Advanced endoscopic bariatric therapy - endoscopic gastroplasty for treatment of obese patients: preliminary results at 6 months follow-up from a prospective, single center, randomized controlled trial

Prof. M. Bulajic[1], MD., PhD, FACG, FASGE, S.F. Vadalà di Prampero[2]
[1]*Department of Digestive Endoscopy, Center of Excellence for Gastrointestinal and Metabolic Disorders, Fatebenefratelli Isola Tiberina- Gemelli Isola, Rome, Italy*
[2]*Mater Olbia Hospital, Olbia, Italy*
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Introduction: Obesity awareness has recently increased following its pandemic evolution (1, 2). Besides nutritional and lifestyle modifications and pharmacological therapy, many other therapeutic strategies have been evaluated.

While surgery (i.e., sleeve gastrectomy and Roux-Y gastric by-pass) is the best approach for severe obesity, I and II grade of obesity management with intragastric balloon is the most prevalent therapeutic option, with an estimated efficacy of 12% total body weight loss and a frequent relapse after its removal (3, 4).

Other techniques (5), among which the Endoscopic Gastroplasty (EG), were recently evaluated (6).

EG is based on gastric body remodeling by multiple full-thickness bites through specific suture devices that are attached to the scope, allowing a mini-invasive incisionless gastric reduction. Nowadays three different techniques are described: endoscopic sleeve gastroplasty (ESG) (Overstitch; Apollo Endosurgery, Austin, TX), endoluminal vertical gastroplasty (EVG) (Endomina; Endo Tools SA (ETT), Gosselies, Belgium), and distal primary obesity surgery endoluminal (POSE-2) (Incisionless Operating Platform; USGI Medical, San Clemente, CA).

They showed similar results in terms of weight loss and improvement of obesit (1, 6).

Aims & Methods: Our study aimed to assess feasibility, safety, and efficacy of these three techniques compared to a control group. This was a prospective, single center, randomized controlled trial (ClinicalTrials.gov NCT04854317) of patients who underwent EG (through ESG or EVG or D-POSE) or a low-calorie Mediterranean diet (1600 and 1400 Kcal/day for men and women, respectively; 50% carbohydrates, 30% fats, 20% proteins) for treatment of obesity. Outcomes included technical success rate, serious adverse event rate, and efficacy of the three EG procedures at inducing weight loss, improving obesity-related comorbidities and quality of life, compared to the diet group.

Results: Between July 2020 and October 2021, 120 obese (body mass index 37.5 ± 3.5 kg/m) patients (mean age, 46 ± 10 years; females 87.8%; obesity class II as the main obesity class in 58.3% cases; hepatic steatosis as the main comorbidity with a 70% frequency) underwent EG (through ESG or EVG or D-POSE, with 30 patients for each procedure, 90 patients in total) or a low-calorie diet (30 patients). In the EG group the technical success rate was 100%. The serious adverse event rate was 0%. At 6 months, 63/90 (70%) patients attended their follow-up visit. They experienced 16% ± 6% total body weight loss

(TBWL) and 39.7% ± 14.9% excess weight loss (EWL), with no significant difference among the three techniques in both of parameters ($p > 0.62$ in TBWL% and $p > 0.94$ in EWL% ANOVA tests). Concerning the low-calorie diet group, 18/30 (60%) patients attended their 6 months follow-up visit; they experienced 1.1% ± 4.7% TBWL ($p < 0.001$ versus EG group) and 2.3% ± 9.8% EWL ($p < 0.001$ versus EG group). Sixty out of sixty-three (95.2%) patients achieved at least 5% TBWL, and 54/63 (85.7%) achieved at least 25% EWL in the EG group, compared to 2/18 (11.1%) and 1/18 (5.6%) in the diet group, respectively. Fatty liver disease, hypertension, hyperlipidemia, diabetes, and obstructive sleep apnea improved after the EG procedure, while no improvement was observed in the diet group. Also, the quality of life measured by EQ-5D test improved at 6-month follow-up ($p < 0.01$) in the EG group, while no significant improvement was detected in the diet group.

Conclusion: EG through ESG, EVG and D-POSE, focusing on gastric body reduction and sparing the fundus and antrum, are technically feasible and safe, and appear to be effective in the short-term (6 months follow-up) for the treatment of obese patients, compared to diet.

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