



# Reinforced POSE: the 18-Plication Solution

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## Abstract

**Background** Obesity is one of the main challenges in the first world nowadays. New alternatives are needed and endoscopic endoluminal approaches are gaining importance against the risky surgery and the non-efficient pharmacological treatments. Nevertheless, these techniques seem to be inefficient in obese III patients. The aim of the study is to demonstrate the safety and efficiency of the new reinforced POSE 18-plication protocol.

**Methods** Mean body mass index (BMI)  $\approx 47$  kg/m<sup>2</sup> obese type III patients were treated in different Spanish centers with the new POSE method consisting of 18 plications in the stomach body. On the other hand, 15 lower body mass patients BMI  $\approx 40$  kg/m<sup>2</sup> were treated with the standard POSE method previously described.

**Results** Three months follow-up shows an overall % total weight loss (TWL) and % excess weight loss (EWL) of 15% and 41% respectively for standard POSE and 17% and 36% for the new reinforced POSE18. Both are equally safe and the endpoint weight loss objectives are reached. Endoluminal procedures have been demonstrated to be useful in overweight and obese type I/II. However, bariatric surgery is recommended for higher BMI  $> 40$  kg/m<sup>2</sup>. We successfully applied a non-standard POSE protocol and the patients reached 17%TWL in 3 months.

**Conclusions** Our study shows that reinforced POSE 18 can be successfully applied in obese type III; it is safer than bariatric surgery and there are no associated risks when compared with standard endoscopic surgery.

**Keywords** Endoscopic · POSE · Bariatric · Weight loss · Satiety · Meta-analysis

## Introduction

Obesity is one of the main challenges in the first world nowadays. Obesity incidence has tripled in the last 50 years and 650 million adults were obese in 2016 according to the World Health Organization. The BMI is considered the best obesity predictor: optimal BMI is 22.5–25 kg/m<sup>2</sup>; 30 kg/m<sup>2</sup> BMI or higher are defined as obese. Every 5 kg/m<sup>2</sup> above the optimal BMI increases the mortality by 29%, the vascular mortality by 41% and diabetes-related mortality by 210% [1]. Reversal of obesity is uncommon without intervention [2]. Obesity is considered a disease [3] with several comorbidity diseases associated such as diabetes type 2 mellitus, hypertension, hyper-

cholesterolemia, stroke, osteoarthritis, gallbladder disease, sleep apnea, coronary heart disease, and non-alcoholic fatty liver disease (NAFLD) [4].

Obesity treatment causes mortality decrease but also comorbidities regression; weight loss therapies include diet and lifestyle, this conservative method is inefficient over a long time because of weight recovery [5]; pharmaceutical approaches for the treatment improve the weight lost from 3 to 9% when compared with lifestyle modification but are associated with unfavorable side effects [6], and bariatric surgery is indicated for BMI higher than 40 but patients may be pulled back because of the surgery-related complications [7].

Endoluminal bariatric surgical procedures bridge the gap between the less efficient lifestyle-diet modification and the complications of surgery, at the same time, physiological alterations in gut endocrine signaling, GI motility, autonomic nervous system signaling, bile acid production, and gut microbiota contribute to weight loss and can be controlled with surgery [8] and these anatomic alterations can be replicated by endoscopic bariatric surgery [9]. Moreover, endoscopic bariatrics, as well as surgery, can revert comorbidities diseases caused by obesity such as diabetes type 2 [10]. Endoscopic

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bariatric therapies are a better option for long-term success when compared with the above methods [11].

Gastric reduction via endoscopy is done by stapling and sutures, two main techniques have been extensively used and described in the literature: endoscopic sleeve gastroplasty (ESG) and the primary obesity surgery endoluminal (POSE), both are endoscopic method, incisionless and without external scars. POSE is a peroral incisionless operating platform used to apply 8–9 plications in the fundus and 3–4 plications in the distal body of the stomach [4]. This method produces satiety [12] but also affects obesity-physiological alteration as described before.

POSE procedure has been used in obese type I and II patients in several studies with optimal weight loss [13–16] while bariatric surgery is recommended for obese class III [17]. The aim of our study is to describe and evaluate a new reinforced 18-plication POSE procedure in type III obese subjects.

## Method

### Patients

Patients were recruited in different centers across Spain between April and November 2018; the exclusion criteria were previous bariatric/gastric or esophageal surgery, pregnant, patient under psychiatric treatment, drug or alcohol abuse, and serious or infectious pathologies such as cancer, heart diseases, HIV, or hepatitis C. Patients were informed about the risk and they signed a written informed consent.

