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Highlights

• New bariatric procedure Laparoscopic Vertical Clip Gastroplasty (LVCG). • Mimics the principle of LSG, but with completely reversible mechanism. • The procedure consists of a nonadjustable clip that is vertically placed parallel to the lesser curvature. • The purpose of this manuscript is to evaluate the patients' satisfaction with various questionnaires.

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Original article

Laparoscopic vertical clip gastroplasty – quality of life

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Abstract

Background: Over the last decade, several techniques have emerged and the bariatric trends have changed. A new bariatric procedure that has been proposed is laparoscopic vertical clip gastroplasty (LVCG), which mimics the principle of laparoscopic sleeve gastrectomy, but with a completely reversible mechanism. The introduction of a new procedure in the bariatric armamentarium necessitated a period of preclinical and clinical studies and a validation of the procedure concerning the quality of life.

Setting: Private hospital, Dominican Republic.

Objectives: The purpose of this manuscript was to evaluate patient satisfaction, measured by various questionnaires after LVCG.

Methods: From November 2012 to February 2017, 138 patients underwent LVCG and demographic data were collected prospectively. A total of 82 were evaluated for quality of life with a minimum follow-up of 6 months after the procedure. The quality of life was also analyzed regarding the complications and resolution of different medical conditions included in the Bariatric Analysis and Reporting Outcome System score.

Results: Eighty-five patients (73.9%) agreed to participate in the study and a total of 82 patients completed the questionnaires at all points in time. Seventy-one patients were female, with an average age of 34 (19–38). Mean body mass index before operation was 42.4 kg/m^2 and declined significantly in both the first and second year postoperatively to 33.7 kg/m^2 (1-year follow-up) in 65 patients and 34.3 kg/m^2 (2-year follow-up) in 37 patients. The results showed failure for 1.2% of patients and were fair for 6.1% of cases. Quality of life was assessed as good for 26 patients (31.8%), as very good for 39 patients (47.5%), and as excellent for 11 patients (13.4%).

Conclusions: LVCG represents a new bariatric procedure that mimics the principle of laparoscopic sleeve gastrectomy, but with a completely reversible mechanism. The procedure consists of a nonadjustable clip that is vertically placed parallel to the lesser curvature. After >3 years of clinical use, the weight loss results seem to be encouraging and up to 92.7% of patients have an improved quality of life. (Surg Obes Relat Dis 2018;xxx:xxx–xxx.)

Keywords: Laparoscopic vertical clip gastroplasty; Reflux; Sleeve; Reversible

There is substantial evidence that surgery is the only valid treatment for morbid obesity [1,2]. Over the last decade, several techniques have emerged and bariatric trends have changed [3,4]. Presently, the most commonly performed technique is laparoscopic sleeve gastrectomy (LSG), after many years of laparoscopic Roux-en-Y gastric bypass being considered the gold standard. This growth can be explained by several advantages that LSG carries over laparoscopic Roux-en-Y gastric bypass, including the

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Table 1
Demographic data.

Demographics	Before surgery
Age	34
Sex	Male 14% Females 86%
Average BMI	42.4 (31.5–54.2)

BMI = body mass index.

absence of most side effects of bypass procedures such as dumping syndrome, marginal ulcers, malabsorption, small bowel obstruction, and internal hernia, allowing it to offer a better quality of life (QoL) compared with gastric banding [5].

One of the main concerns for long-term results after LSG is gastroesophageal reflux disease (GERD). According to several reports [6,7], substantially more patients were taking proton pump inhibitors for GERD late after the procedure than before it. The data in the literature for this issue, however, vary vastly [8]. Nevertheless, an incidence of 21.4% for de novo GERD reported by Himpens et al. [6], in line with other series [9], is a reason for concern regarding an irreversible procedure like LSG, especially given the increased risk of evolution into Barrett's esophagus [10,11].

