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ORIGINAL PAPERS

Endoscopic sleeve gastroplasty (the Apollo method): a new approach to obesity management

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ABSTRACT

Background: Many obese patients cannot lose weight or reject conventional obesity management. Endoscopic sleeve gastroplasty (the Apollo method) is a pioneering coadjuvant, interventionist technique for the integral management of obesity.

Objectives: The goals of this study were to report safety and efficacy results obtained at 6 months in patients undergoing endoscopic sleeve gastroplasty.

Material and methods: A prospective study was performed in 55 patients (13 males, 42 females) who were subjected to the Apollo technique; mean age was 43.5 years (range 25-60) and mean BMI was 37.7 kg/m^2 (range 30-48). All received multidisciplinary follow-up for weight loss. Weight changes and presence of complications were assessed. Through the endoscope a triangular pattern suture is performed consisting of approximately 3-6 transmural (mucosa to serosa) stitches, using a cinch device to bring them nearer and form a plication.

Results: A total of 6-8 plications are used to provide a tubular or sleeve-shaped restriction to the gastric cavity. No major complications developed and patients were discharged at 24 hours following the procedure. Endoscopic and radiographic follow-up at 6 months post-procedure showed a well preserved tubular form to the stomach. After 6 months patients had lost 18.9 kg and 55.3% of excess weight.

Conclusions: Endoscopic sleeve gastroplasty, together with dietary and psycho-behavioral changes, is a safe, effective technique in the coadjuvant management of obese patients.

Key words: Endoscopic sleeve gastroplasty. Obesity management. Bariatric endoscopy.

INTRODUCTION

The World Health Organization (WHO) recognizes the impact of obesity on the development of the most prevalent chronic conditions in our society (type 2 diabetes, cardiovascular disease, musculoskeletal disorders, and an increasing number of cancer types). Obesity also results in body image, self-esteem, and relational disorders, and in relevant both direct and indirect financial costs, as well as a significant use of health care and social resources (health visits, absenteeism, autonomy loss, special needs, etc.) (1,2).

Furthermore, many obese patients cannot lose weight to the point of improving their health with conventional therapies (including drugs, diet, increased exercise, and behavioral intervention), which is primarily due to a high proportion of discontinuations and weight regain (3).

Bariatric surgery provides relevant, long-lasting weight loss, and improves obesity-related comorbidities in a relevant percentage of subjects. However, obesity surgery is not exempt from risk, up to 90% of patients reject it, and it is often inaccessible (because of costs, location, lack of resources). Moreover, bariatric surgery is not indicated for some obesity grades. As a result, only a small percentage of the obese population may access bariatric surgery (4).

From all the above, less invasive endoscopic procedures are under development for the management of obesity (5-7); they provide a higher number of yet untreated obese patients with access to weight loss, allow earlier management, including childhood and juvenile obesity cases, and may be used in the obese elderly.

Endoscopic sleeve gastroplasty (the Apollo method) is a novel endoscopic technique for the treatment of obesity (8). We report here the effectiveness, safety, and 6-month outcome data from a series of 55 subjects.

MATERIAL AND METHODS

Study population

All procedures followed the Good Clinical Practice guidelines and were performed according to the ethical principles for medical

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Conflict of interest: The primary author acts as bariatric endoscopy consultant for Apollo Endosurgery.

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research involving human subjects set forth by the Declaration of Helsinki. The study was approved by the Ethics Committee at Hospital Universitario Madrid Sanchinarro, and registered as 657-GHM. Patients signed a written informed consent.

Similarly, the study was included in ClinicalTrials.gov with ID no. NCT02231970. It uses convenience sampling. Data were prospectively collected for analysis. Patients were selected amongst those visiting the Bariatric Endoscopy Unit at Hospital Universitario Madrid Sanchinarro for obesity between May 2013 and July 2015 who had undergone at least 6 months of multidisciplinary follow-up and who met inclusion criteria.

