Laparoscopic gastric plication for the treatment of morbid obesity by using real-time imaging of the stomach pouch

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BACKGROUND: *Bariatric surgery is a continuously evolving field. Laparoscopic greater curvature plication is a new investigational procedure used to treat patients with morbid obesity. The demand for this operation from the obese patients is also rising. The problem is that during gastric plication the exact dimensions and volume of the pouch are not known so frequently it is too large or too tight thus compromising the results. The aim of the study was to identify the parameters that can improve the outcomes after this procedure.*
METHODS: *We performed laparoscopic greater curvature plication in 75 obese patients during 2013-2015. The last 25 patients underwent surgery with a modified surgical technique using real-time imaging of the stomach pouch. The inclusion criteria for the 25 patients enrolled in this case series were the usual, body mass index higher than 40 or higher than 35 but with comorbidities along with the option of the patients for laparoscopic gastric plication. The operative technique was enhanced by using a computerized device and special intragastric catheters during the procedure that permitted real-time imaging of the gastric geometry. With this new operative approach we obtained the desired volume of the gastric remnant and we avoided strictures, obstruction or irregular shape of the pouch, problems that otherwise could have compromised the outcomes.*
RESULTS: *We found an increased excess weight loss of 55% at six month and 65% over a 12-month follow-up period with alleviation of comorbidities. There were no major complications (gastric outlet obstructions or leaks) and less minor complications (nausea and vomiting) than in the patients operated with classic gastric plication procedure.*
CONCLUSIONS: *This study shows that in case of laparoscopic gastric plication the use of our modified operative technique has better outcomes than in the classical setting. This is a new operative approach in the bariatric literature which can lead to greater acceptance of gastric plication among bariatric surgeons. The target population is represented by the obese patients who want to obtain similar results to those after gastric bypass and sleeve gastrectomy but are concerned about removing a part of their stomach and the postoperative complications that may occur, especially leaks and nutritional complications.*

KEY WORDS: Gastric geometry, Laparoscopic gastric plication, Morbid obesity, Real-time imaging

Introduction

It is well known that currently bariatric surgery is the most efficient treatment applied in morbidly obese patients. Sleeve gastrectomy and gastric bypass are the most often performed and effective operation techniques. Biliopancreatic diversion(Scopinaro) and duodenal switch are used in super-obese patients. Because these operation

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techniques are expensive and they carry the risk of major complications (leaks, nutritional complications), risk of Barrett's metaplasia after sleeve gastrectomy, and high hospital admission rates after Roux-en-Y gastric bypass, new procedures such as laparoscopic greater curvature plication (gastric plication) and minigastric bypass were introduced in an effort to obtain the same results with fewer complications and less costs. Gastric plication (Laparoscopic Greater Curvature Plication-LGCP) is performed especially in developing countries. There is also an increasing demand for gastric plication from the obese population. These patients are concerned about removing a part of their stomach or about the postoperative complications that may occur after the usual bariatric procedures (gastric bypass and sleeve gastrectomy). Another reason for choosing gastric plication by obese patients is the much lower cost. However, the outcomes after applying gastric plication, published so far in the literature, are inferior to sleeve gastrectomy and gastric bypass. We think that a shortcoming of the standard gastric plication procedure is that we don't know the exact dimensions of the pouch at the end of the operation. The pouch is often too large or too tight, leading to complications and poor outcomes. Thus efforts have been made to improve these results by modifying the operative technique. In our case series of gastric plications (LGCP) we propose a novel surgical approach that can lead to better outcomes and fewer complications, in order to provide similar results to those after the established bariatric procedures.

Material and Methods

Study Design

Our department of surgery performed laparoscopic greater curvature plication(LGCP) in 75 patients - 55 female and 20 male patients - with morbid obesity and grade II obesity with comorbidities during 2013 - 2015. The usual investigations for bariatric surgery were undertaken before the intervention (endocrine and gynecologic evaluation, diabetes and helicobacter pylori tests, abdominal ultrasound, and endoscopy). All patients were administered antibiotics and anticoagulants.

