implantable device or the irreversible resection of gastric tissue, however, has limited the acceptance of these procedures by some patients, referring physicians, and surgeons. More recently, endo-luminal technology has been

developed to achieve a similar restrictive effect. ^[9,10] However, these endoscopic therapies achieve restriction with mucosal apposition of the opposing gastric walls, and this has likely compromised the durability of these emerging procedures. In the present guide study, we aimed to demonstrate the probability, safety, and efficacy of laparoscopic gastric plication in which the stomach was infolded to establish serosa to serosa apposition and gastric restriction. 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 re-operation and may even cause death. ^[5,6]

The aim of the present study was to investigate greater curvature plication (GCP), 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.

Inclusion criteria

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 co-morbidity.^[9,10] All patients underwent a multi-disciplinary evaluation (endocrinologist, cardiologist, psychologist, and nutritionist). Blood tests, abdominal ultrasonography, and upper endoscopy were performed pre-operatively 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 2010 to October 2013, 40 subjects (28 females 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). The subjects were considered appropriate candidates for the present study if they were willing to give consent and conform with the evaluation and treatment schedule, were 21-60 years old (inclusive), had a body mass index (BMI) of 35 but 50 kg/m²; a BMI of 35- 40 kg/m² was allowable with 1 significant medical conditions related to obesity. The patients had to meet the National Institutes of Health criteria for bariatric surgery and demonstrate the absence of significant psychopathology that could limit their ability to understand the procedure and comply with the medical, surgical, and/or behavioral recommendations, according to our program's standard of care.

Exclusion criteria

The exclusion criteria included pregnancy or lactation at screening or surgery, a documented history of drug and/or alcohol abuse within 2 years of the screening visit, previous mal-absorptive or restrictive procedures performed for the treatment of obesity, the participation in any other investigational device or drug study (non survey based trial within 12 weeks of enrollment, and any condition that would preclude compliance with the study. Such conditions included inflammatory diseases of the gastro-intestinal tract within the previous 10 years, congenital or acquired anomalies of the gastro-intestinal tract (e.g., atresia or stenosis), severe cardio-pulmonary disease or other serious organic disease making the subject a high-risk surgical candidate, uncontrolled hypertension, and portal hypertension.^[14,15] Additional exclusion criteria included treatment with 50 U/day of insulin, chronic or acute upper gastrointestinal bleeding conditions (e.g., gastric or esophageal varices), cirrhosis, congenital or acquired intestinal telangiectasia, esophageal or gastric disorders (i.e., moderate to severe pre-operative reflux, dysmotility, or Barrett's

esophagus), hiatal hernia, previous surgery of the foregut (i.e., hiatal hernia repair or previous gastric surgery), pancreatitis, an immune-compromised status or autoimmune connective tissue disease, and the use of prescription or over the counter weight reduction medications or supplements within 30 days of the screening visit or during study participation.^[14]

Surgical procedures

Two different procedures were used to achieve laparoscopic gastric volume reduction. In the first group (AP), the anterior gastric wall was folded inward from the fundus to the antrum using 2 rows of 2-0 polypropylene running suture. The greater and lesser curvatures were approximated on the anterior surface of the stomach to create an intra-luminal fold (Fig. 1). In the second group (GCP), the short gastric vessels were divided starting 4 cm from the pylorus and continuing up to the left crus of the diaphragm, similar to the dissection performed for sleeve gastrectomy. After the fundus and body were completely mobilized, the greater curvature was folded inward with 2 suture lines of 2-0 polypropylene suture to create a large intra-luminal gastric fold (Fig. 2). 1 week after surgery, and at 1, 3, 6, and 12 months post-operatively. The subjects completed the visual analog scales for pain after the procedure and before discharge from the hospital.



Patients and Methods

The present study was a prospective, non-randomized feasibility study of 2 gastric plication techniques. The review board approved the present study, and the patients were screened and recruited for enrollment from our standard outpatient population. The consent process was conducted and supervised by the attend surgeon. The patients who attended our program's informational seminars were offered an opportunity to participate in this (and several other) research studies conducted by our surgeons. The present investigational procedure was offered in addition to the standard procedures performed in our program (i.e., gastric bypass, laparoscopic adjustable gastric banding, and sleeve gastrectomy). The patients who expressed interest in the gastric plication procedure participated in an initial screening process conducted by the study co-ordinator. The patients who

