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Endoscopic gastric sleeve-restrictive endoscopic gastroplasty (Apollo method): retrospective results of our obesity unit in a year.

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Summary:

The Endoscopic Gastric Sleeve - EndoSleeve (Apollo method) is a bariatric technique that simulates a gastric sleeve by means of 5-8 triangular pattern sutures that start at the "incisura angularis" and end at the "fundus". A retrospective study of 19 patients, in which the objective is to report the results of weight loss in a year; in terms of improvement of metabolic comorbidities and complications in patients submitted to Endoscopic Gastric Sleeve. 4 cases were lost during follow-up. The percentage of total weight loss (% PTP) at 3, 6 and 12 months was 13.5%, 16.6% and 17.4% and the percentage of excess weight loss (% PEP) was 38.9%, 46.7% and 49.4% respectively. Regarding comorbidities, the resolution of ultrasound-confirmed hepatic steatosis and obstructive sleep apnea syndrome (OSAHS) were observed, as well as improvement in the HbA1c. No deterioration in blood pressure control or lipid profile was observed. In the immediate postoperative period, there was a case of upper gastrointestinal bleeding, treated with conservative measures. No late complications were observed. Based on our results, the Apollo method can be considered a safe and effective endoscopic treatment for weight loss.

Keywords:

- Bariatric Endoscopy
- Obesity
- Apollo
- EndoSleeve

Introduction

Obesity is a multifactorial chronic disease, defined by the World Health Organization as an excessive accumulation of fat that can be harmful to health.[1]

In the treatment of obesity, we have various therapeutic strategies depending on the degree of obesity and the presence of comorbidities associated with it. Conventional measures (diet and exercise) are essential.[2] In certain cases, pharmacological therapy can be chosen; 2 however, with the previously described measures, a 5-10% weight loss is estimated in the medium term [3], which, in many cases, may be insufficient. On the other hand, bariatric surgery is an effective technique that produces significant and lasting weight loss. However, in certain degrees of obesity it is neither indicated nor free of complications.[1,4] As previously described, the bariatric endoscopy is developed as a treatment for obesity: Patients with little or no response to conventional or pharmacological measures and without indication of surgical treatment or with rejection of it, despite being indicated.[5]

The Endoscopic Gastric Sleeve- EndoSleeve (Apollo method) is a bariatric technique that consists of an endoscopic gastric reduction, through 5-8 sutures that start in the distal gastric body / "incisura angularis" and end in the proximal gastric body / gastric fundus. Sutures are made in a triangular pattern, in which the starting point is the anterior wall, it continues in the greater curvature and ends in the posterior wall, to finally repeat the same pattern, but in the opposite direction. In this way, each suture pattern forms a plication, simulating a gastric sleeve.[6,7]

It is indicated in patients with type I obesity (body mass index BMI 30-34.9 kg / m^2) and type II (BMI 35-39.9 kg / m^2), and in type III (BMI 40-49.9 kg / m^2) and type IV (BMI> 50 kg / m^2) with contraindication or rejection of bariatric surgery, or as a bridge to it.5,6 The objective of our study is to report the results of weight loss in a year in patients undergoing EndoSleeve (Apollo method), in addition to analyzing the evolution of obesity-associated comorbidities: Hypertension (HT), Type 2 Diabetes Mellitus (DM2), Dyslipidemia (DLP), Hepatic Steatosis (HE) and Obstructive Sleep Apnea / Hypopnea Syndrome (SAHOS). Likewise, communicate the immediate and late complications that have occurred after the procedure.

Material and methods

A retrospective study of 19 patients (17 women) submitted to the Apollo method during the period April 2016 - January 2019. The post-procedure follow-up was performed t by a multidisciplinary team (Digestive, Endocrinology, Nutrition and Psychology). During follow-up, weight variations were evaluated by determining weight, BMI, total weight loss (PTP), percentage of total weight loss (% PTP) and percentage of excess weight loss (% PEP) according to the recommendations of the American Society for Gastrointestinal Endoscopy (ASGE) and the American Society for Metabolic and Bariatric Surgery (ASMBS).