Recently, a new bariatric procedure has been proposed: laparoscopic vertical clip gastroplasty (LVCG) [12], which mimics the principle of LSG, but with a completely reversible mechanism. The procedure consists of a nonadjustable clip that is vertically placed parallel to the lesser curvature. The introduction of a new procedure in the bariatric armamentarium necessitated a period of preclinical and clinical studies and validation of the procedure concerning QoL. Consequently, the purpose of this manuscript is to evaluate patient satisfaction, measured by various questionnaires.

Methods

From November 2012 to February 2017, 138 patients underwent LVCG, and demographic data were collected prospectively. A total of 82 were evaluated for QoL with a minimum follow-up of 6 months after the procedure. Demographic data are summarized in Table 1. The interrogation was conducted by an independent investigator (P.N.), who collected the data that were further independently analyzed by another author (M.N.).

The score of Moorehead-Ardelt questionnaire [13] is summarized in Fig. 1. The Bariatric Analysis and Reporting Outcome System (BAROS) is a unique scoring method to evaluate, in a single page, the results after bariatric surgery. Points are added or deducted according to weight loss, improvements in co-morbidities, and changes in QOL. Points are deducted for complications and reoperations, before yielding a final score that classifies outcomes in the following 5 categories: failure, fair, good, very good, and excellent. Weight evolution was analyzed in terms of percentage of excess body mass index (BMI) loss, calculated as (initial BMI – current BMI) / (initial BMI – 25) × 100. Weight regain was scored with −1 point and different weight loss was scored as follows: 0% to 25% with 0 points; 25% to 50 % with 1 point; 50% to 75% with 2 points; and >75% with 3 points. The medical co-morbidities were classified as follows: aggravated (one point less), unchanged (0 points), improved (1 point), 1 major resolved (2 points), and >1 morbidity resolved (3 points).

Surgical technique

The surgical technique of LVCG has been described and published previously [12]. Briefly, the first step is to create a small opening at the angle of His with an articulated dissector, followed by a 3- to 4-cm window on the greater curvature, directly inferior to the incisura angularis. The articulated dissector is passed into the lesser sac to the left of the left gastric vessels and articulated to 90°, coming out at the angle of His. The weight loss clip and its flexible closing belt is then inserted through this window and fixed to the stomach both anteriorly and posteriorly after inserting a calibration tube similarly as with LSG. The clip consists of a silicone-covered titanium backbone with an inferior hinged opening that separates a medial lumen from an excluded lateral gastric pouch. The inferior opening allows the gastric juices to empty from the fundus and the body of the stomach into the distal antrum (Fig. 2). The technique thus did not involve extensive dissection of the hiatus.

Statistical analysis

The *t* test was used for the comparison of variation of QoL score between the preoperative and postoperative test. A *t* test's statistical significance indicates whether the difference between 2 groups' averages most likely reflects a "real" difference in the population from which the groups were sampled. The significance threshold was set for $P < .05$.

Results

Between November 2012 and February 2017, 138 patients underwent LVCG. Upon consultation with the European Union regulatory agencies, by protocol, 15 clips were to be removed after different lengths of time of implantation to prove reversibility. Eight other patients had their clips removed for different complications that were discussed in the previous report [12]. After clip removal,