Inclusion criteria were as follows: obese patients (BMI > 30 kg/m^2) who adequately understand and commit themselves to undergo multidisciplinary follow-up for obesity for at least one year.

The technique is contraindicated for the following: acute, potentially bleeding gastric mucosal lesions (ulcers, acute gastritis), neoplastic lesions, hiatus hernia > 3 cm, coagulopathy, and psychiatric disorders (the latter assessed using psychological interviews and various blood tests).

Technique description

The technique is defined as a gastric restriction using endoscopic transmural suturing throughout the gastric wall to provide a gastric sleeve similar but not identical to sleeve gastrectomy in shape.

The gastroplasty uses an endoscopic suture device (OverStitch; Apollo Endosurgery Inc., Austin, Texas, USA) fitted to a dual channel endoscope (GIF-2T160; Olympus Medical Systems Corp., Tokyo, Japan) (Fig. 1, with permission from Apollo Endosurgery Inc., Austin, Texas, USA). In addition to the endoscopist an assistant is also needed to help in loading sutures, in cinching, and in tissue retraction (Helix, Apollo Endosurgery Inc., Austin, TX).

Sutures encompass the whole thickness of the gastric wall in order to provide durability to sleeve gastroplasty. The procedure is performed under general anesthesia with the patient in the left lateral position, and using endotracheal intubation. An overtube is used for convenience and to increase procedural safety. Pre-procedure antibiotic prophylaxis is also given (cefotaxim 2 g IV).

Initially the gastric cavity is distended by carbon dioxide insufflation. An initial endoscopic assessment is first performed to rule out any contraindications to the gastric procedure, and to mark suture sites along the anterior wall, greater curvature and posterior wall with argon. Sutures are carried out from distal to proximal, starting at the incisura angularis and ending up in the fundus.

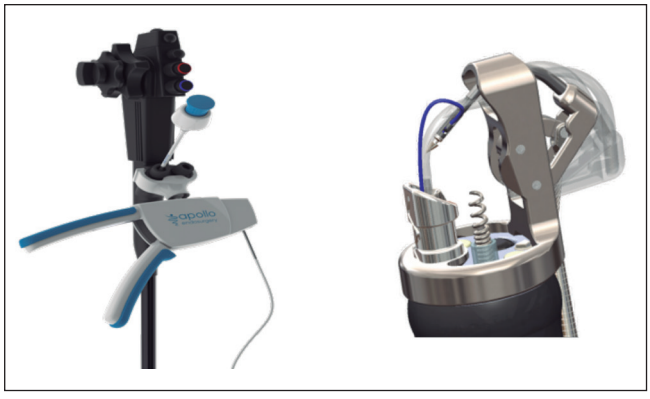

Fig. 1. The Apollo endoscopic suture system.

A triangular suturing pattern is used starting at the anterior wall, followed by the greater curvature and finally the posterior wall, after which the pattern is repeated backwards using the argon marks as a guide for orientation within the stomach. Each triangular pattern consists of approximately 3-6 transmural (mucosa to serosa) stitches, which are then brought together into a plication using a cinching device in place of the usual surgical knot. A total of 6-8 plications are performed in order to reduce the gastric cavity in its longitudinal diameter, and to provide a tubular or sleeve-shaped gastric restriction.

To make sure that stitches pass through the whole thickness of the gastric wall, a corkscrew-like catheter (Helix) is inserted into the muscularis mucosa to bring the tissue into the system. This suture mechanism is crucial for the transmural and durable character of each plication.

Using this technique, we form a gastric sleeve with the anterior wall, greater curvature, and posterior wall, having the lesser curvature as dome, which not only reduces the transversal gastric diameter but also considerably shortens the longitudinal one creating an accordion effect. The technique is shown in figure 2.

After procedure completion a second endoscopy is carried out to ensure the final tubular configuration is there, to examine any defects requiring cupplemental closure, and to rule out potential bleeding.

