

Bariatric endoscopy procedure type or follow-up: What predicted success at 1 year in 962 obese patients?

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submitted 31.5.2019

accepted after revision 16.8.2019

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DOI <https://doi.org/10.1055/a-1007-1769> |
Endoscopy International Open 2019; 07: E1691–E1698
© Georg Thieme Verlag KG Stuttgart · New York
eISSN 2196-9736

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ABSTRACT

Background and study aims It is uncertain if the difference in weight loss outcomes between different endoscopic bariatric therapies (EBTs) is technique-related or multidisciplinary team (MDT) follow-up-related. We hypothesized that at 1 year, the weight loss is determined more by adherence to MDT follow-up than by procedure type. We

aimed to compare 1 year weight loss outcomes of four different EBTs at a single center with a standardized MDT follow-up.

Patients and methods We prospectively collected and retrospectively analyzed outcomes in 962 patients (female-691, 71.2%; mean age, 44.8±10.6 years, mean BMI, 37.8±5.9Kg/m²) treated with Intragastic balloons (IGBs) or endoscopic gastroplasty (EG) at HM Sanchinarro University Hospital between March 2012 to January 2017. The procedures were performed by the same endoscopist and followed up by the same MDT. We compared the percentage total body weight loss (%TBWL) at 1 year. We performed linear and logistic regression to identify predictive factors for weight loss and follow-up adherence at 1 year.

Results Four hundred and eighty-one IGBs (Orbera-80.9%; ReShape Duo-19.1%), and 481 EG (Apollo ESG-51.3%; Primary obesity surgery endoluminal-POSE-48.6%) were performed. Only 480 patients (IGB- 45%; EG- 55%) completed 1 year follow-up. Among them, Apollo ESG achieved significantly higher TBWL (19.5±13%, $P=0.035$), %TBWL (17.4±10.2%, $P=0.025$), and ≥20% TBWL (36.7%, $P=0.032$). However, in linear regression after adjusting for variables, only higher initial BMI ($B=0.31$, $P<0.001$) and higher percentage follow-up attendance ($B=0.24$, $P<0.001$) significantly predicted %TBWL at 1 year in the completion group but not the procedure type ($B=0.02$, $P=0.72$). In logistic regression, we observed female sex ($P=0.01$), high initial BMI ($P<0.001$), endoscopic gastroplasty ($P=0.04$), and high 1-month %TBWL ($P<0.001$) significantly predicted follow-up completion at 1 year.

Conclusions Weight loss at 1 year is dependent on MDT follow-up rather than procedure type. Endoscopic gastroplasty promoted follow-up adherence more than IGBs.

Introduction

Endoscopic bariatric therapies (EBTs) are evolving to be an effective minimally invasive treatment option for patients with obesity and associated comorbidities [1,2]. EBT is performed either as a primary stand-alone therapy or as a bridge treat-

ment before surgery [3]. Currently, three US Food and Drug Administration-approved devices are available for endoscopic treatment of obesity, and a few more are under development [4]. Among them, intragastric balloons (IGBs) and endoscopic gastroplasty (EG) techniques have gained wide popularity and acceptance.

Several studies have established the technical feasibility, reproducibility, safety, and efficacy of IGBs and EG [5–8]

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► **Table 1** Summary of data published on each technique.

Procedure type (ref)	Publication (n)	Patients (n)	%TBWL-12 months (95% CI)	SAE (%)	SAE needing surgery
Orbera [13, 14]	8	8506	10% (6.6–13.6%)	1.5%	0.1%
ReShape Duo [15]	1	202	14.7% (8.02–21.4)	0.03%	16%
POSE [20]	3	402	10.98 (3.48–18.48)	0.03%	0.09%
ESG [24]	9	1542	16.09% (14.24–17.94)	1%	21%

(► **Table 1**). However, considerable variation exists in short-term and long-term total body weight loss outcomes [9, 10]. At 12-month follow-up, Apollo Overstitch sutured gastroplasty (Overstitch; Apollo Endosurgery, Austin, Texas, United States), was shown to achieve total body weight loss (17.6%) with the effect sustained up to 24 months (20.9%) [11]. On the contrary, the total body weight loss with IGBs ranged between 11% and 15% at 6 months with a risk of weight regain after balloon removal [12–15]. Multiple factors, in addition to the anatomical and neuroendocrine signaling changes, may have influenced the difference in weight loss outcomes [16].

