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Biometric and metabolic changes at one-year follow-up in patients with obesity and steatotic liver disease undergoing endoscopic sleeve gastroplasty-EndoSleeve (the Apollo method)

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Abstract

Metabolic-associated steatotic liver disease (MASLD) is the leading cause of chronic liver disease in western countries. It has no specific treatment, and weight loss is the most important therapeu-tic option available. Endoscopic sleeve gastroplasty (ESG) may offer an intermediate option to bariatric surgery for patients with MASLD and obesity. In this retrospective-descriptive study we eval-uated the evolution of analytic and anthropometric parameters and metabolic comorbidities in 32 patients with MASLD who underwent ESG at 1 year after the procedure. The percentage of total weight loss (%TWL) observed was 19.4 at 1 year post-ESG, with a significant beneficial effect on arterial hypertension, pre-diabetes, and obstructive sleep apnoea syndrome. We conclude that ESG (Apollo method) is considered an effective and safe option for the treatment of patients with obesity and MASLD with favourable effect on comorbidities.

Keywords:

- Obesity
- MASLD
- ESG
- Apollo

Introduction

Metabolically-associated fatty liver disease (MASLD), formerly called non-alcoholic fatty liver disease, has become the leading cause of chronic liver disease in western countries. Its prevalence has increased along with the rising prevalence of obesity worldwide, reaching 30% of the general population, with significantly higher levels in specific populations (50-90% in obese individuals and 47-63% in patients with type 2 Diabetes) (1). Its more advanced forms can progress to non-alcoholic steato-hepatitis (NASH), fibrosis and cirrhosis, thus increasing the risk of developing hepatocarcinomas. It is also associated with an increased risk of cardiovascular disease, diabetes and other cancers, increasing the risk of mortality (2, 3). Thus, MASLD-NASH complex becomes one of the main indications for liver transplantation and is a major burden on public health budgets.

There is no specific pharmacotherapy for MASLD, and weight reduction is the most important therapeutic option available. A weight loss of 7-10% has been shown to effectively improve hepatic steatosis, inflammation and fibrosis (4). However, maintaining weight reduction can pose difficulties, even with the help of new anti-obesity drugs. In these cases, endoscopic sleeve gastroplasty (ESG), which has already proven to be a safe and effective procedure for the treatment of obesity and type 2 diabetes mellitus, may offer an intermediate, less invasive option than bariatric surgery for patients with MASLD and NASH (4).

Aims

We aimed to evaluate body weight changes and metabolic comorbidities outcome, as well as the procedure's safety index in patients with obesity and MASLD undergoing ESG.

Patients and methods

In this retrospective-descriptive, single-center study, we included 32 adult patients with MASLD and obesity undergoing ESG between January 2016 and December 2022. In all cases, the procedure was performed using a full-thickness continuous suture system (Apollo ESG-OverStitch®,

Austin (TX), USA). This bariatric technique consists of an endoscopic gastric reduction using 5-8 transmural sutures starting at the distal gastric body and ending at the gastric fundus. The sutures form a plication and reduce the gastric space to a tubular shape similar to a surgical gastric sleeve. Physiological mechanism of action includes delayed gastric emptying and early satiety induction.

All patients underwent general anaesthesia and were admitted to the hospital according to our center's multidisciplinary obesity unit protocols.

Evolution of analytical and anthropometric parameters and metabolic comorbidities were examined and followed-up one year after the procedure. Hepatic steatosis was assessed by abdominal ultrasound and classified by grade according to radiological criteria.

In the statistical analysis, the Chi-square test was applied for qualitative variables. Quantitative variables were compared with the Student's t-test, with $p<0.05$ being considered significant. Multiple linear regression analysis was performed to evaluate variables related to total weight loss percentage (TWL%) at 6 and 12 months.