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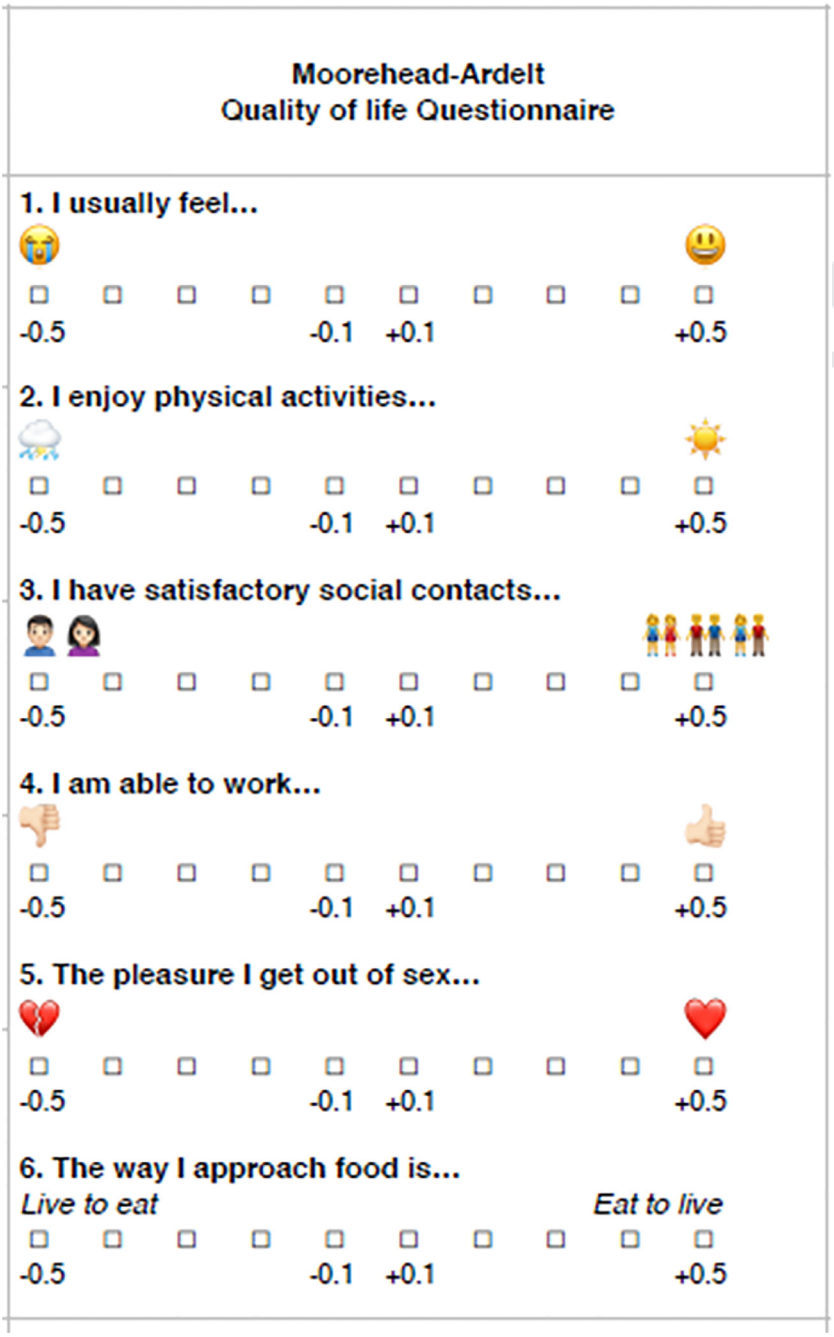

Fig. 1. Moorehead-Ardelt questionnaire.

these patients were not included statistically. Of the remaining, 85 patients (73.9%) agreed to participate in the study and a total of 82 patients completed the questionnaires at all different points in time. Seventy-one patients were female with an average age of 34 (19–38) years. Mean BMI before operation was 42.4 kg/m^2 and declined significantly in both the first and second year postoperatively to 33.7 kg/m^2 (1-year follow-up) in 65 patients and 34.3 kg/m^2 (2-year follow-up) in 37 patients.

The analysis of the Moorhead-Ardelt Quality of Life Questionnaire showed a significant improvement of the scores for each of 6 dimensions. The variation of the scores of QoL is significant ($P < .001$). For item 1 ("I usually feel…"), the QoL was improved by 181%, for item 2 ("I enjoy physical activities") by 262%, for item 3 ("I have satisfactory social contacts") by 69%, for item 4 ("I am able to work") by 19%, for item 5 ("The pleasure I get out of sex") by 41%, for item 6 ("The way I approach

