Background and study aims: Bariatric endoscopy has emerged as an aid in the nonsurgical treatment of obesity. The objective of this study is to critically provide the results and follow-up of endoscopic sleeve gastroplasty 1 year after the procedure.

Patients and methods: Prospective single-center follow-up study of 25 patients (5 men, 20 women) who underwent flexible endoscopic suturing for endoluminal gastric volume reduction. A multidisciplinary team provided post-procedure care. Patient outcomes were recorded at 1 year after the procedure. Linear regression analysis was done to evaluate the variables associated with best results at 1 year of follow-up.

Results: Mean body mass index (BMI) was 38.5 ± 4.6 kg/m² (range 30–47) and mean age 44.5 ± 8.2 years (range 29–60). At 1 year, 22 patients continued with the follow-up (2 dropped out at 6 months and 1 at 3 months). There were no major intra-procedural, early, or delayed adverse events. Mean BMI loss was 7.3 ± 4.2 kg/m², and mean percentage of total body weight loss was 18.7 ± 10.7 at 1 year. In the linear regression analysis, adjusted by initial BMI, variables associated with %TBWL involved the frequency of nutritional (β = 0.563, P = 0.014) and psychological contacts (β = 0.727, P = 0.025). The number of nutritional and psychological contacts were predictive of good weight loss results.

Conclusions: Endoscopic sleeve gastroplasty is a feasible, reproducible, and effective procedure to treat obesity. Nutritional and psychological interaction are predictive of success.

Introduction

Bariatric endoscopy has emerged for nonsurgical treatment of obesity, providing a treatment option for weight loss and associated comorbidities [1]. Fogel in 2008 [2] and Brethauer in 2010 [3] showed the feasibility of endoscopic gastric volume reduction for management of obesity using a superficial endoscopic suturing device that mimicked vertical banded gastroplasty surgical anatomy. In 2013, Abu Dayyeh and colleagues demonstrated the feasibility of creating a full endoscopic sleeve gastroplasty (ESG) that reduces the entire stomach through creation of a small-diameter sleeve along the lesser curvature of the stomach [4]. Since then, clinical experiences with ESG have been published. Outcomes of ESG have been published at 6 months [5,6] and there is interest in outcomes with a longer follow-up period.

In this paper, we provide 1-year outcomes in the first 25 patients reaching this milestone and have identified predictors of favorable weight loss response to aid patient management moving forward.

Patients and methods

Patients
All patients had failed lifestyle modification efforts. All procedures were conducted in accordance with good clinical practice and within the guidelines of the Declaration of Helsinki (WMA, 2004) [7] for studies using human subjects. Written informed consent was obtained from all patients.

The study was registered with the institutional review board of the Madrid Sanchinarro University Hospital. The registration number of the study is 657-GHM.

Clinical Trial registration of clinical trial
The study was registered in ClinicalTrials.gov with identifier NCT02231970.

Data were collected prospectively for analysis. The specific indications for the procedure were based...
on obesity parameters (body mass index [BMI] 30–49 kg/m²) with previous failed attempts with conventional treatment of obesity and the willingness and ability of patients to be treated by a multidisciplinary team for at least 1 year. The procedure was contraindicated in patients with prior gastric surgery, potentially bleeding lesions (e.g., ulcers and acute gastritis) and neuropsychiatric findings. Individuals with psychiatric disorders (mental retardation, manic-depressive psychosis, severe depression, schizophrenia, and untreated eating behavior disorders) that interfere with their ability to actively engage with the post-procedural instruction and recommended lifestyle adjustments were excluded. Coagulopathy and psychiatric disorders were excluded by blood tests and interviews with a psychologist, respectively.

Endoscopic sleeve gastroplasty procedure
As we have described previously (5), we refer to the technique as endoscopic endoluminal greater curvature plication. The procedure was performed with the patient in the left lateral decubitus position and under general anesthesia with endotracheal intubation. Pre-procedure antibiotics were given (Cefotaxima 2g intravenously).

Construction of the gastroplasty was dependent on a cap-based flexible endoscopic suturing system (OverStitch; Apollo Endosurgery, Inc., Austin, Texas, USA), which was mounted onto a double-channel endoscope (GIF-2T160; Olympus Medical Systems Corp., Tokyo, Japan) placed through an esophageal overtube (US Endoscopy, Mentor, Ohio, USA) with carbon dioxide gas insufflation. The goal of this procedure was to reduce the gastric lumen into a tubular configuration, with the greater curvature modified by a line of sutured plications as previously reported. To perform the gastroplasty we deploy interrupted sutures from distal to proximal body. Each suture consists of six bites along the anterior/greater curvature/posterior gastric wall before it is cinched. Because this is not a continuous staple line, but rather, an invagination of the greater curvature of the stomach, intraluminal gaps exist along the plication line. These gaps are of no clinical consequences as far as trapping food and are analogous to gaps seen with surgical plications of the greater curvature for weight loss. Reinforcing stitches are usually placed in the upper body of the stomach. The suture pattern has evolved from a very few corresponding to a BMI of 25 kg/m²) (%EWL), and (4) change in BMI.

c) Post-procedure adverse events: Nausea, constipation, abdominal pain, hematemesis, melena, fever, reflux.