Regarding the initial study of comorbidities, all individuals were asked for an analysis with the following parameters (glucose, HbA1c, total cholesterol and fractions, triglycerides and transaminases) and an abdominal ultrasound. Polysomnography was requested in snorers or patients with BMI ≥35 kg / m². During the follow-up, a complete analysis was requested 6 months after the intervention. At the end of the follow-up (12 months), a laboratory test, an abdominal ultrasound and a polysomnography were requested according to the comorbidities corresponding to each individual.

An improvement in comorbidities after a year was considered in the following cases:

HBP: Decrease in the dose of anti-hypertensive drugs or discontinuance with blood pressure levels <130/85 mmHg.

DM2: HbA1c <7% with the same or lower dose of oral anti diabetic drugs or insulin.

DLP: Decrease in the dose of lipid-lowering drugs or the suspension thereof with levels of total cholesterol <200 mg / dl, LDL cholesterol <130 mg / dl or triglycerides <150 mg / dl.

HE: Reduction of the degree of steatosis by an ultrasound, based on the qualitative scale of 4 points: Being grade 0, without steatosis; grade 1, mild; grade 2, moderate and grade 3, severe.

OSAHS: Decrease in apnea-hypopnea index per hour of sleep (AHI) <5 or withdrawal of CPAP (Continuous Positive Airway Pressure).

The comparison of the average of anthropometric data was performed by means of the T-Student test, with the statistical package SPSS v.18.0 (IBM Corp. Armonk, NY, USA). A p <0.05 was considered significant.

Ethical and legal aspects: approval by the ServiDigest Clinic Teaching and Training committee. The study was conducted with the principles of the Declaration of Helsinki. Participating subjects signed the informed consent and the Data Protection Law.

Results

The average age of all patients undergoing the procedure was 44.84 ± 10.07 years, with a mean initial BMI of 38.91 ± 3.98 kg / m².

As previous comorbidities, 13 patients had a HE confirmed by the abdominal ultrasound, 9 PLD, 4 HT, a 3 OSAH was detected by polysomnography, and 2 DM2. Out of the 19 patients, 4 cases were lost after 3 months of follow-up due to non-medical causes other than the procedure (Table 1).

N	19
M/H	17/2
Age (years)	44.84 ± 10.07
PreEndoSleeve-Comorbidities	
HTA	4 (21%)
DM2	2 (10.5%)
Diet	0
ADOs	2
Dyslipidemia	9 (47.36%)
Astatines	4
SAHOS	3 (15.78%)
CPAP	1
Steatosis	13 (68.42%)
Initial IMC (kg/m²)	38.91± 3.98
30-34.9	1 (5.2%)
35-39.9	12 (63.1%)
40-49.9	6 (31.5%)
Lost cases	4 (21.05%)

Table 1. Distribution of patients according to general characteristics of both groups.

Data expressed as average ± standard deviation or frequencies and percentages. N: Number. W: Woman. M: Man. HBP: arterial hypertension. DM2: Type 2 Diabetes Mellitus. ADOs:

Oral anti diabetics, OSAHS: Obstructive Sleep Apnea Syndrome. CPAP: Continuous Positive Airway Pressure. BMI: Body Mass Index.

A total of 15 patients have completed one year of follow-up. The% PTP at 3, 6 and 12 months was 13.5%, 16.6% and 17.4% and the% PEP was 38.9%, 46.7% and 49.4% respectively. Weight loss (PTP,% PTP,% PEP) was significant after 3 months of follow-up. The evolution of the weight parameters is shown in Table 2.

