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Original Article

Weight loss outcomes of gastric balloon placement vs. intragastric botulinum toxin-a injection: A retrospective analysis

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ABSTRACT

Introduction: This study investigates the effectiveness of intragastric balloon placement (IGBP) and intragastric botulinum toxin-A injection (IGBTI) on weight-loss parameters in overweight and obese patients.

Materials and Methods: The study included 165 overweight and obese patients (matched for age and gender) treated with IGBTI (n=123) or IGBP (n=42). The patients' anthropometric data, such as total weight loss (TWL) and body mass index loss (BMIL), were evaluated and compared retrospectively in the first, third, sixth, and twelfth months after the intervention.

Results: Mean age, TWL, and BMIL values at all follow-up points in patients with IGBP were significantly higher than in patients with IGBTI (p<0.001). Similarly, the BMIL of patients who underwent IGBP at the end of the first, third, sixth, and twelfth months was significantly higher than the BMIL of patients who underwent IGBTI (2.54±0.20 vs. 1.80±0.13, p=0.002; 3.8±0.24 vs. 2.41±0.18, p<0.001; 4.19±0.45 vs. 2.38± 0.21, p<0.001; 4.19± 0.45 vs. 1.27±0.21, p<0.001; respectively). At the end of twelve months, 97 (68%) patients with IGBTI lost weight, while weight loss was observed in 35 (81.5%) patients with IGBP.

Conclusion: Significant decreases in weight and BMI were observed in patients after both IGBP and IGBTI. Based on TWL and BMIL values, we conclude that IGBP is superior to IGBTI.

Keywords: Intragastric balloon placement, intragastric botulinum toxin-a injection, endoscopic weight loss treatment, obesity

Introduction

Obesity is a global public health problem that causes an increase in the prevalence of some diseases, such as type 2 diabetes, coronary heart disease, sleep apnea, and stroke.[1] As per the 2023 World Obesity Atlas report, 38% of the world's population presently falls into the categories of overweight or obese, exhibiting a body mass index (BMI) exceeding 25 kg/m^2.[2] Projections indicate that by 2035, the global prevalence of overweight and obesity is expected to climb to 51%, showing the trajectory of the obesity epidemic. The economic impact of obesity and related disorders on the global economy was 1.96 trillion US dollars, which contributed to 2.4% of the total gross domestic product (GDP) in 2020. These numbers are estimated to double by 2035 with an economic impact of 4.32 trillion US dollars, contributing to 2.9% of total GDP.[2]

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Even a 5-10% reduction in body weight is significant for treating obesity and related diseases.[1] The treatment options are lifestyle modifications, pharmacological treatments, and bariatric surgery to reduce the excess weight of individuals with obesity.[3] However, permanent weight loss is often tricky with lifestyle changes and pharmacological treatment alone. Therefore, invasive weight loss treatments have become the primary method of treatment for severe obesity.[4] The most effective weight loss intervention for obesity is bariatric surgery.[5] Bariatric surgery achieves better long-term weight loss and reduction of comorbidities[6] and is mainly indicated for patients with a Body Mass Index (BMI) over 35 kg/m^2. Bariatric surgery is more costly and more invasive and, therefore, might be less preferable for some groups of patients.[7] For an intermediate group of patients who do not respond to medical treatment and are not suitable for or do not want to have a bariatric procedure; new endoscopic techniques have emerged in recent years that offer less invasive and more cost-effective options. These methods include intragastric balloon placement (IGBP), intragastric botulinum toxin-A injection (IGBTI), transpyloric shuttle, transoral gastroplasty, transoral endoscopic restrictive implant system, duodenal-jejunal bypass liner, and gastric electrical stimulation.[8-10]

IGBP is a safe option for class I obesity and is also used as a bridging procedure for patients with severe obesity before bariatric surgery.[11] The gastric balloon causes satiety by reducing stomach capacity and slowing gastric emptying due to its space-occupying effect. A systematic review of IGBP reported that patients treated with IGBP lost 13.16% of their total body weight (TBWL) in 6 months.[12] In another review, TBWL was 9.7% in the first six months, and the effectiveness of IGBP decreased after six months.[11] However, the primary limitation of IGBP therapy is the common occurrence of weight gain, which is thought to result from the necessary removal of the balloon.[13,14] The most common side effects associated with IGBP range from simple reactions such as nausea, vomiting, and abdominal pain to more severe pancreatitis and stomach perforation.[15,16]