Results

Mean age of this study's population was 44 +/- 8.5 years, 72% female and 28% male. Mean baseline body mass index (BMI) was 39 +/- 5.47 kg/m2, with the following distribution: 6% type I obesity (BMI 30-34.9), 57% type II obesity (BMI 35-39.9) and 34% type III obesity (BMI 40-44.9), while 1 patient (3%) was overweighted. Regarding hepatic steatosis, 10 patients (32%) showed grade I, 12 (36%) grade II, and 10 (32%) grade III steatosis (Table 1).

Population (n)	32 patients
Average age	44+/-8.5 years
Gender (M/F)	9 (28%) / 23 (72%)
BMI (mean baseline)	39 +/- 5.47 kg/m2
Degree of obesity (BMI) I (30-34,9) II (35-39,9) III (40-44.9) Overweight	 2 (6%) 18 (57%) 11 (34%) 1 (3%)
Degree of steatosis I II III	 10 (32%) 12 (36%) 10 (32%)

Data expressed as mean ± standard deviation or frequencies and percentages.
M: Male, F: Female. BMI: Body Mass Index

Table 1: Characteristics of the study population

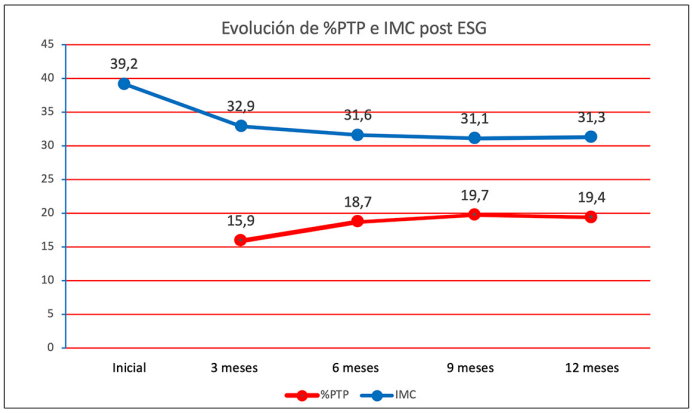
At pre-ESG assessment we found 7 patients with high blood pressure (HBP) (28%), 2 with type 2 diabetes mellitus (T2DM) (8.7%), 6 with pre-diabetes (26%), 10 with dyslipidemia (47.6%) and 3 with severe obstructive sleep apnoea syndrome (OSA) (17%). At 1-year follow-up, we found resolution of HBP in 3 patients (p; 0.003), pre-diabetes in all cases (p; 0.000), dyslipidemia in 6 cases (p 0.361) and OSA in 1 case (p; 0.020) (table 2). We also observed significant decreases in basal glycaemia (p; 0.025), glycosylated haemoglobin (p;0.046) and triglycerides (p;0.013) (Table 2).

Comorbidity	Pre-ESG (basal)	Post-ESG	P
HBP	7 (21%)	4 (12%)	**0,003**
T2DM	2 (6%)	2 (6%)	0,450
Pre-diabetes	6 (18%)	0 (0%)	**0,000**
Dyslipidaemia	10 (31%)	4 (12%)	0,361
Severe OSA	3 (9%)	2 (6%)	**0,020**

Data expressed as frequencies and percentages. HBP: high blood pressure, T2DM: type 2 diabetes mellitus, OSA: obstructive sleep apnoea syndrome.

Table 2. Comorbidities outcome at one year of follow-up

Total weight loss (TWL%) observed was 18.7 % at 6 months and 19.4 % at 1 year after the procedure, while the BMI was 31.6 kg/m2 and 31.3 kg/m2 respectively. We found significant differences in TWL% mainly at month 6 of treatment: 18.7% TWL (p; 0.004) which was maintained at the 1-year assessment (Figure 1).



TWL%: total weight loss. BMI: body mass index. ESG: endoscopic sleeve gastroplasty.

Figure 1.

On the other hand, excess weight loss (EWL%) was 48.82% at 6 months and 48.07% at 1 year follow-up.