The first 50 patients underwent the classical surgical intervention. The last 25 patients operated on subsequently received a new surgical approach by using the EndoFLIP - Crospon Imaging System that measures the size and volume of the gastric pouch in real-time and displays its estimated shape on a color monitor. We didn't find any paper in the literature regarding this operative technique. The machine works by using impedance planimetry that can transform voltage into millimeters to help determine the geometry of the stomach. The monitor displays diameter units or French (Fr), the cross sectional area, the volume in milliliters and a reconstruction model of the shape of the stomach (Fig. 1). Consequently, throughout the surgery, we monitored the dimensions of the pouch during the whole procedure, thus avoiding to obtain too large pouches, uneven plications or strictures which usually compromise the results. The demographics and comorbidities of the patients are shown in Table I.

Fig. 1: Endo-Flip device.

Table I - *Demographics of the patients.*

	Gastric plication with Endo Flip	Standard Gastric plication
Nr. of patients	25 (23 women, 2 men)	50 (40 women, 10 men)
Age	25-50 years (average 38)	30-55 years (average 42)
BMI (body mass index)	39	42
Comorbidities		
– Diabetes Mellitus	5	11
– Arterial Hypertension	3	12
– Artrosis	16	21

Surgical procedure

We changed the classic operative technique by using the Endo Flip device during the LGCP. The kit consists of a central computer and balloon catheters that are introduced in the stomach during the procedure. The balloon contains an array of electrodes that measure voltage. The main unit transforms these voltages in millimeters to estimate the diameter at 16 points, 10 mm apart, along the measurement area (16 cm). On the screen we could see during the procedure the shape, dimension and volume of the pliated stomach and we could modify it in real time by additional sutures in case we considered it necessary. We could also avoid strictures or an irregular shape by tailoring the gastric pouch (Fig. 2).

The phases of the operation are similar to the classic technique of laparoscopic gastric plication (LGCP). The patient lies flat with legs apart and the surgeon stays in between. The assistants are located on the right and left side of the patient. We used five trocars. The most important is the optical one (10mm), situated above the umbilicus at 2/3 on the midline, 3 fingerbreadth to the left. The other trocars are inserted in a way that they enable easy access to the cardia and greater curvature: one trocar 5 mm under the xiphoid process, another one 5 mm in line with the optic trocar, 1 fingerbreadth to the right, then another one 10 mm left subcostal in the midclavicular line and the last one 5mm in the axillary line. We skeletonized the greater curvature up to the gastro-esophageal junction, preserving the angle of Hiss and down to 5 cm from the pylorus. We had to maintain a safety margin, to avoid lesions of the gastric wall that could lead to leaks. During the severance of the short gastric vessels we paid attention to the spleen. After the liberation of the stomach a 34 Fr probe was introduced along the small curvature, which entered the duodenum through the pylorus, procedure that might be troublesome but very important to perform. This way we could better calibrate the stomach pouch. We started the plication of the greater curvature at 2 cm from the angle of Hiss extending to approximately 5 cm from the pylorus. We used 2.0 non-absorbable sutures in a continuous row.

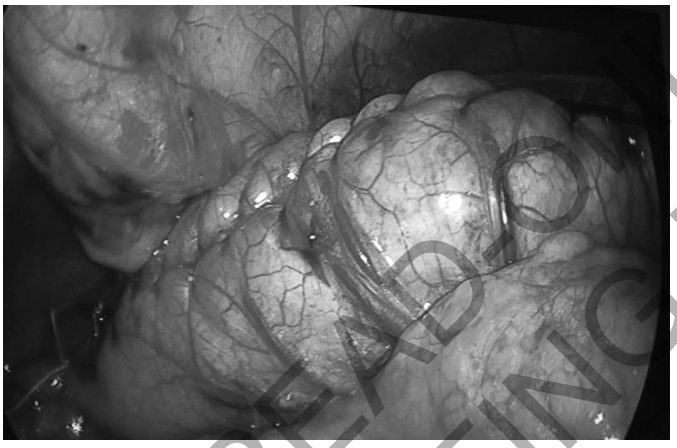

Fig. 2: Intraoperative image of the plicated stomach.