In our prior experience treating 25 patients (body mass index [BMI] > 30 kg/m²) with Apollo ESG, we found that the number of contacts with the nutritionist and psychologist during follow-up significantly predicted the weight loss at 1 year [17]. Currently, it is unclear if the weight loss results between different EBTs is related to the technique or multidisciplinary team (MDT) follow-up or both. Most centers differ in the nutrition and follow-up protocol and there is a lack of evidence comparing weight loss outcome of different EBTs within an identical follow-up program.

Since 2011, our bariatric endoscopy unit has standardized EBT techniques, adopted a structured post-procedure follow-up protocol, and performed a variety of EBTs. In this study, we aimed to compare weight loss outcomes of different EBTs within the same follow-up program and evaluated factors that predicted weight loss and follow-up adherence at 1 year.

Patients and methods

Study design

We prospectively collected and retrospectively studied data from patients who underwent EBTs at the Bariatric Endoscopy Unit of HM Sanchinarro University Hospital, Madrid, between March 2012 and January 2017. The institutional review board approved the study. All authors had access to the study data and reviewed and approved the final manuscript. All the procedures were performed following the ethical principles detailed in the Declaration of Helsinki and were consistent with the Good Clinical Practices recommendation.

Study patients

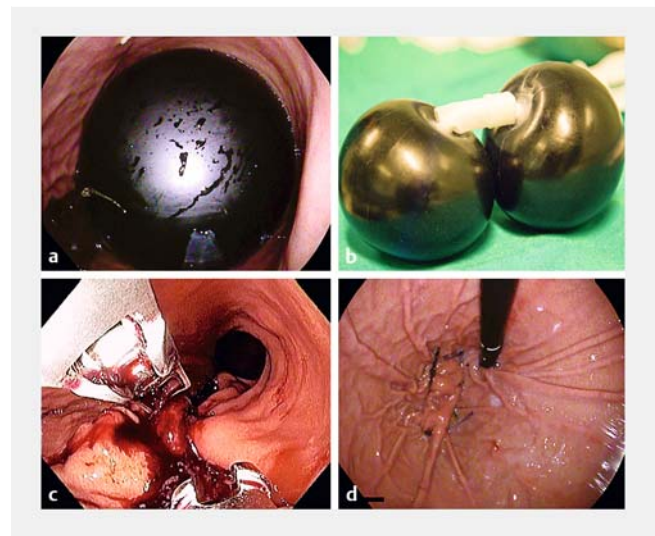
We included 1013 patients who received EBTs during this period. All the patients were referred to our unit after failed conservative therapy at other centers. The EBTs were offered as a self-pay procedure and not covered by health insurance. We discus-

sed the different endoscopic bariatric treatment options with the patient and explained the risks, benefits, and cost (EG > IGB) of each procedure. Choice of EBT was decided based on patient preference. We did not have a personalized or preferred treatment approach based on patient profile. All the patients included paid the treatment expenses upfront, and the cost of MDT follow-up was identical. We extracted data on demographics, weight parameters, type of EBT, and compliance to follow-up from our obesity database for analysis. All patients consented to the procedure. We excluded those who were referred for EG after failed IGB.

Intervention

Procedure

The EBTs performed during this study included Intra-gastric balloon placement (Orbera, Apollo Endosurgery, Austin, TX; ReShape Duo, Apollo Endosurgery, Austin, TX) and endoscopic gastroplasty using Apollo Overstitch or Primary obesity surgery endoluminal (POSE, USGI Medical, San Clemente, USA) (► **Fig. 1**). All the procedures were performed by the same endoscopist and were followed-up by the same multidisciplinary team (nutritionist and psychologist). We have previously described in detail our technique on different IGB placement, Apollo ESG, and POSE in our prior publications [7, 8, 18–20].



► **Fig. 1** Endoscopic image of 4 different EBTs. **a** Orbera IGB. **b** ReShape Duo IGB. **c** Apollo endoscopic sleeve gastroplasty. **d** POSE.

We do not routinely perform repeat endoscopy to assess the integrity of the sutures with the endoscopic gastroplasty procedures.