Eighteen women and 3 men, mean age 40, were selected and they were separated into 2 groups following body mass index (BMI) criteria: the first group had 15 patients with an average of  $BMI\ 39.9 \pm 3.7\ \text{kg/m}^2$  and the second group formed by 6 obese type III subjects with  $BMI\ 47.23 \pm 4.1\ \text{kg/m}^2$ .

### Study Design

TWL and safety were the outcomes from the study. The new reinforced method was evaluated and approved by our endoscopic professionals.

Group 1 was operated on standard POSE, from now POSE 12, and the group 2 was operated on reinforced POSE 18 as described below. After intervention, patients were followed up weekly for 3 months by our nutritionist and psychologist to support the treatment with diet and lifestyle; the patients started with liquid-diet 3 days pre-POSE and the same diet was recommended for 21 days post-POSE. Weight and height were recorded at baseline and used to calculate the BMI as described below. Recovery time and diet and lifestyle

recommendations were the same for 12-plication and 18-plication methods.

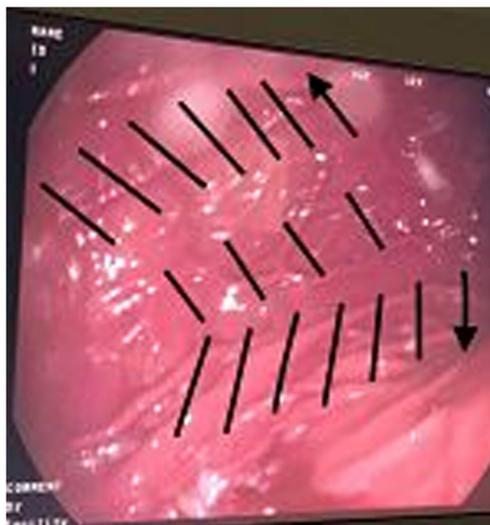
### Outcomes Assessment

Baseline and post-POSE follow-up at 3 months are included. Weight and height were measured in our centers using calibrated scales and wall-mounted stadiometer, and BMI is calculated with the formula  $BMI = \text{weight}/(\text{height}^2)$ , the ideal weight is calculated  $IW = \text{height}(\text{m})^2 \times 25\ \text{kg/m}^2$ . The outcomes after 3 months are as follows: (1) excess weight  $EW = \text{weight}(\text{kg}) - IW$ ; (2)  $EW\%$ ; (3) total weight loss (TWL); and (4)  $TWL\%$ .

### Reinforced POSE Method

The POSE method is detailed in previous reports [13] using the non-invasive endoscopy instrument developed by USGI medical (San Clemente, California, USA). In short, POSE is performed endoscopically using the g-Cath™ EZ Delivery Catheter as support for the g-Lix™ tissue grasper with a helical tip designed to catch the target tissue and bring it to g-Prox EZ® endoscopic grasper; the g-Prox can bring the folded tissue closer, then, the g-Cath EZ™ Suture Anchor Delivery Catheter, that includes a catheter system with a needle at its distal tip, sutures the tissue targeted by the g-Lix and folded by the g-Prox.

The methodology is the same than in standard POSE, but 18 plications are applied in the stomach body following the same pattern as indicated in Fig. 1. Average time for POSE with 18 plications was 25 min and the standard POSE requires 20 min.



**Fig. 1** Suture pattern in the stomach body. Eighteen sutures are applied following the pattern

**Table 1** Weight loss comparing standard POSE and reinforced POSE 18 plications. Body mass index (BMI) in kg/m<sup>2</sup>; TWL total weight loss; and EWL excess of weight loss are shown and *t* test *p* value compares both techniques

	Baseline		3 months	
	<i>n</i>	BMI	%TWL	%EWL
Standard POSE	15	40.33 ± 4.02	14.93 ± 5.08	41.18 ± 15.06
POSE 18	6	47.37 ± 4.09	16.87 ± 4.36	35.88 ± 8.35
<i>p</i> value		0.0058*	0.32	0.4

**Statistical Analysis**

POSE 12 and POSE 18 results were compared using Student’s *t* test; all *p* values are two-tailed and statistical significance was determined with 95% CI (*p* < 0.05).