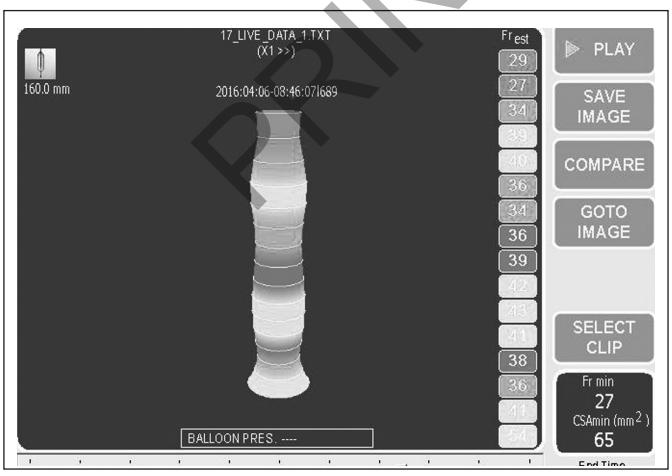

Fig. 3: The diameter of the gastric pouch at different levels.

Devices like EndoStich can make suture easier. Another option is the V-Loc suture. After the first row of sutures the bougie was removed and we introduced the inflatable balloon catheter until we could see the tip leaning against the antrum wall. Then the balloon was inflated with 30 ml of saline solution. We could monitor the shape, volume and diameter on the display at different levels. With the second row of sutures we adjusted the final aspect of the pouch making sure that the diameter was between 34-38 Fr and the shape was even and regular (Fig. 3). Dilated or narrowed areas were presented in different colors so we could fix them by adding or removing stitches. Thus we could also avoid strictures that often appear at the incisura angularis or obstruction at the gastro-esophageal junction by the fold, situations that need revision surgery. Last but not least, we were aware of the exact volume of the pouch along the 16 cm of the probe. First day postoperatively after the gastrografin meal the nasogastric tube was removed and patients were allowed oral fluids. They were discharged from hospital after three days and were administered anticoagulants for at least one month period.

Results

The mean operative time was 90 minutes. Intraoperatively, we had two cases of minor bleedings, arrested by pressure or clips. We monitored three parameters: the minimum diameter of the pouch (in mm or Fr), the minimum cross sectional area and the volume of the plicated stomach alongside the 16 cm of catheter. We noticed that strictures did not develop in the postoperative phase even at a size of 28 Fr. Analyzing the

TABLE II - *Outcomes after Gastric plication with Endo Flip and Standard Gastric plication.*

	Gastric plication with Endo Flip	Standard Gastric plication
Excess weight loss (%)	55% at 6 month	51 % at 6 month
Major postoperative complications	0	4(8%)
– Leaks	0	1
– Gastric outlet obstruction	0	2
– Hemoperitoneum	0	1
Complications treated medically		
– Gastric bleeding		1
– Deep vein thrombosis	1	2
Minor complications		
– Nausea and vomiting	5(20%)	20(40%)
Nutritional complications	0	0
Revisional surgery	0	3(6%)

minimum diameter of the gastric tube (Fig. 4) we observed that most of the time values were greater than 28 Fr (p≤0.001) and the mean value was 30.96±2.263 Fr. For the minimum cross sectional area, the mean value was 80.42± 10.85 mm^2 (Fig. 5) and for the volume of the pliated stomach 26.88± 3.043 (Fig. 6). The values of the reduced volume are comparable with those after gastric sleeve and gastric bypass.

Fig. 4: Illustration showing the minimum diameter of the gastric pouch.

Postoperatively, no major complications (as gastric outlet obstruction or leaks) were encountered. Minor complications were nausea and vomiting that ceased after the administration of medication in five cases (20%). In one case, a patient who did not take anticoagulants for the recommended period developed deep vein thrombosis solved with medical therapy. We did not experience other complications reported in the literature as: bleedings due to the trocars, liver hematoma, intraesofageal fold herniation, pneumonia, mesenteric thrombosis.

A thorough follow-up was conducted with interviews at three month, six month and one year. We gathered data regarding % EWL, alleviation of comorbidities, quality of life and late complications. The % excess weight loss (EWL) was 55% after six month and 65% at one year (Table II).

