



Original article

Laparoscopic gastric plication for treatment of severe obesity

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Abstract

Background: Current gastric restrictive procedures include either a prosthetic device or gastric resection. We present the results of a feasibility study using laparoscopic gastric plication for weight loss achieved without stapling or banding.

Methods: After institutional review board approval, 2 methods were used to achieve laparoscopic gastric volume reduction. In the first group (anterior plication [AP]), the anterior gastric wall was folded inward from the fundus to the antrum using 2 rows of running sutures. The greater and lesser curvatures were approximated to create an intraluminal fold of the stomach. In the second group (greater curvature plication [GCP]), the short gastric vessels were divided, and the greater curvature was folded inward, with 2 suture lines to reduce the gastric capacity by a large intraluminal gastric fold.

Results: The average preoperative body mass index was 43.3 kg/m² (range 36.9–49.0), and 3 patients were men. Of the 15 patients, 9 underwent AP. For the 9 patients who underwent AP, the 6- and 12-month endoscopic evaluations demonstrated comparable-size plications over time, except for in 1 patient, who had a partially disrupted fold. Of the 6 patients who underwent GCP, the 6- and 12-month follow-up endoscopic examinations demonstrated a durable intraluminal fold, except for in 1 patient, with a partial disruption at the distal fold owing to a broken suture. For patients completing 1 year of follow-up, the percentage of excess weight loss was 23.3% ± 24.8% in the AP group (n = 5) and 53.4% ± 22.7% in the GCP group (n = 6). No bleeding or infectious complications developed. The first patient in the GCP group required reoperation and plication reduction owing to gastric obstruction.

Conclusion: Our initial experience has suggested that a reduction in gastric capacity can be achieved by way of plication of the anterior stomach and greater curvature. The early weight loss results have been encouraging, with better weight loss in patients who underwent GCP. The use of laparoscopic GCP warrants additional investigation as a primary bariatric procedure. (Surg Obes Relat Dis 2010;xx:xxx.) © 2010 American Society for Metabolic and Bariatric Surgery. All rights reserved.

Keywords: Gastric; Plication; Greater curvature; Anterior

Historically, many types of restrictive procedures have been performed to achieve weight loss [1]. Most of these have been abandoned owing to poor long-term weight loss, food intolerance, or severe gastroesophageal reflux. These

gastroplastic procedures were designed to partition the proximal stomach horizontally or vertically, with a small outlet to achieve gastric restriction. 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 gas-

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tric 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, endoluminal technology has been developed to achieve a similar restrictive effect without subjecting the patient to the risk of surgery [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 pilot study, we aimed to demonstrate the feasibility, safety, and efficacy of laparoscopic gastric plication in which the stomach was infolded to establish serosa-to-serosa apposition and gastric restriction.

Methods

The present study was a prospective, nonrandomized feasibility study of 2 gastric plication techniques. The institutional review board approved the present study, and the patients were screened and recruited for enrollment from our standard outpatient population. The study was registered with www.clinicaltrials.gov (clinicaltrials.gov identifier NCT00721227) before patient enrollment. The consent process was conducted by a research nurse coordinator assigned to the study full time and supervised by the attending 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 coordinator. 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 contingency plans were made or agreed to at this point for if the weight loss were to be suboptimal or unexpected complications occurred, except that these issues would be handled on a case-by-case basis at the discretion of the surgeon. No crossovers 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 our psychologists and nutritionists. Once the patient was cleared by the psychologists and nutritionists and their medical evaluation was complete, they were scheduled for surgery.

The present study was funded by Ethicon Endo-Surgery, and the sponsor paid for all the preoperative testing and consultations, surgery, treatment of any potential complications, and all the follow-up testing and visits after surgery during the study period. No costs were included in the budget for reoperation in the case of weight loss failure.