Follow-Up Schedule

Patients were followed-up weekly or biweekly post-procedure by a nutritionist, psychologist, and physiotherapists. When their condition stabilized, we extended the visits to once a month. We recommend achieving 24 clinic visits over 1 year irrespective of the procedure type. The follow-up program comprised dietary instructions, psychological support, physical activity, and a planned counseling schedule, as well as a timeline for future visits.

Body requirements and individual taste preferences were taken into account while designing the hypocaloric diets. Energy requirements were calculated from the Harris-Benedict formula. Based on the type of physical activity, we decreased caloric intake by about 2.6 MJ/day to induce an approximate weight loss of between 0.5 and 1 kg/week. In the first month after EG, we maintained patients on a strict liquid diet (4 weeks). We subsequently escalated intake to semi-solid and solid food as tolerated. In the IGB patients, we initiated a solid meal within 2 weeks. We used a Mediterranean type diet in which distributions of principal components were as recommended by the Spanish Society of Community Nutrition [21].

We devised an individualized exercise plan and avoided an increase in intra-abdominal pressure during the first month. We encouraged walking in the initial phase and then progressively increased exercise intensity. There were no other differences in the follow-up plan between the two groups, and the patients were counseled to adhere to follow-up even after balloon explantation.

Study outcomes

The primary outcome was to compare the weight loss results of four different EBTs at 1 year. Our secondary outcome was to identify factors that predict weight loss and follow-up completion at 1 year.

Study variable description

We collected information on the following variables.

1. Gender
2. Age: Continuous variable and we classified them into two groups (Group 1 ≥ 45 years; Group 2 <45 years)
3. Type of EBTs: We segregated them into IGB group (Orbera and ReShape Duo IGB), EG group (Apollo ESG, and POSE)
4. Weight Parameters: We measured weight, height, and BMI at baseline and during each follow-up visit. We classified them into two groups based on severity of obesity (Group 1 ≥ 40 kg/m², and Group 2 <40 kg/m²).
5. Attendance to follow-up: We defined it as the percentage of scheduled visits to which the patient went during the first year of follow-up. We divided follow-up attendance in the completion group into three tertiles to understand its relationship with the weight parameters [17].
6. End of Treatment Response: We classified them into two groups. Completion group are those who had weight results

recorded at 1 year. Drop-out group are those who failed to complete the 1 year recommended follow-up. Patients were considered drop-out if they had no weight loss results recorded at 1 year irrespective of the prior follow-up attendances.

7. Weight loss parameters: We measured %TBWL and %excess weight loss (%EWL) with the four EBTs at the end of 1 year. We grouped them into those who achieved $\geq 10\%$ TBWL and those who met $\geq 20\%$ TBWL.

Statistical analysis

We expressed continuous variables as mean \pm standard deviation (SD) and categorical variables as a percentage. Comparisons of means between groups were calculated using the Mann-Whitney or Kruskal-Wallis test (for not normally distributed variables). Bivariate analyses of proportionality of distribution of categorical variables were estimated using the Chi-square test. We performed a linear regression analysis to evaluate the relationship of age, gender, initial BMI, procedure type, and % follow-up attendance on %TBWL at 1 year. We performed a logistic regression analysis to study the association between age, sex, initial BMI, and procedure type on follow-up adherence at 1 year. We used Kaplan-Meier survival curves to illustrate patient attrition over treatment time. $P < 0.05$ was considered statistically significant. We analyzed the data analyses using Statistical Package for the Social Sciences 19.0 software (SPSS Inc., Chicago, Illinois, United States).

Results

Patient characteristics

We identified 1013 patients who underwent EBTs during the study period. We excluded 51 cases as they were treated using an alternative swallowable IGB (Elipse, Allurion Technology, United States) device with a shorter follow-up duration (4 months). Among the remaining 962 patients, we treated half (50%, $n=481$) using IGBs and the rest with EG. We used Orbera balloon in 389 (40.4%) and ReShape Duo IGB in 92 (9.6%) cases, and performed Apollo ESG in 247 (24.3%) and POSE in 234 (25.7%) patients, respectively (► **Table 2**). The mean number of follow-up visits to the MDT was 7.6 ± 5.3 (median-7; IQR-7; range-0 to 36). Only half the patients ($n=480$, 49.9%) had weight loss results recorded at 1 year (► **Fig. 2**). The remaining patients dropped out from follow-up at a different time interval. Characteristics of the study participants are detailed in ► **Table 3**. Mean age was 44.8 ± 10.6 years, and mean BMI was 37.8 ± 5.9 kg/m². The majority of participants were female (71.2%, $n=691$).