Fixed model meta-analysis was performed with the following inclusion criteria: articles from 2015 to 2019 with specified %TWL mean and standard deviation/variance and available data for 6 months maximum and published in MEDLINE database [12, 13, 15, 16, 18–21]. Statistical heterogeneity was evaluated by means of *I*<sup>2</sup> and *Q* values, *I*<sup>2</sup> > 40% was considered heterogeneous. Three months %TWL was chosen when available; if not, the closest follow-up data was chosen, 6 months in some cases and 12 in one study.

Statistics were calculated using R (R Core Team (2018). R: a language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL <https://www.R-project.org/>).

**Results**

**Weight Loss Outcomes**

All the 21 patient’s data, 15 for POSE12 and 6 for reinforced POSE 18, were available for the 3 months follow-up. Data for TWL, EWL, and the percentages are shown in Table 1. Overall %TWL and %EWL were 15% and 41% respectively for POSE 12 and 17% and 36% for the reinforced POSE 18.

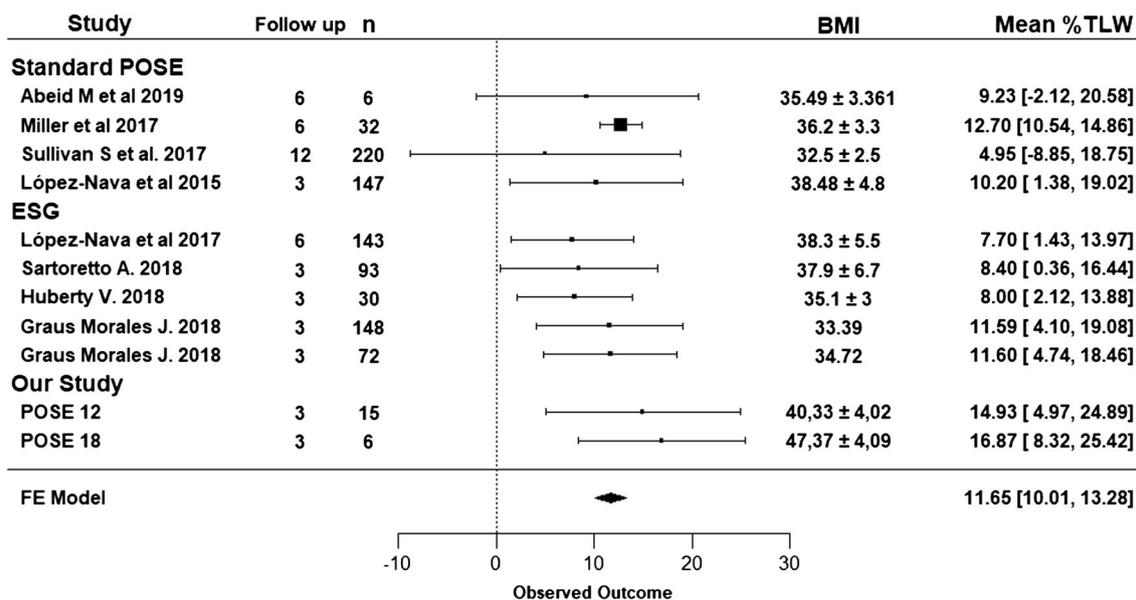
*p* values are also showed in Table 1; TWL and EWL were similar in both groups.

Reinforced 18-plication POSE shows the same post-operative symptoms than the standard POSE patients, vomiting and nausea in the 3 following days after the procedure, abdominal pain and they felt satiated. Twenty-four-hour hospitalization was mandatory in all cases.

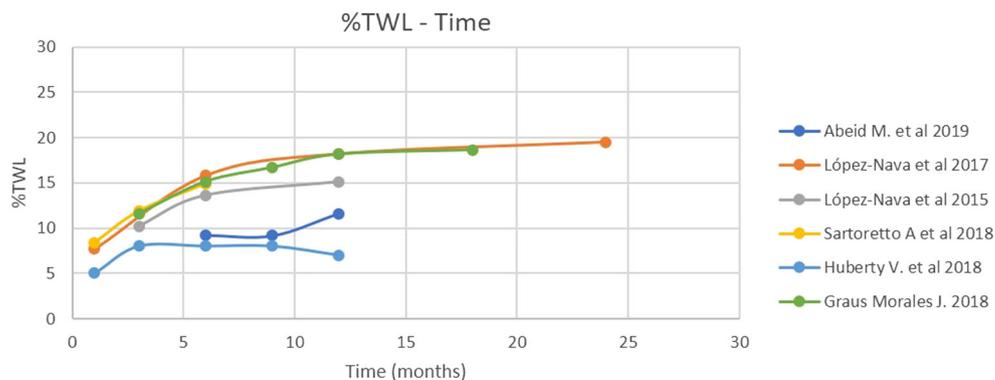
**Discussion**

Obesity is a global concern; every year, the percentage of overweight and obese subjects is higher despite the effort to change diet habits and the public health cost designated to treat obesity and obesity comorbidities is increasing in Europe and the USA.