Inclusion criteria

The subjects were considered appropriate candidates for the present study if they were willing to give consent and comply 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 malabsorptive or restrictive procedures performed for the treatment of obesity, the participation in any other investigational device or drug study (nonsurvey-based trial) within 12 weeks of enrollment, and any condition that would preclude compliance with the study. Such conditions included inflammatory diseases of the gastrointestinal tract within the previous 10 years, congenital or acquired anomalies of the gastrointestinal tract (e.g., atresias or stenosis), severe cardiopulmonary disease or other serious organic disease making the subject a high-risk surgical candidate, uncontrolled hypertension, and portal hypertension. 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 severe preoperative reflux, dysmotility, or Barrett's esophagus), hiatal hernia, previous surgery of the foregut (i.e., hiatal hernia repair or previous gastric surgery), pancreatitis, an immunocompromised 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.

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 intraluminal 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 intraluminal gastric

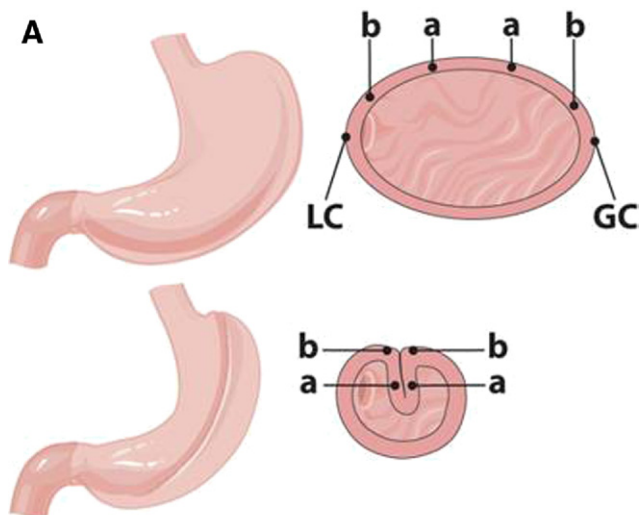


Fig. 1. (A) Diagram and intraoperative picture of completed AP procedure. LC = lesser curvature; GC = greater curvature; A = initial or interior suture line; B = final or outer suture line. Amount of gastric capacity that can be reduced using this approach is limited by size of anterior gastric wall. (B) Intraoperative image of completed AP procedure (Diagram provided by Ethicon Endo-Surgery, Cincinnati, OH).

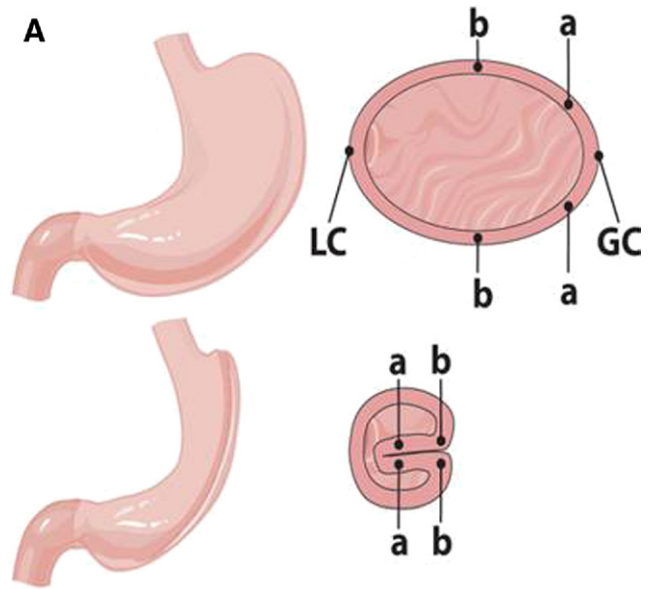


Fig. 2. (A) Diagram and intraoperative picture of completed GCP procedure. LC = lesser curvature; GC = greater curvature; A = initial suture line to invert greater curvature; B = second, outer suture line to achieve large intraluminal gastric fold. (B) Intraoperative image of completed GCP procedure (Diagram provided by Ethicon Endo-Surgery, Cincinnati, OH).

fold. The fold was started just below the angle of His and continued distally to within 4 cm of the pylorus (Fig. 2). In both procedure groups, full-thickness suture bites were used to secure the plications. This was confirmed by intraoperative endoscopy.