met the criteria for the present study were then evaluated by the surgeon. During the surgeon visit, the details of the procedure were discussed, and it was clearly stated to the patient that these procedures were investigational. As we gained some experience with each procedure, our early findings and complications were discussed with the subsequent potential patients. No emergency plans were made or agreed to at this point for if the weight loss were to be sub-optimal or un-expected complications occurred, except that these issues would be handled on a case-by-case basis at the judgment of the surgeon. No cross-overs were planned to another procedure in the protocol. The anterior plication (AP) procedures were performed first in our series, with the greater curvature plication (GCP) procedures performed subsequently. This was per protocol and not because of lower weight loss in the AP group. In the present feasibility study, we believed that gaining experience with both procedures would be valuable, and the comparative outcomes would guide our future research. Patients who agreed to proceed in the present study signed the informed consent document and underwent a second level of screening, including laboratory tests, a routine preoperative evaluation, and evaluations by psychologists and nutritionists. Once the patient was cleared by the psychologists and nutritionists and their medical evaluation was complete, they were scheduled for surgery. No costs were included in the budget for re-operation in the case of weight loss failure.

Surgical Procedure of GP

All surgical procedures took place under general anesthesia with the patient in supine position. Closed pneumo-peritoneum was achieved using a five-trocar port technique similar to that employed in laparoscopic Nissen fundoplication. Trocar placement 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. 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 and opening the greater omentum at the transition between the gastric antrum and gastric body. (Fig. 3) 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 Vicryle (Fig. 4.5). This row guided two subsequent rows created with extra-mucosal running suture lines of 2-0 Prolene. The reduction resulted in a stomach shaped like a large sleeve gastrectomy (Fig. 6). Leak tests were performed with methylene blue in all cases. No drains were placed. In the post-operative 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 post-operative 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.



All procedures were performed laparoscopically without conversions. Mean operative time was 90 min (60 to 120 min). Mean hospital stay was 48 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) 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) 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 post-operative 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. Post-operative upper endoscopy and radiologic evaluation were performed 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 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.

Table 1: Excess weight loss for anterior Gastric plications Procedure

Visit (mo.)	Patients (n.)	Mean% EWL	±SD
1	9	17.8	5.3
3	9	23.4	6.2
6	6	28.4	10.7
12	5	23.3	24.9

Table 2: Excess weight loss for Greeter curvature Gastric plications Procedure.

Visit (mo.)	Patients (n.)	Mean% EWL	±SD
1	6	23.3	4.9
3	6	38.5	7.9
6	6	49.9	12.1
12	6	53.4	22.7

4. 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] The field of bariatric surgery is continually evolving. Since the introduction of surgical procedures to induce weight loss, many different operations have been tried and abandoned owing to the poor long-term weight loss and/or metabolic or mechanical complications. During the past decade, the use of sleeve gastrectomy has gained popularity, and it has become widely accepted as a primary bariatric operation, as well as a first stage operation for high-risk patients. Five-year data are now emerging that supports the durability of sleeve gastrectomy.^[12,13] The creation of a long staple line during sleeve gastrectomy can lead to complications, such as leaks and bleeding, and the irreversibility of this operation has been a detractor for some surgeons and patients.^[14] The gastric plication operations evaluated in the present study are intended to mimic some of the effects of sleeve gastrectomy (gastric restriction) without the same degree of risk. The initial procedure concept of plicating the anterior stomach was intriguing, because it did not require division of the short gastric vessels or mobilization of the greater curvature and could potentially reduce the risk to the patient.^[26, 27] The GCP procedure does not require division of the short gastric vessels, but it does not require stapling or resection and therefore might have some advantages compared with sleeve gastrectomy. The mechanisms of GCP have not yet been studied. Because gastric resection is not performed, it is unlikely that the ghrelin levels will decrease as they do with sleeve gastrectomy. Our subjective clinical experience with the present small group of patients has demonstrated reasonably good hunger control but to a lesser degree than what we have observed after sleeve gastrectomy. Patients have reliably reported early satiety during meals and pain with any overeating. As experience increases with this procedure, mechanistic studies will be needed with an emphasis on gut hormone and gastric emptying changes.^[12,13] Gastric plication relies on serosal adhesion formation within the fold to maintain durability. Menchaca et al. have demonstrated short-term durability and fibrous serosal apposition in gastric folds using a variety of suture materials.^[14] Ramos et al. have recently reported their results for 42 patients who underwent laparoscopic GCP.^[15] No intra-operative complications occurred, and all patients experienced a %EWL of 20% after 1 month. The mean %EWL was 62% (range 45-77%) in 9 patients after 18 months.^[15] A study by Sales reported 69.6% EWL at 1 year in 100 patients.^[16] That study included patients with a lower BMI, with 69% of patients having a pre-operative BMI of 45 kg/m² and 25% having a BMI of 35 kg/m². No major complications or mortality was reported in that series.^[16] Talebpour and Amoli have published the largest