The immediate postoperative period includes inpatient surveillance for 24 hours. At 8 hours after the procedure liquid tolerance is tested. Blood tests are performed at 6 and 24 hours after the procedure to rule out bleeding, and barium X-rays are used to check the gastroplasty configuration.

Figure 3 shows images obtained at 24 hours after the procedure and figure 4 shows endoscopic images obtained after 1 year.

Follow-up

During the first month the patient is on a progressive consistency liquid diet. Follow-up is performed tightly by a multidisciplinary team including a nutritionist, a psychologist, and an exercise coach. Visits occur 2-4 times per month, either at the clinic or via the telephone.

Radiographic and/or endoscopic checks are also scheduled at various times.

Weight parameter assessment

Variations in weight parameters were estimated based on measurements at baseline and at 1, 3 and 6 months; variables included total weight (kg), BMI (kg/m^2), total weight loss (TWL), percentage of total weight loss from baseline (%TWL), and percentage of excess weight loss (%EWL). Ideal weight was estimated as corresponding to a BMI of 25 kg/m^2.

Statistical analysis

A descriptive analysis of study variables was performed using central tendency and dispersion statistics for qualitative variables

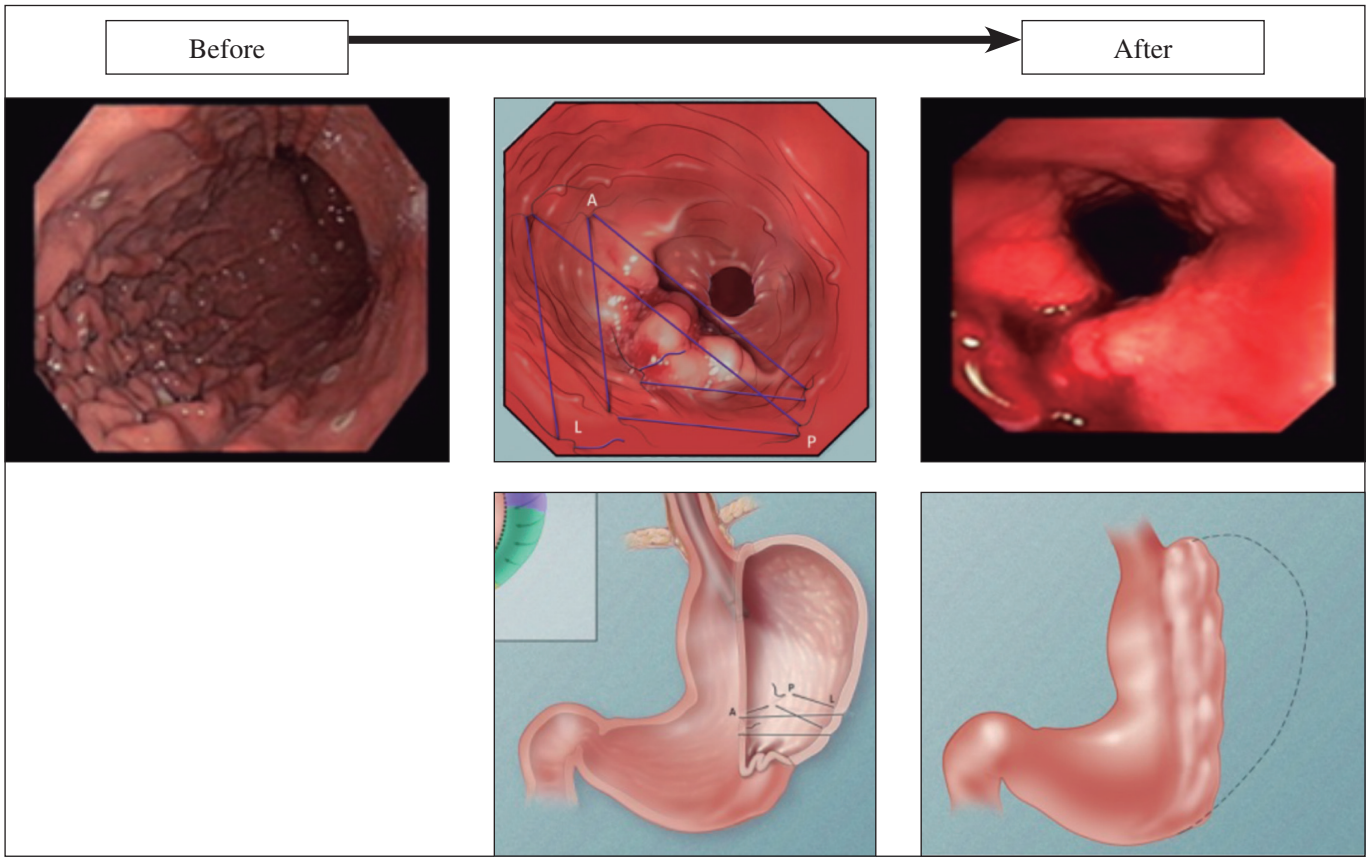

Fig. 2. Endoscopic sleeve gastroplasty technique (the Apollo method).

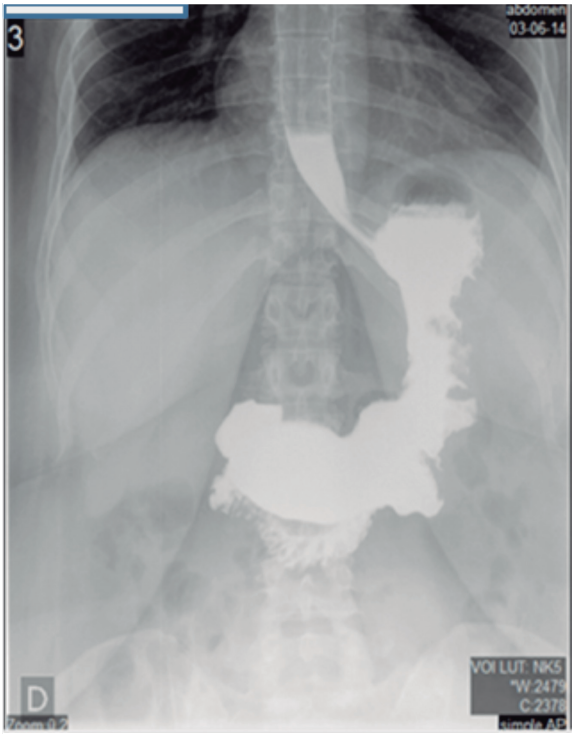

Fig. 3. Contrast RX image post-procedure.

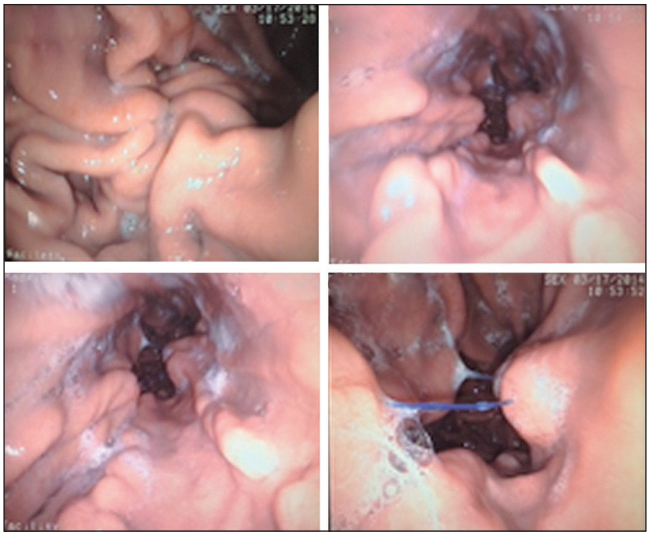

Fig. 4. Luminal endoscopic view of the gastric body.