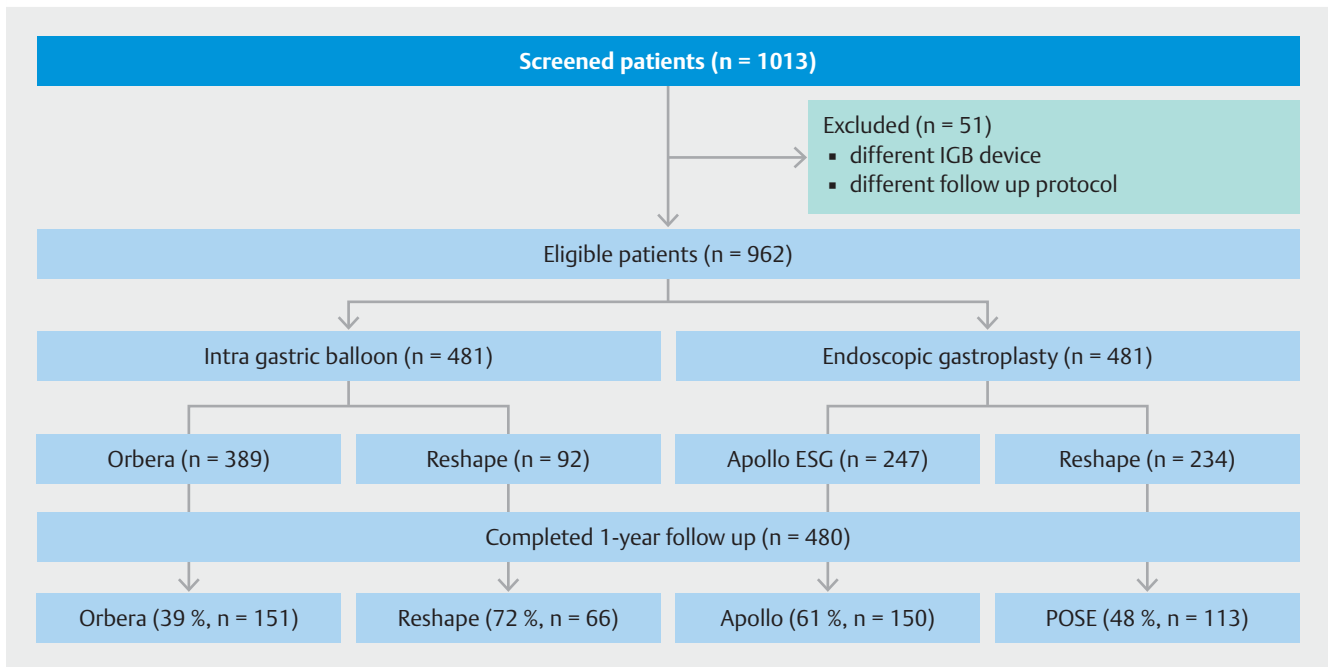
Weight loss results with four EBTs

Among the 480 patients who reached 1 year follow-up (completion group), 45% were treated with IGBs and 55% using EG techniques. Overall mean TBWL, %TBWL and %EWL of the bariatric program involving the four EBTs were 18 ± 11.9 kg, $16.3 \pm 9.3\%$, and $51 \pm 30.8\%$, respectively. Ninety-one percent achieved $\geq 5\%$ TBWL ($n=436$), 77% obtained $\geq 10\%$ TBWL ($n=370$), and 31% reached $\geq 20\%$ TBWL ($n=150$). Among the EBTs,

► **Table 2** Baseline characteristics of EBTs.

Variables	Orbera	Reshape Duo	Apollo	POSE	P value
Age	42.9±11	42.3±12.8	45.9±9.6	47±10.1	<0.001
Sex	70.2%	79.3%	70.4%	73.1%	0.32
Initial BMI	37.6±6.7	38.4±5.2	38.3±5.7	37.6±4.8	0.052
BMI>40 kg/m ²	29.6%	33.7%	36.4%	27.8%	0.16

EBT, endoscopic bariatric therapy; BMI, body mass index

► **Fig. 2** Flowchart describing the study population.► **Table 3** Characteristics of study groups.