2. Psychology
a) Patient contacts: The number of contacts was divided into tertiles to study its relationship with the weight parameters. The tertiles were as follows: low adherence = T1, medium adherence = T2, and high adherence = T3.
b) Behavioral measures (baseline and 1-year): (1) disorganization; (2) “five meals a day” compliance; (3) speed eating, (4) snacking, (5) binge eating, (6) physical activity (PA), and (7) sleep quality.

Post-procedure program structure
The programmatic follow up mirrored that which was applied to the initial pilot patient group reported earlier.

First 4 weeks
A liquid diet was started the day before the procedure and continued for 2 weeks, followed by progression from hypocaloric li-
quids to small semisolids over 4 weeks. Exercise initially consisted of walking, with a progressive increase in intensity that paralleled the diet progression. Weekly contacts were made to evaluate performance and provide solutions for problems related to compliance with lifestyle treatment that patients may have experienced.

**Months 2 – 12**

Individual taste preferences were taken into account in designing hypocaloric diets. Aerobic exercise was adjusted to patient capability and involved walking, jogging, cycling, aerobics, or swimming for a minimum of 30 minutes, 3 times a week. Patients were advised to add physical activity to any daily routine, (e.g. walking instead of taking mechanized transport and climbing stairs rather than using the elevator).

**Statistical analysis**

Descriptive analyses of the variables were performed using the test of proportions for qualitative variables and measurements of central tendency (mean) and measures of dispersion (standard deviation: s.d.) for quantitative variables. The association between changes in the initial and final values of weight parameters used the student t test for related pairs. For comparisons of continuous variables, the comparisons of absolute means between groups were calculated using the student t test.

Multivariate means and the 95% confidence interval (CI) for quantitative variables. The means were adjusted for age, sex, and initial BMI. Finally, univariate linear regression analyses were fit to assess the association between %TBWL and number of nutritional contacts, and between %TBWL and number of psychological controls, both controlling for initial BMI. All P values presented were two-tailed, and statistical significance was defined a priori at P=0.05. Data analyses were performed using SPSS 19.0 (SPSS Inc., Chicago, Illinois, USA).

**Results**

The treatment group consisted of 25 patients (5 men, 20 women). Three patients dropped out, one at 3 months and two at 6 months. The final sample consisted of 22 patients with completed follow-up at 12 months.

Among the 25 patients, mean BMI was 38.5 ± 4.6 kg/m² (range 30 – 47) and mean age 44.5 ± 8.2 years (range 29 – 60). The mean procedure time was 80 minutes (range 50 – 120 minutes). All patients underwent successful gastroplasty. There were no major intra-procedural, early, or delayed adverse events. No bleeding complications were found. During this period, patients received analgesics and antiemetics on an as-needed basis. Post-discharge pain (2 – 4 days) and nausea (1 day) were experienced by 50% and 20% of the patients, respectively. Oral contrast studies to assess the gastroplasty at 24 hours showed no leaking contrast and intact reductions. All patients were discharged the day after the procedure.

**Weight change**

Table 1 shows the results of the evolution of the weight parameters. The initial parameters and the values collected at the post-procedural time intervals differed significantly. The largest decreases were seen in the first month after the procedure, when patients were on no solid foods.

**Nutritionist Follow-up**

During the first year of follow-up, the mean number of nutritional contacts was 19.6 ± 9.9 (range 3 – 32). Fig. 1 shows the weight loss parameters (BMI changes, %TBWL, and %EWL) across the tertiles of nutritional contacts. Tertiles are distributed as follows: T1 (0 – 16 contacts/year), T2 (17 – 24 contacts/year), and T3 (24 – 32 contacts/year).

As shown in Fig. 1, the magnitude of the weight loss increased significantly (P<0.05) in individuals who had more nutritional contacts. After adjustment for age, sex, and initial BMI, a linear trend was found for changes in %TBWL (P=0.045) and %EWL (P=0.013).

**Psychological follow-up**

During the first year of follow-up, the mean number of psychological contacts was 9.2 ± 7.2 (range 0 – 23). Tertiles are distributed as follows: T1 (0 – 3 contacts/year), T2 (4 – 12 contacts/year), and T3 (13 – 23 contacts/year).