series to date using the laparoscopic GCP technique. In their report, the investigators described a slightly more restrictive GCP procedure than was performed in our present study. They reported the results from 100 patients who had undergone GCP.^[17] Their study has clearly demonstrated that gastric perforation or leak from the suture line can occur and that this type of procedure cannot eliminate these risks completely. The possible mechanisms for post-operative gastric perforation include acute distension of the stomach or severe vomiting with a resultant full-thickness tear at the suture line, as well as delayed thermal injury of the stomach that occurs during division of the short gastric vessels, particularly if the attachments to the upper pole of the spleen were very short. Therefore, the possibility of gastric leak must be considered after these operations if a patient develops any signs of infection or early sepsis. The concern for a gastric leak should prompt a radiographic evaluation or re-exploration. We had 1 patient who required reoperation because of obstruction of the gastric lumen by the intra-luminal fold. This was the first GCP procedure we performed, and we did not account for the considerable amount of edema and venous congestion that occurs in the fold post-operatively.

This resulted in obliteration of the gastric lumen by the edematous fold. The area of the incisura is at particularly high risk of this complication if the intra-luminal fold infringes on the lesser curvature or creates a kink in the lumen. Although this problem can potentially be managed in non-operatively to allow the edema to resolve, this was early in our experience and the patient was quite uncomfortable owing to the severe nausea and an inability to tolerate liquids. We have not seen any new-onset or worsening of gastro-esophageal reflux during our follow-up period. The fundus was mobilized and the GCP was started 1 or 2 cm below the angle of His. This disruption of the normal anatomy could potentially lead to gastro-esophageal reflux, particularly because the procedure does not involve resecting the stomach but simply folding the stomach in. In contrast, the upper part of the fold can be seen endoscopically as the scope passes through the gastro-esophageal junction. This fold could potentially serve as an antireflux mechanism; however no physiologic data are available yet to support this idea. In our limited experience, however, gastro-esophageal reflux has not been a problem after GCP. Additional studies are required to assess this potential long-term complication. The results from our small series have compared favorably to those of the small number of published GCP series in terms of safety and efficacy. All studies have reported rapid weight loss similar to that seen with sleeve gastrectomy, and the small number of patients in published study who have reached 3 years of

follow-up have maintained 57% EWL. No other study has evaluated the AP procedure in humans. In our small feasibility study, the AP procedure did not result in any major complications. The weight loss for this procedure in its current form at 1 year (23% EWL), however, would not justify the risk of surgery for the morbidly obese patient. The patients did have encouraging weight loss initially (and 2 have had sustained weight loss), but the remaining volume of the posterior stomach after only the anterior surface was plicated did not provide a sustained effect. The failure of 4 patients in the AP group to return for the 1-year endoscopic evaluation was likely because of a poor weight loss result. We do not believe laparoscopic AP warrants additional investigation. This concept does potentially have promise if it could be reproduced using a less-invasive endoscopic approach, however. No patient in the AP group requested reoperation or conversion to another procedure. Revisional options for these patients would include repeat plication to achieve improved restriction, revision to sleeve gastrectomy, or conversion to gastric bypass. Well-established serosa-to-serosa adhesions were present, but a dissection plane could be developed similar to that for other gastric revisional procedures. Our present study was limited to patients with a BMI of 35-50 kg/m². From our early results, the GCP is an effective procedure in this BMI range. Similar to other bariatric surgery options, patient preference, expectations, and risk tolerance play important roles in the procedure selected. GCP does offer rapid weight loss without gastric resection or an implanted device, and this is likely to appeal to many patients. Although reversibility has not been definitively proved, we believe this procedure can be reversed and that this will also be a factor in some patients' decision-making.^[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 (greater than 60% EWL), with improvements in co-morbidities 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 esophagitis, 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, and 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.^[19] 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 post-operative period.^[7] In two separate papers, Fusco et al. report an increased effect from plication of the greater curvature when compared to plication of the anterior surface.^[12, 13] 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.^[6, 21] A key difference between LGCP and VSG is the presence of the endo-luminal 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.^[22,23] 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 BMI > 50 kg/m², and the incomplete follow-up period.

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.