Study endpoints

Weight loss. The primary study objective was to assess the weight loss after gastric plication. The weight loss assessments included the absolute change in weight, the change in BMI, and the percentage of excess weight loss (%EWL). The weight was measured by the study coordinator at the initial screening visit, on the day of surgery, and 1, 3, 6, and 12 months after surgery.

Adverse events. The occurrence of adverse events was carefully monitored throughout the entire study period and re-

corded as applicable on the day of surgery, 1 week after surgery, and at 1, 3, 6, and 12 months postoperatively. The subjects completed the visual analog scales for pain after the procedure and before discharge from the hospital.

Endoscopic evaluation. The patients were excluded from the present study if they had a hiatal hernia documented at an endoscopy or upper gastrointestinal 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 disqualifying 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. Intraoperative 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 monofilament nonabsorbable suture in the gastric tissue and to eliminate the depth of suture placement as a variable in plication durability. We performed postoperative endoscopy in the outpatient setting at 3, 6, and 12 months postoperatively to assess plication durability. Pre- and postoperative upper gastrointestinal 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.

Quality-of-life assessment. Two quality-of-life surveys were administered during the study period. The Impact of Weight on Quality of Life-Lite (IWQOL-Lite) and the Multi-purpose Short Form Survey-12 (SF-12) were administered at the study screening visit and 1, 3, 6, and 12 months postoperatively. The IWQOL-Lite (31 questions) is a shorter version of the IWQOL (74 questions), the first instrument designed to assess the effects of obesity on the quality of life of those seeking weight loss treatment options. The subjects' IWQOL-Lite total scores were considered to have shown meaningful improvement from baseline to 1 year after treatment if the scores had increased 7–12 points, depending on the baseline severity compared with the normative mean. For the present study, the IWQOL-Lite domain and component scores, and the changes in the scores, were assessed at baseline and 1, 3, 6, and 12 months postoperatively. The results were calculated separately for the AP and GCP groups.

The SF-12 Health Survey is a generic assessment of 12 questions extracted from the SF-36 survey. The instrument was administered at the baseline visit and approximately 4 weeks postoperatively. The SF-12 includes both a physical component score and a mental component score. As with the SF-36, a greater score indicates generally better health.

Results

A total of 15 patients (3 men) were enrolled in the present study. Their mean age was 42 years (range 26–58), and the average preoperative BMI was $43.3 \pm 4.1 \text{ kg/m}^2$ (range 36.9–49.0). No significant differences were present in age or BMI between the AP and GCP groups.

The mean procedure duration for the AP group was 89 minutes (range 68–147). Of the 9 patients in the AP group, 2 required 3 rows of sutures to complete the procedure and 7 required 2 rows of sutures to complete the procedure.

The mean procedure duration for the GCP group was 72 minutes (range 48–106). Of the 6 patients in the GCP group, 2 suture rows were placed in 5 patients, and 1 patient required a third row of sutures to complete a satisfactory plication.

A longitudinal intraluminal fold was achieved in all patients as determined by the endoscopic assessment in the operating room. The mean hospital length of stay was 37 hours. The first 2 patients in the GCP group experienced severe nausea requiring a longer length of stay (77 hours) to control their symptoms. No difference in postoperative pain was found between the AP and GCP groups, as determined from the visual analog scale assessments before discharge (score 2.0 versus 2.4, respectively, $P = .8$).

Follow-up endoscopy

Of the 9 patients who underwent AP, 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 (Fig. 3A). One patient in the AP group had a partially disrupted distal fold found at the 3-month endoscopic evaluation. At 12 months, additional fold disruption was noted in this patient.