As shown in Fig. 2, the magnitude of the weight loss increased significantly (P<0.05) in individuals who had more psychological contacts. After adjustment for age, sex, and initial BMI, no linear trend was found for changes in %TBWL and %EWL.

**Changes in nutritional habits**

Fig. 3 shows initial and final values for nutritional habits. Initially, the worse habits were “not eating 5 meals a day” (94.1%) and “not eating slowly” (93.3%). One year after the procedure, the most notable changes were “not eating 5 meals a day” (from 94.1% to 29.4%) and binge eating (from 68.8% to 12.5%).

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**Table 1** Changes in weight-related parameters following endoscopic endolumenal greater curvature plication for the treatment of obesity at 3 months, 6 months, and 1 year post-procedure.

<table>
<thead>
<tr>
<th>Variable</th>
<th>1 month mean ± SD</th>
<th>3 months mean ± SD</th>
<th>6 months mean ± SD</th>
<th>12 months mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (kg/m²) loss</td>
<td>2.8 ± 0.8</td>
<td>4.9 ± 1.6</td>
<td>6.9 ± 2.9</td>
<td>7.3 ± 4.2</td>
</tr>
<tr>
<td>Total weight loss (kg)</td>
<td>7.9 ± 2.7</td>
<td>14.1 ± 5.5</td>
<td>19.6 ± 9.1</td>
<td>21.1 ± 12.6</td>
</tr>
<tr>
<td>Percentage of weight loss (%)</td>
<td>7.4 ± 2.3</td>
<td>12.9 ± 4.3</td>
<td>17.8 ± 7.5</td>
<td>18.7 ± 10.7</td>
</tr>
<tr>
<td>Percentage of excess weight loss (%)</td>
<td>24.0 ± 11.8</td>
<td>40.5 ± 16.5</td>
<td>53.9 ± 24.8</td>
<td>54.6 ± 31.9</td>
</tr>
</tbody>
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BMI, body mass index.

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Among the initially sedentary patients, 55.6% began physical activity (walking or doing cardiovascular exercises in the gym), and 75% of those who were initially not sedentary improved their level of physical activity (increasing walking time or doing other activities in the gym).

Factors predictive of success
The result of the linear regression analysis, controlling for initial BMI, showed that the number of nutritional contacts predict the %TBWL ($\beta = 0.563$, $P = 0.014$) and that the number of psychological contacts predict the %TBWL ($\beta = 0.727$, $P = 0.025$).

Gastroplasty at 1 year
Fig. 4 shows the radiologic images at 24 hours and 1 year post-procedure. Fig. 5 shows the endoscopy image at 1 year post-procedure.

Gastroplasty assessment was more successful than our earlier pilot experience and obtained in 90% of the patients, 50% endoscopically and 80% by contrast study. Based on these studies, one patient underwent a revision partial gastroplasty because of loosened plications. A tubular configuration of the gastroplasty was otherwise confirmed in the remaining patients.

Discussion
This extended experience demonstrates that endoscopic sleeve gastroplasty offers a safe and effective endolumenal weight loss option with durability at 1 year. The procedure does produce discomfort for patients in the immediate post-procedure period, with 50% experiencing moderate abdominal pain and 20% experiencing nausea, both of which can be controlled pharmacologically. No long-term complications were observed. At 1-year follow-up, patients reached 54.6% of EWL and 18.7% of TBWL. The subgroups with the highest number of nutritional and psychological interactions demonstrated the most favorable weight loss. This is not surprising, given our earlier pilot experience and general knowledge regarding the value of comprehensive supportive care post-procedure.

The study does have limitations. First, the sample size, although larger than the originally reported pilot group, is small. In addition, there is no control group in which the technique was not performed with which to compare results, although the patients who were treated persistently failed lifestyle modification. Regarding the demonstrated benefit of greater nutritional and psychological interaction, we are uncertain as to whether that was due to patient motivation stimulated by early post-procedure weight loss or if it is due to a unique motivational success of our nutritional and psychological programs.
Factors predictive of success with endoscopic sleeve gastroplasty and the technique is reproducible and repeatable. Therefore, reintervention remains effective and helpful. It should be noted that along with the weight loss results, suggest that this endolumenal technique for weight management: technique and feasibility in 18 patients. Obes Surg 2011; 21: 166–171.

The durability of the Endoscopic Sleeve gastroplasty at 1-year, however, does not provide an opportunity for reintervention as demonstrated a mean %EWL of 44.9±24.4. This procedure, when poor results in patients are associated with a low number of visits with the multidisciplinary team.

We can conclude that after 1 year, sleeve gastroplasty is an effective, safe, and well-tolerated procedure for treatment of patients with obesity, with regular monitoring by a multidisciplinary team a key measure to success.

Competing interests: Dr. Lopez-Nava and Dr. Galvao are consultants for Apollo Endosurgery in the United States.

References