Characteristics	Completion Group (n = 480)	Drop-out Group (n = 482)	P value
Age ± SD, years	45.3 ± 11.3	44.3 ± 10	0.04
▪ <45 years	45%	55%	
▪ >45 years	52%	48%	
Gender			0.01
▪ Male	44%	56%	
▪ Female	52%	48%	
Initial BMI ± SD, kg/m ²	38.5 ± 5.8	37.2 ± 6	<0.001
▪ <40 kg/m ²	46%	54%	
▪ ≥40 kg/m ²	59%	41%	
Procedure type			0.002
▪ IGB	217 (45%)	264 (54%)	
▪ EG	263 (55%)	218 (45%)	

BMI, body mass index; IGB, intragastric balloon; EG, endoscopic gastroplasty

► **Table 4** Weight loss outcomes with different techniques at 1 year.

Outcomes	Orbera (n = 151)	Reshape Duo (n = 66)	POSE (n = 113)	Apollo (n = 150)	P value
Mean ± SD TBWL	18.7 ± 12.6	15.3 ± 8	16.6 ± 10.6	19.5 ± 13	0.035
Mean ± SD %TBWL	16.9 ± 9.3	14.4 ± 6.7	15.3 ± 8.7	17.4 ± 10.2	0.025
≥ 10% TBWL	79.5%	74.2%	71.7%	80%	0.337
≥ 20% TBWL	35.1%	19.7%	25.7%	36.7%	0.032
Mean ± SD %Attendance	56.3 ± 26.9	31.9 ± 23.8	25.1 ± 17.7	59.3 ± 25.6	0.001

TBWL, total body weight loss

► **Table 5** Weight loss outcomes with different techniques at 6 months.

Outcomes	Orbera (n = 228)	Reshape Duo (n = 53)	POSE (n = 148)	Apollo (n = 195)	P value
Mean ± SD TBWL	17.2 ± 9.8	13.5 ± 6	15.6 ± 8.3	17.7 ± 9.2	0.008
Mean ± SD %TBWL	15.7 ± 7.5	12.6 ± 4.9	14.5 ± 6.8	16.1 ± 7.4	0.007
> 10% TBWL	82.2%	75.6%	71.6%	83.1%	0.135
≥ 20% TBWL	37.2%	24.4%	24.2%	37.7%	0.071
Mean ± SD %Attendance	45.3 ± 26.9	37.4 ± 23.5	18.5 ± 15.9	49.6 ± 27.5	0.001

TBWL, total body weight loss

Apollo ESG demonstrated significantly higher mean ± SD TBWL (19.5 ± 13 kg, $P=0.035$), %TBWL (17.4 ± 10.2, $P=0.025$), ≥ 20% TBWL (36.7%, $P=0.032$) and had the highest percentage follow-up attendance at 1 year (59.3 ± 25.6%, $P=0.001$) (► **Table 4**). To better compare and synchronize with balloon removal, we analyzed results in patients who completed follow-up at 6 months (n = 624) and found Apollo ESG achieved significantly higher mean ± SD TBWL (17.7 ± 9.2 kg, $P=0.008$), %TBWL (16.1 ± 17.4, $P=0.007$), and higher percentage follow-up attendance (49.6 ± 27.5%, $P=0.001$) (► **Table 5**).

We analyzed the relationship between weight loss parameters (TBWL, %TBWL, %EWL) and MDT follow-up. We classified attendance to MDT follow-up into three groups: low-attendance (T1, attendance < 28%), medium attendance (T2, attendance 28%–57%), and high attendance (T3, attendance > 57%) [17]. We found the magnitude of weight loss increased significantly in patients who achieved high MDT follow-up attendance in the completion group at 6 months and 1 year. ($P<0.01$) (► **Fig. 3** and ► **Fig. 4**).