All 6 patients in the GCP group completed the 6- and 12-month follow-up endoscopic evaluations. Durable intraluminal folds were seen in 5 patients (Fig. 3B); 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 postoperatively.

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/m^2 (range 43.1–37.6; mean 10.7% decrease in BMI re-

tients reported new-onset gastroesophageal 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 in the SF-12 scores at the 12-month visit compared with the baseline scores. However, the GCP group showed significant improvement ($P < .001$) for the physical component score (questions 1–6) at 12 months but not the mental component score (questions 7–12), 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 (question 10) by the 12-month visit. Of the 6 subjects in the GCP group, 5 noted that pain did not interfere with their normal work (question 8, not at all) 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.

By domain, the first 11 IWQOL questions reference the effect a person's weight has on their physical function. Both the AP ($P = .0179$) and GCP ($P = .0069$) groups had significant improvements from baseline through all postprocedure visits.

The remaining questions address the effects of weight on "self-esteem," "sexual life," "public distress," and "work." The postprocedure scores for self-esteem improved significantly ($P = .0096$) in the GCP group from just after the procedure through the end of the study period. The public distress scores also improved during the study period ($P =$

Fig. 3. Endoscopic images of (A) AP and (B) GCP 12 months postoperatively.

corded 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 reoperation 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, monofilament sutures were noted in either group. No pa-

Table 1
Excess weight loss for anterior and greater curvature plications

Procedure	Visit (mo)	Patients (n)	Mean %EWL \pm SD
Anterior plication	1	9	17.8 \pm 5.3
	3	9	23.4 \pm 6.2
	6	6	28.4 \pm 10.7
	12	5	23.3 \pm 24.9
Greater curvature plication	1	6	23.3 \pm 4.9
	3	6	38.5 \pm 7.9
	6	6	49.9 \pm 12.1
	12	6	53.4 \pm 22.7

%EWL = percentage of excess weight loss [(weight at baseline – weight at each visit)/(weight at baseline – ideal body weight)] \times 100.

$P < .001$ (type III F-test) for visit effect determined using repeated mixed model with %EWL and following covariates: visit, procedure, and visit \times procedure.

$P = .033$ (type III F-test) for procedure effect determined using repeated mixed model with %EWL and following covariates: visit, procedure, and visit \times 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 \times 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.

Discussion

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 support the durability of sleeve gastrectomy [11]. 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 detraction for some surgeons and patients. 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. The GCP procedure does 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.

These concepts were initially evaluated by Fusco et al. [12,13] in a rat model. In the initial study, 30 Wistar rats were divided into 3 groups (sham anesthesia, sham laparotomy, and greater curvature gastric plication). The investigators demonstrated a significant decrease in weight gain in the greater curve plication group at 21 days. Fusco et al. [12,13] continued this research with another rat study in which they compared 10 rats that had undergone GCP and 10 rats that had undergone AP without division of the greater curve vessels. They did not find a significant difference at 28 days between the 2 groups in their weight gain or epididymal fat pad size. Gastric plication relies on serosal adhesion formation within the fold to maintain durability. Menchaca et al. [14] have demonstrated short-term durability and fibrous serosal apposition in gastric folds created in

a canine model using a variety of suture materials and fasteners. This preclinical work was a precursor to our current pilot clinical study.

Ramos et al. [15] have recently reported their results for 42 patients who underwent laparoscopic GCP. The mean operative time was 50 minutes (range 40–100), and the mean hospital stay was 36 hours. No intraoperative complications occurred, and all patients experienced a %EWL of $\geq 20\%$ 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 preoperative BMI of $<45 \text{ kg/m}^2$ and 25% having a BMI of $<35 \text{ kg/m}^2$. No major complications or mortality was reported in that series [16].