(mean and standard deviation), and frequency and proportion for quantitative variables.

The Student's t-test for dependent samples was used to compare weight parameter changes between subjects. A $p < 0.05$ level of significance was considered for all tests.

Analyses were carried out using the SPSS 17.0 software package (SPSS Inc., Chicago, Illinois, USA).

RESULTS

The sample was made up with 55 patients (13 males, 42 females) with a mean age of 43.5 ± 8.1 years (range 25-60) and a mean BMI of 37.7 ± 4.5 kg/m^2 (range 30-48). No major complications or bleeding events occurred in the immediate post-operative period, although some patients had abdominal pain (50%) and nausea (20%), which were treated with pain killers and antiemetics. In 4 cases symptoms required that hospital stay be prolonged for an additional 24 hours. One patient had severe abdominal pain, his condition being attributed to an esophageal condition upon discharge after 24 hours, during which other conditions were ruled out and the subject received antacids.

Evolution of weight parameters

Table I shows how weight parameters evolved. All differences were significant both with respect to baseline weight and, in each time point, to the data obtained in the previous cut-off.

DISCUSSION

The primary results from this study show that endoscopic sleeve gastroplasty (the Apollo method) is a safe, reproducible technique when performed by expert hands. In our experience no major complications occurred. From the results obtained for weight loss we may claim that the technique, when used as an adjuvant of dietary and behavioral modifications, is effective to manage obesity.

As for study limitations we should mention that our sample included 55 patients presently at 6 months of follow-up. Also, all procedures were performed by an endoscopist highly experienced in bariatric endoscopy, and follow-up was accomplished by nutritionists and psychologists with great expertise in the management of patients undergoing bariatric endoscopy. Hence, results must be extrapolated with caution in accordance with the above limitations.

Table I. Evolution of weight parameters after endoscopic sleeve gastroplasty

Variable	*Baseline (n = 55)*	*1 month (n = 55)*	*3 months (n = 55)*	*6 months (n = 55)*
Weight (kg)	106.6 ± 18.3	98.9 ± 16.4	92.2 ± 15.6	87.6 ± 14.7
BMI (kg/m^2)	37.7 ± 4.5	35.0 ± 4.2	32.7 ± 4.3	31.1 ± 4.5
TWL (kg)		7.7 ± 2.9	13.3 ± 4.0	18.9 ± 9.5
%TWL		7.1 ± 2.2	13.3 ± 4.0	17.3 ± 7.0
%EWL		23.1 ± 10.2	43.0 ± 16.2	55.3 ± 23.8

TWL: Total weight loss; %TWL: % of total weight loss; %EWL: % of excess weight loss.

Bariatric endoscopy has presently emerged as a therapeutic option for obesity in patients not eligible for surgery and failing to respond to conventional treatment, or who just refuse to undergo surgery (9).

As regards endoscopic sleeve gastroplasty (Apollo method), Abu Dayyeh et al. first showed in 2013 (8) that the technique was safe and feasible in a pilot study with 4 patients. Then, once the procedure's technical aspects were published (9), and following the first study by our team (10) in 20 patients who had results at 6 months including a %TWL of 53.9%, Sharaiha et al., in 2015 (11), reported 6-month results for a different clinical subset of 10 patients with a baseline BMI of 45.2 kg/m^2, in which a %EWL of 30% was recorded after 6 months.

Other bariatric endoscopy techniques are available, including intragastric balloons, which remain inplanted for 6 months. Several prospective studies with mid-term follow-up have shown that the Orbera intragastric balloon (IGB) is effective for losing weight (12); mean TWL at 3 and 6 months was 12.9 kg and 16.0 kg, respectively, which suggests that most weight loss (80% of that obtained at 6 months) occurs within the initial 3 months and is later maintained. In the 2008 review by Dumonceau et al. (13) (30 studies and 4,877 patients), including non-randomized studies, mean TWL at 6 months after IGB implantation, plus dietary and exercise recommendations, was 17.8 kg.