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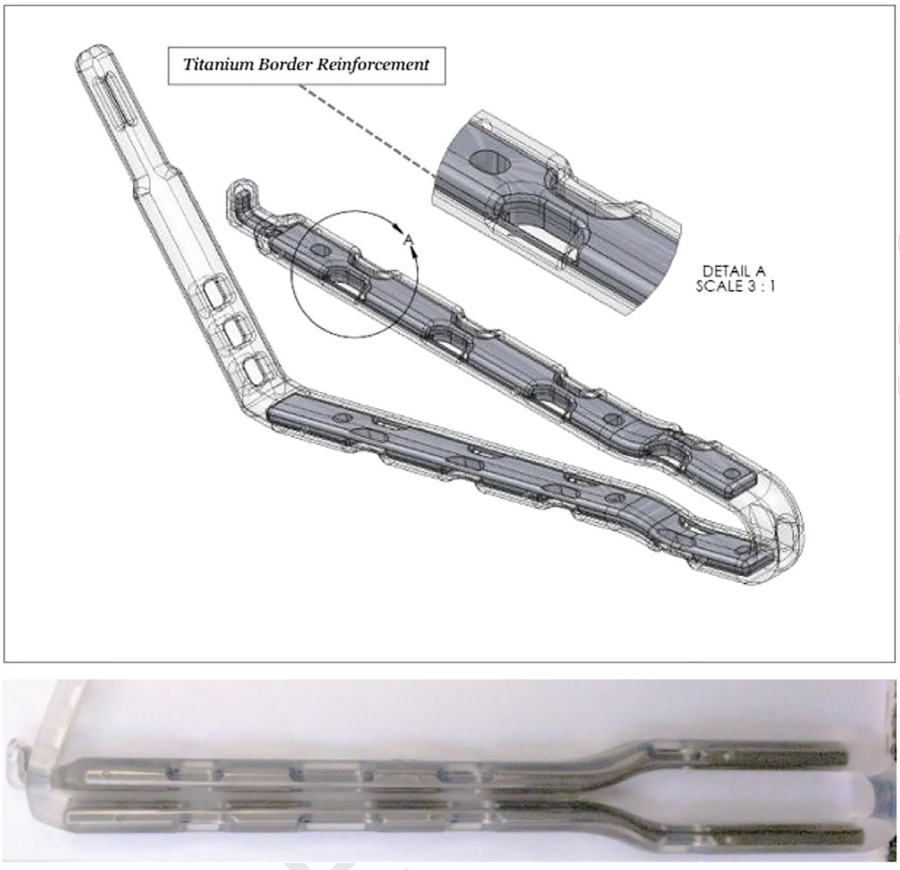

Fig. 2. Laparoscopic vertical clip gastroplasty.

food is….") by 418%. Each patient's answers for each of these 6 items are summarized in Figs. 3 and 4.

The QoL was also analyzed regarding the complications and resolution of different medical conditions included in the BAROS Score. The results showed failure for 1.2% of patients and were fair for 6.1% of cases. The QoL was assessed as good for 26 patients (31.8%), as very good for 39 patients (47.5%), and as excellent for 11 patients (13.4%).

Discussion

The constant need to find a new bariatric operation represents a clear sign that all the current procedures have certain limitations and complications. LSG became the most common performed bariatric procedure probably because of its good ratio between complications and weight loss results and its high popularity in social media. Still, many surgeons implicate the LSG for 2 major disadvantages: postoperative GERD and irreversibility. The LVCG has the same restriction principle as LSG with a similar gastric tube volume. It restricts oral intake with no need of resection (requires no stapling), does not change gastric anatomy (compared with LSG), causes no malabsorption (compared with laparoscopic Roux-en-Y gastric bypass), and does not require any adjustment (compared with laparoscopic adjustable gastric band [LAGB]).

Because reversibility is considered one of the main advantages of this new procedure (especially compared with sleeve), particular attention was paid to the closing pressure of the device during the preclinical studies.