Different methods are being used to fight this problem: healthy diet and exercise fails in mid- and long-term weight loss and pharmacology are not good enough [22], bariatric surgery is not accepted by the patients because



**Fig. 2** Meta-analysis forest plot. TWL total weight loss (%); BMI body mass index (kg/m<sup>2</sup>); and the follow-up is expressed in months

**Fig. 3** Evolution of TLW vs time

of the surgery-associated risk [23], and hospitalization time and endoscopic bariatric seem to be the best option for these patients because the procedure is performed via endoscopy, it is less invasive and the risk is lower. However, bariatric endoscopy methods have not demonstrated to be efficient in high body mass index patients and no literature is available.

In our study, we develop a new POSE strategy consisting an increased number of plications. This varies in the standard POSE with a mean of 12 plications and we increased the number of sutures to reach the 18-fix number for higher body mass index until 50 kg/m<sup>2</sup>. The outcome of our study is that the reinforced 18-POSE is as safe as the normal 12 plications; the postoperative symptoms described by the patients are the same in both groups: nausea, vomits, pain, and bad feeling the first days after the procedure.

BMI is significantly different between all the studies included and the POSE 18 patients, but no statistical difference is observed in the percentage of weight loss, expressed as %TLW or %EWL, when both groups are compared; we suggest that reinforced 18-POSE is, at least, as good as the standard POSE method for losing weight.

Different studies were performed in the last years to show the weight loss effect of POSE and ESG, the percentage of weight loss mean is used to compare the heterogeneity of the different studies and POSE and ESG were included (Fig. 2). The BMI of the patients used in the different studies are indicated in the forest plot; BMI ranges are from 33 to 39 kg/m<sup>2</sup> and the meaning %TWL are from 9 to 12.7%. Consistent with previous studies [9], our meta-analysis (Fig. 2) shows the weight loss described in the literature by different endoscopic bariatric procedures. Heterogeneity test shows a result  $I^2 = 0$  indicating no heterogeneity in %TWL in the different studies in patients treated with POSE or ESG. TWL has a non-significant positive trend in high BMI patients. We had no access to 3 months data for all the studies so we had to choose

the closes available follow-up; we are conscious that exact dates would give us a more accurate result; anyway, these approximations are good enough because when we are taking higher time points, we are overestimating the studies (Fig. 3) but not our studies. We have no evidences to assume that weight is already stabilized in POSE 18 or standard POSE in 3 months, and we think that TWL is going to be increased in the following months, as we said before, until month 6–9.

Our study successfully applies endoscopic bariatrics in obese type III (BMI >40 kg/m<sup>2</sup>) patients for the time first. We propose a new POSE protocol for these patients, usually associated with bariatric surgery, less invasive and safer than external surgery. This method has lower costs and the procedure is done in 25 min so it is faster than ESG, which takes 2 h, or external surgery meaning lower anesthesia dose and trauma for the patient, creating security and a positive intervention attitude. For same reasons, there is no evidence that supports the use of reinforced POSE 18 for BMI <40 kg/m<sup>2</sup>; in that cases, standard POSE with 12 plications is recommended for being a faster and cheaper method.

Longer follow-up is needed to evaluate the reinforced POSE 18 in order to evaluate the long-term weight loss. The same studies used for the meta-analysis were used for plotting %TWL against the follow-up time (Fig. 3), and error bars are deleted for a cleaner view. The plot reveals that the weight is stabilized at month 6–9; we expect our patients to increase the weight loss until stabilization in the same range.

In conclusion, our study shows that reinforced POSE 18 can be successfully applied in obese type III with the same postoperative symptoms than other endoscopic techniques. With that protocol, the high BMI patients have a different alternative than bariatric surgery. Higher number of patients and longer follow-up are ongoing to assess the effect of this new POSE 18 in long-term result and to prove the reproducibility of the protocol.

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## Compliance with Ethical Standards

**Ethics Statement** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Conflict of Interest** The authors declare that they have no conflict of interest.

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