In our experience, the results obtained with a conventional IGB in a study of 714 patients (14) represented a mean TWL of 18.8 kg, slightly higher than those obtained with a different balloon, namely, a dual intragastric balloon (15), of 16.6 kg, although the significantly smaller sample size renders such comparison inconclusive.

Longer-term follow-up studies, such as the review by Gaur in 2015 (12), show that only 52% of TWL as obtained with an IGB persisted 12 months after explantation. In the study by Angrisani et al. in 2006 (16) a mean 43% of TWL persisted after 12 months following IGB explantation. Recently, The American Society for Gastrointestinal Endoscopy (ASGE) has published a systematic review and meta-analysis assessing endoscopic techniques (17), and they conclude that IGB was adequate for obesity management as it obtained > 25% EWL at one year after the procedure and an incidence of serious adverse events < 5%, as recommended by this Society (5). This same institution has presented the grounds that should support the use of bariatric endoscopy techniques (18), emphasizing adequate patient selection, need for an experienced multidisciplinary team, and appropriate training for involved professionals.

Other endoscopic techniques for gastric reduction include the POSE method (USGI Medical, San Clemente, California, USA) (19,20). The goal of this technique is to provide volume reduction and to prevent gastric fun-

dus accommodation, as well as to induce antral dysmotility using a number of transmural plications in the fundus (between 7 and 9 g-Cath™ plications) and proximal antrum (3-4 plications) in order to prolong satiety. The initial results were reported by Espinós et al. in 2013 (19) on 45 obese patients, and show a mean TWL of 13 kg at 6 months, with a %EWL of 49%, and good tolerability. In our experience, regarding the initial results at 1 year reported in the literature (20), we obtained a TWL of 14.8 kg and a %EWL of 42.1% in 131 patients at 6 months, and at 1 year we obtained, in a sample of 116 subjects, a mean TWL of 16.6 kg and a %EWL of 44.9%.

The present study addressed three primary questions on these techniques: Are they safe techniques? Are they effective? Are they durable?

Regarding the first concern, namely safety, the results obtained show that the technique, when used by expert endoscopists in an appropriate hospital setting with patient surveillance during the immediate post-operative period, is a low-risk one.

As regards effectiveness, we consider that patients should be thoroughly informed that multidisciplinary follow-up is key after the procedure, and that they should commit themselves to follow the instructions provided by a nutritionist and a psychologist in order to lose weight, to manage obesity-associated comorbidities, and to change their life style as appropriate to maintain the results obtained partly by the procedure. The goals of bariatric endoscopy include the induction of weight loss and the improvement of associated comorbidities with an acceptable safety profile. Weight loss following a surgical or drug-related intervention is often established according to %TWL or %EWL changes in order to define efficacy.

At present we have available recommendations issued by the American Society for Gastrointestinal Endoscopy (ASGE) and the American Society for Metabolic and Bariatric Surgery (ASMBS) (5), wherein it is considered that a bariatric endoscopy procedure for the primary treatment of obesity should obtain at least 25% of %EWL with less than 5% of serious adverse events. The results obtained by the Apollo method more than adequately meet these requirements.

Regarding effect duration, results at 6 months suggest that, at least during this period, the technique remains effective and helpful. In this respect, the fact that no irreversible anatomic changes occur is to be highlighted, hence the technique may be repeated and other measures may be taken in the future in order to obtain durable results.

Further reliable studies using verified methods are needed to unveil which newer options may allow this technique, the long-term results, its potential use for other indications such as overweight and weight recovery after bariatric procedures, whether surgical or endoscopic, and its cost-effectiveness. A promising future awaits the management of obesity, currently considered as the second cause of avoidable mortality in Spain after tobacco (21), with an estimated annual cost of €2,500 million (22).

CONCLUSIONS

The new approach to the interventionist management of obesity entailed by endoscopic techniques opens up a promising way of reaching more patients who may be presently without treatment.

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