The first gastric clip was developed in the 1980s without any success, mainly because it was associated with complications [14]. The rigidity of the device, its components, and its oblique position at the upper part of the stomach explained the high rate of obstruction and erosion at that time. It was more an obstructive procedure than a restrictive one and was placed more like a nonadjustable gastric band than a Bari Clip. Currently, the Bari Clip is designed to minimize the closing force so that the limbs will simply oppose the anterior and posterior walls of the stomach to minimize the possibility of erosions and ischemia. The experience with the gastric band with the 2 different techniques (pars flacida and perigastric) taught us a lesson about gastric migration. Himpens et al. [15] reported a rate up to 28% for band erosion with the perigastric technique. Even if a further review [16] showed a decreased incidence of band erosion with the modification to the pars flacida

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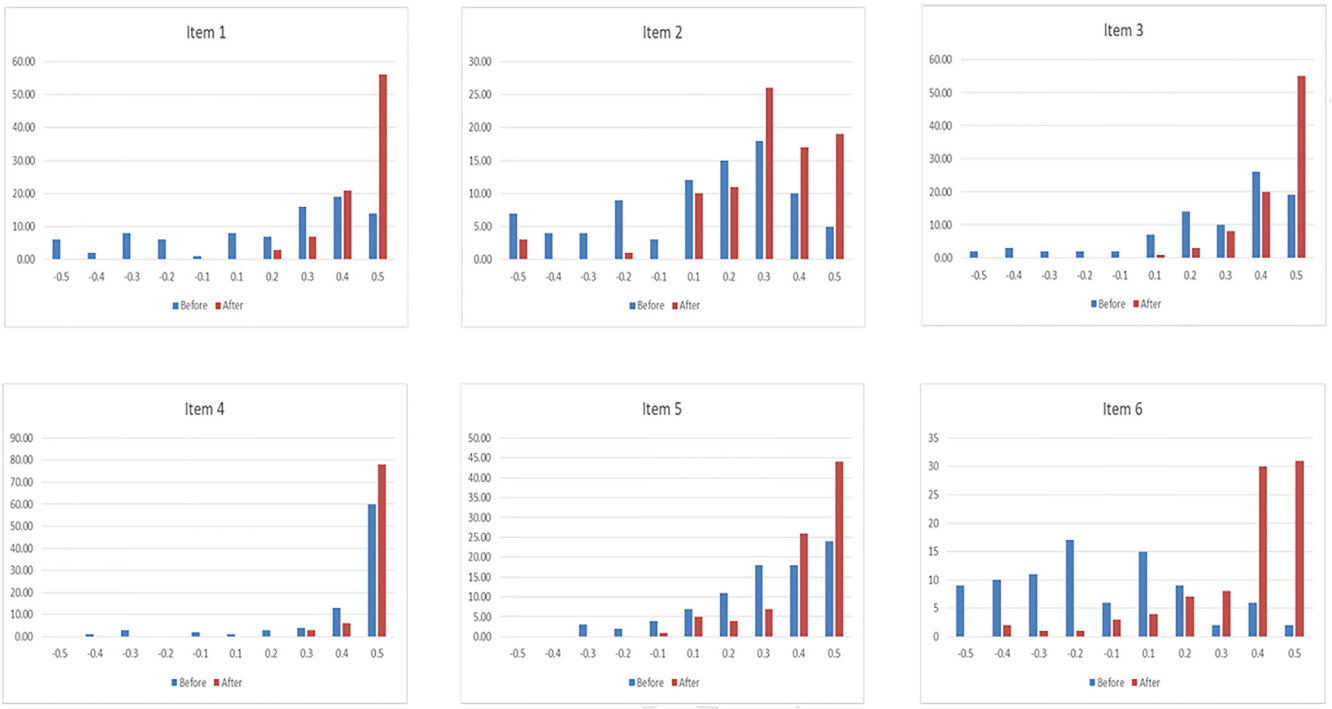

Fig. 3. Items evolution of Moorehead-Ardelt questionnaire.

technique, this complication remains one of the inconveniences of the LAGB.