Predictive factors for weight loss and follow-up completion at 1 year

We performed a linear regression analysis, after controlling for study variables, to identify predictive factors for %TBWL in the completion group (n = 480). We found %follow-up attendance ($B=0.24$, $P<0.001$) and initial BMI ($B=0.31$, $P<0.001$) predicted higher %TBWL at 1 year. Type of EBT did not influence weight loss at 1 year ($B=0.02$, $P=0.72$). These findings were identical when we performed the analysis at 6 months (n =

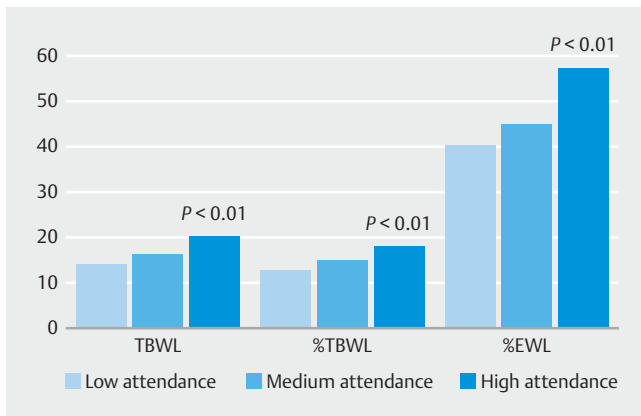
624). Procedure type did not influence weight loss ($B=0.01$, $P=0.72$) (► **Fig. 5** and ► **Fig. 6**).

We performed a logistic regression analysis to identify factors that predicted follow-up completion at 1 year in the entire cohort. We found gender (females adhered better), initial BMI (higher BMI-higher adherence), procedure type (endoscopic gastroplasty-longer follow-up), and %weight loss at 1 month (higher weight loss- longer follow-up) significantly predicted follow-up completion at 1 year (► **Table 6**). However, when analyzed at 6 months, type of procedure did not predict follow-up adherence ($P=0.2$).

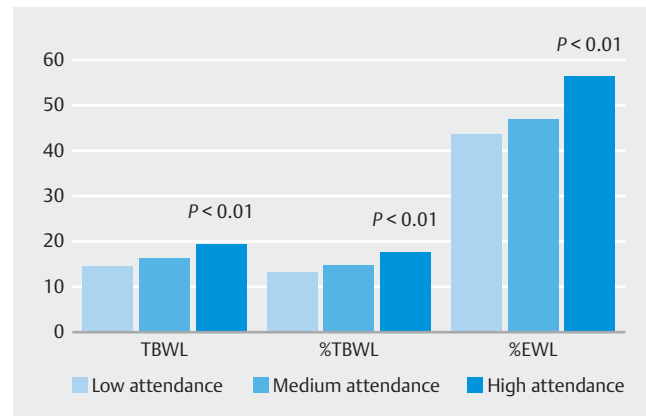
We performed additional analysis to identify variables associated with high attendance to MDT (T3, attendance > 57%), independent of treatment completion at 1 year. We found initial BMI ($B=0.103$, $P=0.012$), female sex ($B=0.12$, $P=0.002$) and % weight loss at 1 month ($b=0.276$, $P<0.001$) but not procedure type ($B=0.02$, $P=0.63$) predicted high MDT attendance.

Discussion

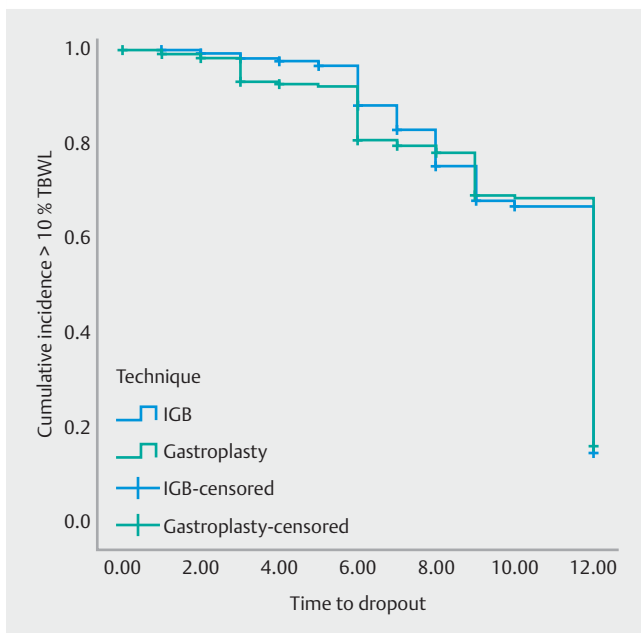
We report 1 year weight loss outcome of four EBT techniques in a structured bariatric program and present the predictive variables for better results. We found the Apollo ESG demonstrated higher weight loss results at the end of 1 year. However, in regression analysis, adherence to MDT follow-up predicted weight loss at 1 year independent of procedure type. Only 50% of patients completed follow-up, and among them, endoscopic gastroplasty (Apollo ESG and POSE) promoted more compliance with follow-up appointments.