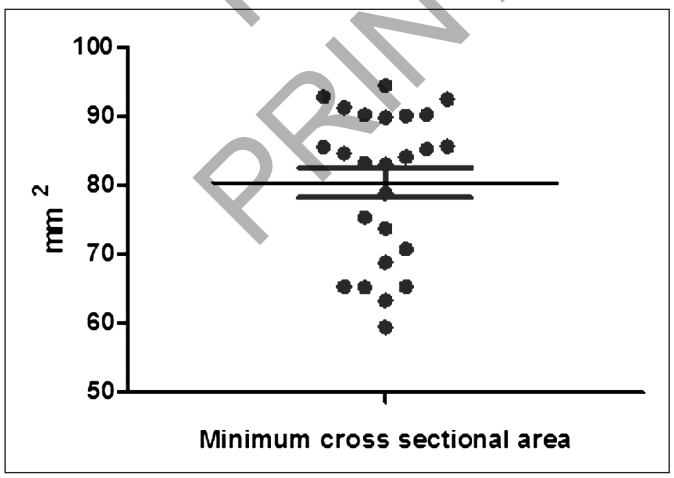

Fig. 5: Illustration showing the minimum cross sectional area of the gastric pouch.

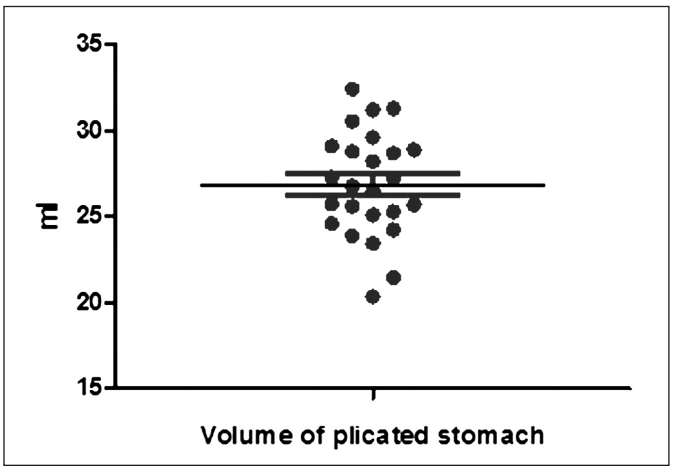

Fig. 6: Illustration showing the size of the plicated stomach.

Discussions

Obesity currently shows epidemic proportions. Bariatric surgery is the most effective treatment for patients with severe obesity [1,2]. Surgery also alleviates comorbidities as type 2 diabetes mellitus (T2DM), so bariatric procedures are at the same time metabolic interventions [3]. The history of weight loss surgery begins in 1954 but the first popularized procedure was the jejuno-ileal bypass in 1963 [4]. From this point, during the years, numerous operations and procedures were employed worldwide for weight loss. An important issue is to bring order and honesty in this vast field [5]. The number of weight loss surgeries has grown exponentially, nowadays over 200,000 procedures are performed yearly only in the US [3].

Worldwide, there are two leading bariatric procedures: sleeve gastrectomy (LSG) and gastric bypass. For a long time, gastric bypass was the most often performed bariatric procedure [6,7]. The operative technique evolved constantly leading to better outcomes, especially in the laparoscopic setup [8]. The excellent results in long term [9,10] consolidated its position, even though it may have upsetting complications [11]. Recently, a paper from Denmark showed high hospital admission rates after Roux-en-Y gastric bypass in long term follow up [12].

Adjustable gastric banding was the most common operation in Europe in the 90's [13] but today the number is decreasing. Good results were publised after Mason-McLean vertical gastroplasty, an operation that respects the digestive and nutritional physiology [14]. The procedure can be performed even in the presence of hiatal hernia.

Sleeve gastrectomy, after becoming a stand-alone procedure, was embraced rapidly by many surgeons due to its simplicity and good results so nowadays these two procedures are the state-of-the-art in bariatric surgery. However, concerns are rising about the high incidence (14%) of Barrett's metaplasia after sleeve gastrectomy in long term follow up [15].