Talebpour and Amoli [17] 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, with a mean age of 32 years and a mean preoperative BMI of 47 kg/m^2 (range 36–58). The mean %EWL loss at 1, 6, 12, 24, and 36 months was 21.4%, 54% (72 cases), 61% (56 cases), 60% (50 cases), and 57% (11 cases), respectively. The average follow-up was 18 months. The mean operative time was 98 minutes (range 70–152), and the mean length of stay was 1.3 days (range 1–4). Nausea and vomiting were the most common complications. The reoperation rate was 2.6% in their series (1 suture line leak, 1 prepyloric perforation, 1 liver abscess, and 1 kinking of the stomach requiring revision), with no late complications [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 postoperative 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 intraluminal 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 postoperatively. 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 intraluminal fold infringes on the lesser curvature or creates a kink in the lumen. Although this problem can potentially be managed

nonoperatively 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, therefore, managed this problem by returning to the operating room, removing the outer row of sutures, and replicating the outer row more loosely to restore some of the gastric lumen. This was done with endoscopic guidance in the operating room to ensure that the fold was not in direct contact with the lesser curvature or incisura after the replication was completed. This patient did well after the reoperation, had excellent weight loss, and had a durable fold on follow-up endoscopy. Persistent or late obstructions have not occurred in our experience but would be managed in a similar fashion.

We have not seen any new-onset or worsening of gastroesophageal 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 gastroesophageal 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 gastroesophageal 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, gastroesophageal 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 studies

who have reached 3 years of follow-up have maintained 57% EWL (Fig. 4).

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. We believe that conversion to Roux-en-Y gastric bypass would be the optimal choice and would be technically feasible. In a recent study using a canine model (data not yet published), we were able to laparoscopically take apart gastric plications and restore the normal stomach anatomy in 5 animals at 2 months after gastric plication. Well-established serosa-to-serosa adhesions were present, but a dissection plane could be developed similar to that for other gastric revisional procedures. The dogs were then monitored for 2 weeks without complications. From these results and our experience converting other gastric procedures (Nissen fundoplication, laparo-

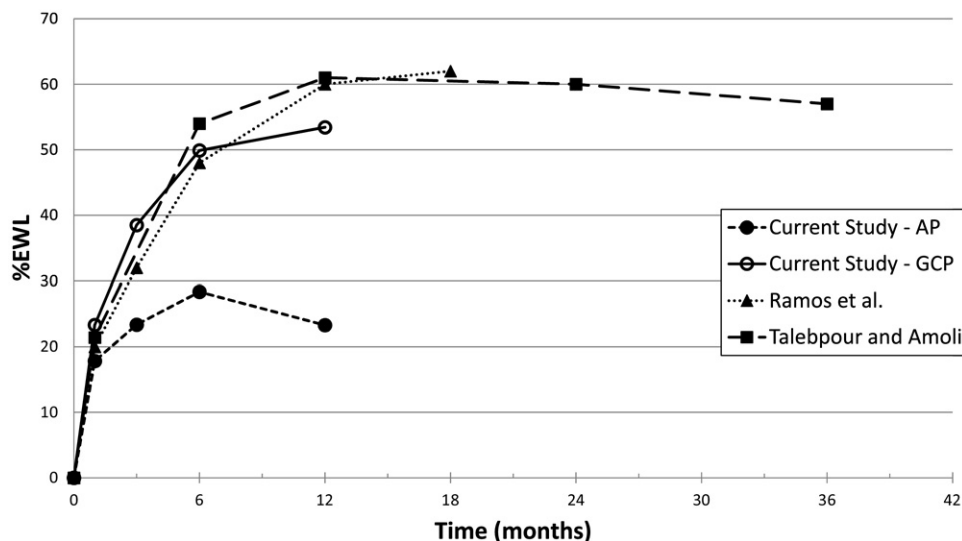


Fig. 4. %EWL over time for gastric plication procedures. Black circles indicate results for AP in present study; white circles, results for GCP in present study; black triangles, results from Ramos et al. [15] for GCP; and black squares, results from Talebpour and Amoli [17] for GCP.

scopic adjustable gastric banding, and vertical banded gastroplasty) to gastric bypass, we believe the revision of gastric plication procedures could be performed with a risk profile similar to that of these other 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.