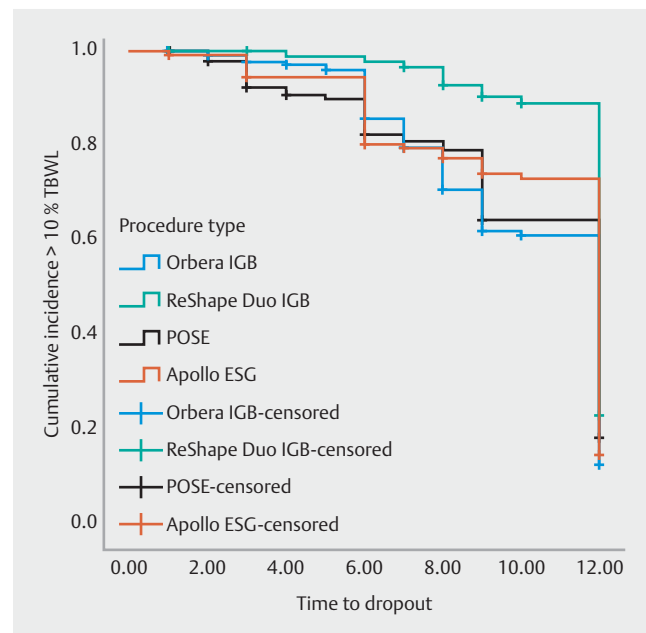
► **Fig. 3** Weight loss outcome based on percentage follow-up attendance at 12 months in the completion group (n=480). The best weight loss outcome was observed in the high-attendance group.



► **Fig. 4** Weight loss outcome based on %follow-up attendance at 6 months in the completion group (n=624). The best weight loss outcome was observed in the high-attendance group.



► **Fig. 5** Kaplan-Meier curve indicating cumulative incidence of achieving > 10%TBWL at time of last contact (dropout) with the MDT team in the IGB and EG groups. Procedure type did not influence weight loss results ($P=0.83$)



► **Fig. 6** Kaplan-Meier curve indicating the cumulative incidence of achieving > 10%TBWL at time of last contact (dropout) with the MDT team for the four different EBTs.

ESG is a minimally invasive, incisionless endoscopic treatment that functions by shortening and narrowing the gastric volume using a series of full-thickness sutures placed from the distal body to the fundus of the stomach. Weight loss achieved with ESG is related to delay in gastric emptying, reduced hunger, and early satiety [16]. Prior studies have reported that ESG can achieve up to 17% to 20% TBWL at 12 and 24 months [7, 22,23]. Weight loss results in our study are consistent with the published literature [24]. There is scant data comparing the outcome of different IGB to EG. A retrospective study (n=88), which is published only in abstract form, showed no significant difference in %TBWL at 6 months and 1 year between EG and IGB [25]. Our results are in agreement with this finding. We

showed that weight loss at 1 year was not dependant on type of procedure but was determined by follow-up attendance (► **Fig. 3** and ► **Fig. 4**). We postulated that frequent interaction with the MDT might have provided an opportunity to identify "at risk of failure" patients and intervene at an early stage. Besides, the psychological counseling and motivation of early responders may have promoted sustained weight loss at 1 year.

Despite its significance, non-adherence and loss to follow-up is still an unresolved problem with many obesity treatments [26,27]. We observed that half the patients were lost to follow-up at 1 year. Our drop-out rates were similar to those described in bariatric surgical series and with conventional therapies [28–30]. Surgical studies have identified several variables

► **Table 6** Logistic regression assessing predictive factors for follow-up completion in 962 patients.