We observed a good correlation between TWL%, age and BMI: younger patients with higher BMI had higher TWL%.

84% of patients completed the scheduled follow-up check-ups with the Endocrinology and Nutrition Service.

There were no complications in the study population.

Discussion

MASLD is defined as the presence of hepatic steatosis in combination with at least one metabolic dysfunction, in the absence of alcohol intake and other discernible causes(5). It is the most common liver disease worldwide(1) and is settled as one of the major epidemics of 21st century.

The goal of treatment of any disease is to achieve clinically meaningful benefit. In the case of MASLD, this has been particularly focused on liver-related outcomes, although the potential impact on other diseases (e.g. cardiovascular and metabolic) and quality of life is part of a holistic approach that is more appropriate(3). In the absence of any specific pharmacological treatment, weight reduction is the cornerstone in the search of a solution for this disease. In this regard, bariatric endoscopy has emerged as a complementary treatment in patients in whom lifestyle changes are insufficient, and without indication or refusal of surgical treatment.

In this group of patients with MASLD who underwent ESG, the EWL% obtained was 48.07 at 1-year follow-up, exceeding the 25% required by the American Society for Gastrointestinal Endoscopy and the American Society for Metabolic and Bariatric Surgery to be considered an effective technique as primary treatment for obesity(6). Our cohort showed a TWL% of 18.7 at 6 months and 19.4 at 12 months. These results exceed the median of 16.2% TWL reported in a recent meta-analysis including 23 studies and 5659 patients(7). This difference could be due to the sample size, the characteristics of the patients studied, the number and type of sutures, and the follow-up schedule. Additionally, the results obtained are comparable with the 19.7% TWL at 12 months follow-up for this procedure previously published by our group(8).

Regarding the factors associated with a better response, previous studies had already shown a relationship between follow-up programme adherence and weight loss(8, 9), a fact that has been confirmed in this study. These studies also described a better outcome in those patients who attended more psychological support appointments, included in our multidisciplinary follow-up plan, as recommended by various consensuses for the treatment of obesity (8). Likewise, higher BMI(10) and younger age have also been described as predictors of better response to this intervention(11).

There were no procedural complications in these patients, so ESG can be considered a safe technique. Additionally, unlike surgical gastroplasty, it is potentially reversible.

This study is limited by its retrospective-descriptive design, the lack of a control group, and the single-centre nature of the study, which introduces a potential patient selection bias. In addition, the small number of cases reduces the generalizability of these findings and prevents definitive conclusions regarding the use of this technique as a stand-alone treatment for MASLD in patients with obesity.

Although we did not re-evaluate hepatic steatosis level at 1-year follow-up, a pooled analysis of 35 studies with data from 7.525 patients confirmed that ESG is effective in inducing resolution of MASLD and obesity-associated comorbidities(7), and other studies have shown that obese patients with MASLD undergoing ESG evidenced a sustained effect on weight loss as well as an improvement in liver histology, with 20% of patients with baseline F3-F4 fibrosis regressing to F0-F2 fibrosis(12).

Our analysis does not extend beyond one year, and would need longer-term confirmation as a percentage of patients may experience weight regain due to the chronic and relapsing nature of obesity. Despite the fairly extended recruitment period, only a limited percentage of patients achieved long-term follow-up, which prevented us from having sufficient statistical robustness to perform an adequate analysis beyond 12 months post-ESG. Indeed, loss to follow-up is an important and frequent problem in routine clinical practice in patients with obesity, and is difficult to overcome.

Conclusions

The ESG-Apollo method can be considered an effective and safe option for the treatment of patients with obesity and MASLD, with a positive impact on the evolution of associated metabolic comorbidities. Although the results obtained in this study are encouraging, further research with larger numbers of patients and robust methodological designs

are needed to confirm these findings and establish their relevance to medical practice with greater certainty

The authors have no conflicts of interest affecting this publication.

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