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.

Disclosures

S. A. Brethauer, M. Kroh, and P. R. Schauer are consultants and speakers for Ethicon Endo-Surgery, and J. L. Harris is an engineer for Ethicon Endo-Surgery and contributed to the protocol and technique development and data analysis.

References

- [1] Buchwald H, Buchwald JN. Evolution of operative procedures for the management of morbid obesity 1950–2000. *Obes Surg* 2002;12:705–17.
- [2] Balsiger BM, Poggio JL, Mai J, Kelly KA, Sarr MG. Ten and more years after vertical banded gastroplasty as primary operation for morbid obesity. *J Gastrointest Surg* 2000;4:598–605.
- [3] Ramsey-Stewart G. Vertical banded gastroplasty for morbid obesity: weight loss at short and long-term follow up. *Aust N Z J Surg* 1995;65:4–7.
- [4] Salmon PA. Failure of gastroplasty pouch and stoma size to correlate with postoperative weight loss. *Can J Surg* 1986;29:60–3.
- [5] MacLean LD, Rhode BM, Forse RA. Late results of vertical banded gastroplasty for morbid and super obesity. *Surgery* 1990;107:20–7.
- [6] Kim CH, Sarr MG. Severe reflux esophagitis after vertical banded gastroplasty for treatment of morbid obesity. *Mayo Clin Proc* 1992; 67:33–5.
- [7] Nightengale ML, Sarr MG, Kelly KA, Jensen MD, Zinsmeister AR, Palumbo PJ. Prospective evaluation of vertical banded gastroplasty as the primary operation for morbid obesity. *Mayo Clin Proc* 1991;66: 773–82.
- [8] Balsiger BM, Murr MM, Mai J, Sarr MG. Gastroesophageal reflux after intact vertical banded gastroplasty: correction by conversion to Roux-en-Y gastric bypass. *J Gastrointest Surg* 2000;4:276–81.
- [9] Moreno C, Closset J, Dugardeyn S, et al. Transoral gastroplasty is safe, feasible, and induces significant weight loss in morbidly obese patients: results of the second human pilot study. *Endoscopy* 2008; 40:406–13.
- [10] Deviere J, Ojeda Valdes G, Cuevas Herrera L, et al. Safety, feasibility and weight loss after transoral gastroplasty: first human multicenter study. *Surg Endosc* 2008;22:589–98.
- [11] Bohdjalian A, Langer FB, Shakeri-Leidenmuhler S, et al. Sleeve gastrectomy as sole and definitive bariatric procedure: 5-year results for weight loss and ghrelin. *Obes Surg* 2010;20:535–40.
- [12] Fusco PE, Poggetti RS, Younes RN, Fontes B, Birolini D. Comparison of anterior gastric wall and greater gastric curvature invaginations for weight loss in rats. *Obes Surg* 2007;17:1340–5.
- [13] Fusco PE, Poggetti RS, Younes RN, Fontes B, Birolini D. Evaluation of gastric greater curvature invagination for weight loss in rats. *Obes Surg* 2006;16:172–7.
- [14] Menchaca HJ, Harris TL, Thompson SE, et al. Gastric plication: a pre-clinical study of the durability of serosa-to-serosa apposition. *Surg Obes Relat Dis* 2010, in press.
- [15] Ramos A, Galvao Neto M, Galvao M, Evangelista LF, Campos JM, Ferraz A. Laparoscopic greater curvature plication: initial results of an alternative restrictive bariatric procedure. *Obes Surg* 2010;20: 913–8.
- [16] Sales Puccini CE. Surset gastriccode sales: una alternativa para cirurgia bariatrica restrictiva. *Rev Colomb Cir* 2008;23:131–5.
- [17] Talebpour M, Amoli BS. Laparoscopic total gastric vertical plication in morbid obesity. *J Laparoendosc Adv Surg Tech A* 2007; 17:793–8.