Covariables	6-months			1 year		
	Exp (B)	95% CI	P value	Exp (B)	95% CI	P value
Gender	1.17	0.77–1.78	0.45	1.64	1.11–2.42	0.01
Age	0.99	0.9–1.01	0.67	1.004	0.99–1.02	0.63
Initial BMI	1.04	1.01–1.77	0.01	1.82	1.25–2.64	<0.001
Procedure type	1.28	0.86–1.89	0.21	1.44	1.0–2.07	0.04
1-month %weight loss	1.07	1.01–1.14	0.02	1.134	1.07–1.20	<0.001

Variables: Gender (male vs. female); age (continuous); initial BMI (continuous); procedure type (IGB vs. EG)
 BMI, body mass index; IGB, intragastric balloon; EG, endoscopic gastroplasty

for long-term success but have a limited description of follow-up compliance. In the current study, we found that EG procedure (Apollo ESG, POSE), female sex, and high initial BMI predicted higher follow-up adherence at 1 year. It is understandable that EG, a more lasting treatment option, promoted more follow-up adherence than the temporary IGBs, which are usually removed at 6 months. However, the finding that high BMI, independent of the patient's age, predicts adherence is in contrast to published studies. In fact, among bariatric surgical cases, high BMI and advanced age are considered as poor predictors for treatment compliance [28, 31, 32]. We are uncertain about the reason for this discrepancy. The cohort of patients with high BMI who choose EBT are those who declined surgery because of its invasiveness and risk. We believe these patients are different from bariatric surgical patients and that they are more motivated to achieve results with a less invasive treatment option. Increased adherence to follow-up observed among patients who achieved significant weight loss at 1 month lends support to this hypothesis. Also, achievement of early desired weight loss in the low BMI group may have given them confidence to self-manage their condition and drop-out from follow-up.

Our study has several strengths. It represents one of the largest bariatric endoscopy cohorts to date that has the weight loss outcome recorded for different EBTs at the end of 1 year. Performance of the procedures by the same endoscopist eliminated technique-related bias. Most centers tend to specialize in one technique and focus on performing only a specific type of EBT. Also, they differ considerably in their nutritional plan and follow-up protocol. Thus, to study and compare the outcome of different EBTs from a heterogenous bariatric endoscopy program may be difficult. We have standardized the follow-up program, built an MDT team with experience in bariatric endoscopy care, and have demonstrated the importance of the MDT program in achieving weight loss at 1 year. We have also added new information on predictive factors for weight loss and follow-up compliance in the EBT cohort, which were previously less described.

Our study has certain limitations which are inherent to a retrospective analysis. The study population was mainly Spanish, and all the procedures were performed by a single endoscopist

in a single center. Reproducibility of similar results in other centers needs to be studied. Although our post-procedure follow-up was standardized across different EBTs, there was a slight variation in nutrition escalation during the first month between IGBs and EG. It possibly could have contributed to excess weight loss with EG at 1 month but is unlikely to have influenced the outcome at 1 year. We are uncertain whether the demonstrated benefit with adherence to MDT follow-up is a reflection of the true success of our follow-up protocol or the motivation status of the patients. Although challenging to differentiate, our prior experience, and results from bariatric surgical series provide support for the importance of standardized follow-up [17, 33]. We did not evaluate some technical factors, such as suture pattern, number of sutures placed and patient-related factors such as educational status, economic status, comorbidities, prior pharmacotherapy, and mental health in predicting weight loss and compliance to follow-up at 1 year. We could not obtain this information from our database. However, available studies on different ESG patterns have reported no significant difference in weight loss. Similarly, the evidence assessing the role of other parameters in the bariatric surgical series has only yielded conflicting results [31, 32, 34, 35]. In our previous study, we did not find any difference between presence of comorbidities and treatment completion [27]. A prospective study assessing the relevance of these variables in EBT patients ought to be performed.

Conclusion

In summary, all four EBTs are effective in achieving weight loss within a standardized bariatric endoscopy program at 1 year. In particular, endoscopic gastroplasty procedures (Apollo ESG, POSE) promote higher adherence to MDT follow-up than IGB. Careful monitoring is required in order for low-responder-profile patients (male, BMI <40 kg/m², and less 1-month %TBWL) to achieve good results. Our study provides insight on the importance of MDT follow-up and centers planning to establish a bariatric program should focus on building a robust MDT and not just focus on the procedures alone.

Competing interests

Dr. Lopez-Nava is a consultant for Apollo Endosurgery, USA and USGI Medical, USA.

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