Endoscopic evaluation

The patients were excluded from the present study if they had a hiatal hernia documented at an endoscopy or upper gastro-intestinal contrast examination before screening for surgery. The patients underwent upper endoscopy at surgery to evaluate for any findings that would disqualify the patient from the present study. The patients were made aware during the consent process that if any Dis-qualifying condition was discovered during the initial endoscopy in the operating room, the surgeon would not proceed with the planned gastric plication procedure. The endoscope was left in place during the plication procedure. Intra-operative endoscopy provided guidance in terms of the size and shape of the fold being created. It also confirmed that full-thickness bites had been taken during creation of the plications. In the present initial series, full-thickness bites were placed to demonstrate safety of this suture depth with a mono-filament non-absorbable suture in the gastric tissue and to eliminate the depth of suture placement as a variable in plication durability. We performed post-operative endoscopy in the outpatient setting at 3, 6, and 12 months post-operatively to assess plication durability. Pre-and post-operative upper gastro-intestinal contrast studies were not performed because the endoscopic appearance of the folds was the primary concern, and endoscopy provided the necessary information to achieve the goals of the present study.

Follow-up endoscopy;

The 9 patients who underwent GCP, 4 did not attend the 12-month follow-up clinic visit or endoscopic evaluation. The 5 patients who had completed the 6- and 12-month endoscopic evaluations had comparable size plications at both follow-up points. One patient had a partially disrupted distal fold found at the 3-month endoscopic evaluation. At 12 months, additional fold disruption was noted in this patient. Durable intra-luminal folds were seen in 5 patients. The sixth patient had disruption of the distal portion of the fold owing to a broken suture noted on endoscopy. The proximal two thirds of that patient's fold were intact at 12 months post-operatively.

Weight loss;

The weight loss data for both groups at 1 year are listed in (Table 1). At 1 year, the %EWL for the AP and GCP groups was 23.3% and 53.4%, respectively. The difference in weight loss for the 2 groups was marginally statistically significant ($P = .0649$) at the 12-month visit using a 2-sample (t test). Because the present study was a feasibility trial with a small sample size (and low retention in the AP group), this result was not unexpected. The difference in the %EWL between the AP and GCP groups across visits was statistically significant ($P = .0078$). The AP group

had an average decrease in BMI of 4.7 kg/m² (range 43.1-37.6; mean 10.7% decrease in BMI recorded at 1 year). The change in BMI was not statistically significant for the AP group. The GCP group had an average decrease in BMI of 10.7 points (*P*.054). The mean BMI decreased from 43.7 to 32.9 kg/m², a 24.4% change in BMI at 1 year (*P* .0001). The percentage of change in BMI compared with the AP group was significantly different statistically across visits (*P*.0001).

Complications

No bleeding or infectious complications were found. The first patient in the GCP group required re-operation and plication reduction because of gastric obstruction 2 days after the initial procedure. Mild to moderate nausea occurred in all patients (2 severely) and had resolved within 2 weeks in all patients. At 11 months after GCP, 1 patient required laparoscopic cholecystectomy for acute cholecystitis. No complications associated with using full-thickness, mono-filament sutures were noted in either group. No patients reported new onset gastro-esophageal reflux or worsening of their existing reflux (patients with moderate to severe reflux were excluded) during the follow-up period.

Quality of life

The AP group had no significant change at the 12-month visit compared with the baseline scores. However, the GCP group showed significant improvement (*P* .001) for the physical component score at 12 months but not the mental component score, because the mean scores had returned to the baseline values by month 12. Although not statistically significant, all subjects in the GCP group had noted an increase in energy by the 12-month visit. Of the 6 subjects in the GCP group, 5 noted that pain did not interfere with their normal work at the 12-month visit.

The overall (total) IWQOL score had improved significantly (*P* .0086) in the GCP group at the 12 month visit. No statistically significant improvement (*P*.3753) was observed for the AP group. Both the AP (*P* .0179) and GCP (*P* .0069) groups had significant improvements from baseline through all post-procedure visits.

Percentage of excess weight loss %EWL [(weight at baseline weight at each visit)/ (weight at baseline ideal body weight)] 100). *P*.001 (type III F-test) for visit effect determined using repeated mixed model with %EWL and following covariates: visit, procedure, and visit procedure. *P* .033 (type III F-test) for procedure effect determined using repeated mixed model with %EWL and following covariates: visit, procedure, *P* .0078 (type III F-test) for interaction effect between procedure and visit determined using repeated mixed model with %EWL and following

covariates: visit, procedure, and visit procedure. *P* .065 for difference between procedure groups at 12 months using 2-sample (t test.0282) in the GCP group. No statistically significant improvements were seen in the AP group at the conclusion of the treatment period.

Conclusion

Our initial experience has suggested that a reduction in gastric capacity can be achieved using plication of either the anterior stomach or greater curvature. The early weight loss results were encouraging, with better weight loss for the patients who underwent GCP. GCP is promising from a risk/benefit standpoint and warrants additional investigation. A multicenter prospective trial is ongoing.

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