Variable	Initial (n=15)	3m (n=15)	6m (n=15)	12m (n=15)
Weight (kg)	108.4 ±14.0	93.5 ± 12.0	90.2 ± 13.5	89.20 ± 13.5
IMC (kg/m²)	39.0 ± 4.2	33.5 ± 3.3	32.2 ± 3.0	31.9 ± 3.6
PTP (kg)		14.9 ± 6.0 *	18.2 ± 9.2	19.2 ± 11.0
%PTP		13.5 ± 4.5 *	16.6 ± 7.5	17.4 ± 8.3
%PEP		38.9 ± 12.4 *	46.7 ± 18.0	49.4 ± 19.1

Table 2. Weight loss in patients after a year of follow-up.

Data expressed as average ± standard deviation. n: number. m: month BMI: Body Mass Index. PTP: Total Weight Lost. % PTP: Percentage of total weight loss. % PEP: Percentage of excess weight loss. (*) p <0.05.

Regarding the previous comorbidities of the individuals who completed the year of follow-up, 10 patients had HE, 8 PLD, 4 HT, 3 OSAHS (1 being a carrier of CPAP) and 2 DM2. At the end of the 12 months post-procedure, it was possible to withdraw the statin treatment in 2 patients without observing a worsening of the lipids and, a resolution of the steatosis confirmed by ultrasound was observed in 5 patients. Likewise, no deterioration of blood pressure control was observed, with anti-hypertensive medication being withdrawn in 3 patients. Regarding the hydrocarbon metabolism, an improvement in HbA1c was observed, however, the patients continued with drug therapy. In patients with OSAHS, there was a resolution

of the above, in addition to removing the CPAP in the patient who carried it; 2 pending control polysomnography (Table 3).

Table 3. Evolution of metabolic comorbidities in patients with one year of follow-up

Comorbidities	Beginning	12 months
HTA	**4 (26.6%)**	**1 (6.6%)**
Hypotension	4	1
DM2	**2 (13.3%)**	**2 (13.3%)**
HbA1c (%)	7.25	5.90
ADOs	2	2
Dyslipidemia	**8 (53%)**	**8 (53%)**
LDL (mg/dl)	118	128
Diet	3	5
Astatines	5	3
SAHOS	**3 (20%)**	**2 (13.3%)**
CPAP	1	0
Steatosis	**10 (66.6%)**	**5 (33.3%)**

Data expressed as frequencies and percentages. HBP: arterial hypertension. DM2: Type 2 Diabetes Mellitus. OADs: Oral Anti diabetics. OSAHS: Obstructive Sleep Apnea Syndrome. CPAP: Continuous Positive Airway Pressure.

Regarding complications in the immediate postoperative period, there was a case of upper gastrointestinal bleeding, treated with conservative medical measures (Clavien Dindo grade II scale). No late complications were observed. So far, no patient has subsequently required other endoscopic procedures and / or bariatric surgery.

Discussion

The Endoscopic Gastric Sleeve - EndoSleeve (Apollo method) is a bariatric technique documented for the first time in 2013.6,8 Since it is a relatively new technique, questions arise regarding its effectiveness, safety and maintenance in weight loss.[7]

To consider an effective and safe technique as the primary treatment of obesity, the American Society for Gastrointestinal Endoscopy (ASGE) and the American Society for Metabolic and Bariatric Surgery (ASMBS) require a 25% loss of% PEP after 12 months with less than 5% of serious adverse events [7,9], requirements we have met in our study. In addition to being sufficient, the weight loss has been adequate and comparable with previous studies [10,11,12]. To achieve these results, we consider that changing habits and the follow-up by a multidisciplinary team are essential.

Regarding the durability of this intervention, there are few long-term studies (> 24 months) 11,12, so we keep a follow-up program to assess weight loss and its maintenance after 12 months of the intervention.

However, the weaknesses of this study include the small sample size (n = 15) and the lack of evaluation of other metabolic parameters that could be of interest, such as the abdominal obesity measured by the waist circumference, the insulin, and the HOMA index.

Conclusions

The Endoscopic Gastric Sleeve can be considered a promising, minimally invasive, safe and effective technique for the treatment of obesity. More patients and longer-term results will be needed to reaffirm our conclusions.

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