Up to 4 years, with LCSG, erosion was seen in 2 patients (1.4%), both located at the antrum of the stomach. This was diagnosed 24 and 48 months postoperatively in asymptomatic patients after being identified during routine endoscopic surveillance. This complication was explained after reviewing the recorded video. The reason for this complication in the first patient was due to both the use of a first-generation 13-cm clip instead of a 14.5-cm clip and trauma to the antrum during placement. The gastric clip was removed laparoscopically without complications. For the second patient erosion was explained by chronic slippage of the clip, which we chose at the time to manage conservatively. We have since decided to change the management of the potential asymptomatic chronic slippage by explanting or repositioning the clip.

The postoperative QoL after bariatric surgery is thought to depend on the quantity of weight loss, resolution of co-morbid medical conditions, improved function in daily activities, and the absence of postoperative complications. No reference standard yet exists for the assessment of bariatric postoperative QoL. BAROS, introduced by Oria and Moorehead in 1998 [13], is an established and recognized tool for QoL evaluation in people with obesity [17]. BAROS QoL survey (incorporating the Moorehead-Ardelt quality of life questionnaire) is simpler and more widely used. We believe the BAROS survey might oversimplify QoL assessment. Bobowicz et al. [18] used BAROS to evaluate LSG outcomes in 84 patients 5 years after surgery. An overall very good result was achieved in 30% of patients, whereas no effects were reported by 13% of respondents. Similar or even greater results were recorded with LCSG. For up to 60% of 82 patients, the QoL post-LVCG was assessed as very good or excellent and no effect was recorded for 7.3% of respondents. In the significant majority of the remaining group, the QoL was assessed as average, corresponding to the general standard. Ribaric et al. [19] presented a 3-year follow-up health-related QoL on BAROS of patients operated on in France using the Swedish adjustable gastric band method. The results were evaluated in the preoperative period and 1, 3, 6, 12, 18, 24, and 36 months after surgery. It was found that weight loss resulted in improved QoL over the 3 years of observation. The overall BAROS score increased from 1.4 preoperatively to 3.6 (2.2, $P < .001$) after 3 years. In our study, the BAROS score improved from 1.08 (SD $\pm$.96) preoperatively to 5.34 (SD $\pm$1.70) after LVCG. Our study showed an important variation of the scores of the dimensions "The way I approach food is…." and "physical activity", with mean increases of 418% and 262%, respectively. They are the most important variations. On the physical plan, weight loss facilitates movement by decreasing the handicap caused by the patient's weight and volume. The resumption of normal physical activities is facilitated. The dimension "I am able to work…" was not strongly modified in postoperative period, the score being increased by only 19%.