Biliopancreatic diversion (Scopinaro) and duodenal switch accounts for only 1% of the bariatric operations despite its excellent results in weight loss [16-18] and alleviation of type 2 diabetes [19]. This procedure is reserved for super-obese patients. Best results are achieved in large volume centers were the procedures are adapted depending the patient needs [20].

Because today there is no ideal weight loss operation and the bariatric field is continuously evolving, new procedures as mini-gastric bypass [21,22] and gastric plication (LGCP) emerged, which are still under investigation. Recognizing the shortcomings of the standard bariatric procedures, renowned bariatric surgeons, such as Buchwald [3], consider LGCP a "rival and possibly safer alternative to SG".

LGCP was introduced by Talebpour [23] in 2006 but it was based on the work of Wilkinson [24] and the aim of this operation was to mimic sleeve gastrectomy with less cost and to avoid the risk of leaks, the presence of foreign bodies and the removal of a portion of the stomach. The procedure has been popularized in developing countries. Large series of case studies comprising 800-1000 patients, who underwent LGCP, were published [25]. Ramos reported a mean % EWL of 62 % after 18 month of follow-up [26] and Sales 69.6 % in 1 year [27]. Another systematic review showed an EWL of 56.6 % at 6 month [23]. Long term outcomes were published by Talebpour [28] showing 55% EWL at five years. Comorbidities as T2DM are also significantly improved [29].

The operative technique is now well established, with minor modifications from different authors, for instance two or more rows of suture or the technique with three folds, described by Skrekas [30]. Brethauer also described the anterior gastric wall plication [31].

LGCP is technically a challenging procedure that involves fine suturing skills. If the technique is not accurate enough the results evidently are not the expected ones. The reported long term results considering %EWL, are not as good as after gastric bypass, sleeve gastrectomy or biliopancreatic diversion. One randomized (LGCP v LSG) study revealed inferior results at 3 years for LGCP [32], in spite of similar results at one year [33, 34]. The problem with gastric plication is that the surgeon cannot assess the real volume of the gastric remnant, most of the times the restriction is not sufficient. On the other hand if the surgeon is overzealous, the risk of strictures is high and revision operation is needed. These issues, besides the fact that there is still a learning curve, explain the criticism of this operation technique.

Therefore we propose a new approach in gastric plication by modifying the operative technique. We did not encounter in the bariatric literature any operative technique that is using real time imaging during LGCP. We have had a rewarding experience regarding bariatric surgery. Three surgeons of our department operated on over 300 obese patients so far. 75 patients underwent LGCP. The results after the first 30 cases were published [35]. In order to improve the results (% excess weight loss) and to diminish complications after gastric plication, in the last 25 patients we used a device that displays in real time the shape, dimensions and volume of the gastric pouch. Monitoring the diameter of the gastric pouch during the whole procedure and maintaining it around 34-38 Fr, we avoided the formation of strictures at the incisura angularis or at the gastro-esophageal junction. Additional stitches were used for the larger areas of the gastric pouch in order to obtain even plication.

Conclusion

Nowadays bariatric surgery is a continuously evolving field. LGCP is a bariatric procedure introduced ten years ago and there is a rising demand for this operation from the obese patients because the operation has a low rate

of complications, does not involve gastric resection, presence of foreign bodies and is cost-effective. However the procedure carries the risk of major complication and the excess weight loss is lower than after the established bariatric operations. In order to improve the outcomes after LGCP we propose a novel surgical approach that we did not encounter in the literature, by using a device that displays in real time the dimensions and the volume of the gastric remnant during the procedure thus helping us to obtain the desired dimensions and shape of the pouch. In our case series, the use of this technique is associated with increased excess weight loss and fewer complications compared to the classic gastric plication. Further studies are needed to evaluate the long term results after this improved surgical technique.

Disclosure

The study was financially supported by the University of Medicine and Pharmacy, Tirgu Mures, Romania. The funds covered the price of the inflatable catheters. The main device (Endo Flip) was borrowed from Crospon Ltd. for five month. All 25 patients underwent surgery during the five-month period of the study.

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