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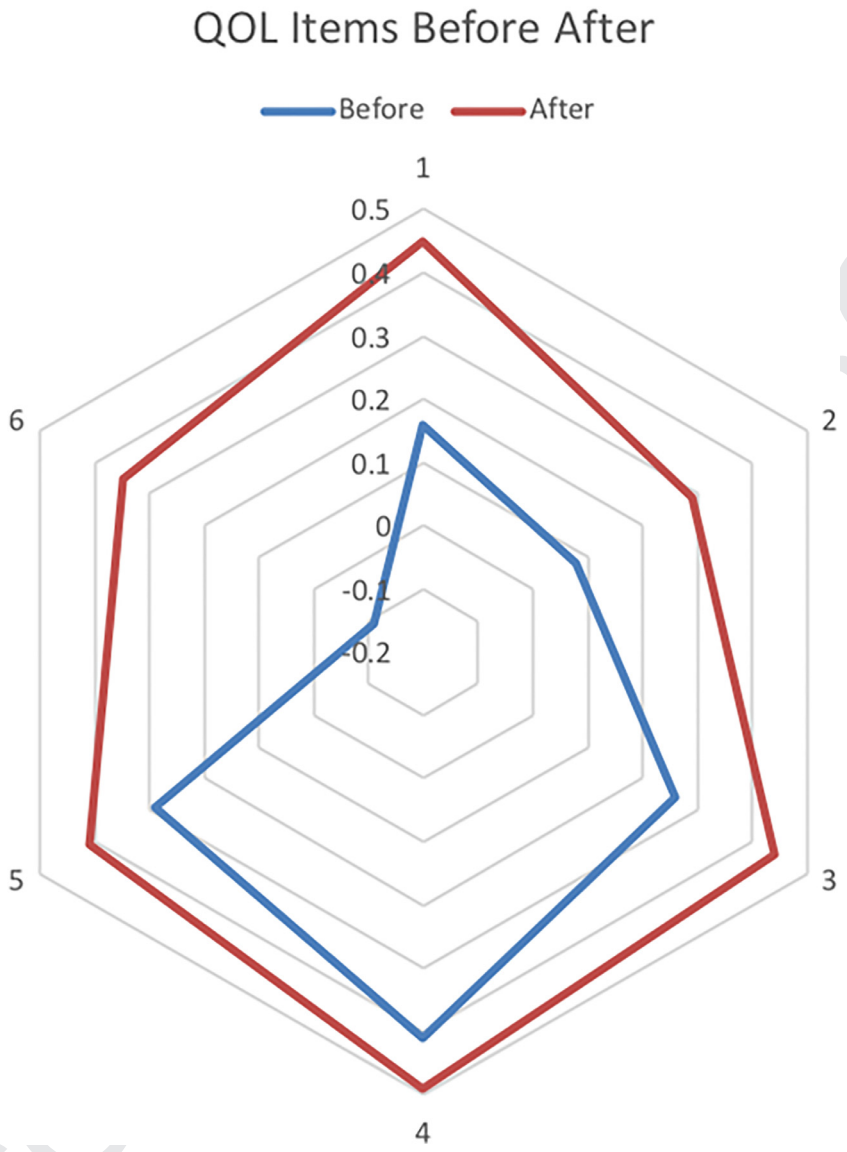

Fig. 4. Quality of life items.

At the beginning of LSG, many surgeons were impressed by the rapidity with which patients shifted toward chosing LSG instead of LAGB, mainly due to the significantly greater rates of vomiting in the LAGB groups [5,20]. LCSG represents a new bariatric procedure with a device implanted (more or less similar to LAGB), but our results showed that the QoL results and vomiting episodes (6.52%) are more similar to LSG. One of the limitations of our study and of LVCG will be represented by the surgeon's enthusiasm in offering a novel procedure that is likely to influence some patients toward that procedure, despite our best efforts (independent investigators) to provide impartial and evidence-based information. For this reason, another multicenter prospective trial will start in well-selected centers that subsequently will be involved in the surgeons' training for this new procedure (Table 2).

Table 2
Complications after LVCG.

Complication	Rate	Management
Slippage	6.52% (n = 9)	2 explanted, 2 revised, 5 treated conservatively
Erosion	1.44% (n = 2)	Explanted
GERD	5% (n = 7) the first month .72% (n = 1) after 1 mo	PPI

LVCG = laparoscopic vertical clip gastroplasty; GERD = gastroesophageal reflux disease; PPI = proton pump inhibitors.

Postoperative gastroesophageal reflux

The lack of objective measurements such as pH-metry, impedance, and high-resolution manometry does not provide robust evidence on the effects of LSG on GERD. The Roux-en-Y gastric bypass represents the most common

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option, especially for patients with severe gastroesophageal reflux after LSG. Newer strategies like Stretta, Linx, or Endostim [21,22] need to be explored and could represent a future alternative. To avoid GERD after LSG, a new procedure, N-sleeve [23], was proposed, with the following 2 main limitations: incomplete gastric fundus removal and difficult revisional procedures in case of weight regain or recurrence of GERD. Compared with this, LVCG presents complete exclusion of the gastric fundus. With its minimal dissection of the hiatal region, a revisional procedure will be less difficult, with decreased risk of complications.

Conclusion

LVCG represents a new bariatric procedure that mimics the principle of LSG, but with a completely reversible mechanism. The procedure consists of a nonadjustable clip that is vertically placed parallel to the lesser curvature. After >3 years of clinical use, the weight loss results seem to be encouraging, and up to 92.7% of patients report improved QoL.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

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