Botulinum toxin A (BTxA) is a neurotoxin produced by the bacterium Clostridium botulinum that decreases smooth and striated muscle contractions by preventing the release of the neurotransmitter acetylcholine from the axon terminals of the neuromuscular junctions by blocking synaptic vesicles. It is applied in a wide variety of different medical situations, such as strabismus, cervical dystonia, achalasia, anal fissure, and hyperhidrosis.[17] The application of BTxA in treating obesity is rooted in its potential to affect the functioning of the stomach muscles. BTxA injections reduce gastric emptying, trigger an extended fullness, and decrease the appetite by hindering the muscles' contractions in the stomach's antrum and corpus. However, given conflicting research results on IGBTI, it remains a controversial approach to weight loss.[18]

Few studies have performed comparative analyses of IGBP and IGBTI. Therefore, in this article, we investigate the effectiveness of IGBP and IGBTI in individuals with overweight and obesity during the 12-month post-intervention period. By understanding the potential benefits and drawbacks of these endoscopic treatments, we aim to contribute valuable insights into the evolving landscape of obesity management, offering patients and healthcare providers a nuanced perspective on the available options.

Materials and Methods

The patients who had intragastric balloon placement (IGBP) or intragastric botulinum toxin-A injection (IGBTI) for treatment of overweight and obesity who were prospectively followed up for at least 12 months between January 2018 and October 2022 were analyzed retrospectively for this study. A cohort of 123 patients had IGBTI, and 42 had IGBP. This study was conducted per the tenets of the Declaration of Helsinki, and written informed consent was obtained from all subjects and approved by the local ethics committee (TUTF-GOBAEK 2024/219).

Endoscopic weight loss treatments were not applied to patients under the age of eighteen, elderly patients aged 65 and above, female patients who were pregnant or lactating, patients with myopathy or neuromuscular disorders, patients with a history of hypersensitivity to BTxA, patients with cardiovascular disease, and those with psychiatric disorders. Further, IGBTI or IGBP were not performed if gastric ulcers, tumors, erosive gastritis/esophagitis, hiatal hernia, or food residues were found during endoscopy. Patients were not under any anticoagulant or antiaggregant treatments. Retrospective data were retrieved from the patients' files, including sociodemographic, anthropometric, procedural details, and weight loss parameters. Patients lacking follow-up data were excluded from the study.

The indication criteria for both procedures were the same: age between 18 and 65 years and body mass index (BMI)>25 kg/ m^2. Body weight and height were measured, and BMI was calculated before the procedures [body weight (kg)/ height (m^2)]. Body weight and BMI were measured in the first, third, sixth, and twelfth months. Patients' complaints related to the procedures were collected during the follow-ups.

IGBTI Procedure

After 8–12 hours of fasting, the patients underwent upper GI endoscopy under sedation. As mentioned above, the first step was to evaluate endoscopic findings that might complicate further BTxA injection or IGB placement. AbobotulinumtoxinA (Dysport® 500 IU Ipsen Pharmaceuticals, France) was injected in two different doses, 250 IU and 500 IU. Each BTxA flacon was diluted with 20 ml of 0.9% saline and 0.1 ml of blue dye. Injections were administered at 10 points in the gastric antrum and 5 points in the corpus and the fundus, each containing 1 ml of prepared solution using a sclerotherapy needle.

IGBP Procedure

The patients fasted 8-12 hours before the procedure and received sedation for upper GI endoscopy. The primary step was to ensure that no anatomical or endoscopic pathology would prevent placing a space-occupying device in the stomach. The endoscope was removed to advance the balloon introducer manually to the stomach and reintroduced to inflate the balloon under direct vision of the scope. Two types of intragastric space-occupying devices were used: MedSil® and Spatz®. The balloon was inflated with 550 ml saline and 5 ml of blue dye for both devices. After the inflation was completed, the adapter was removed, and the stomach was evaluated for any leak of blue dye or bleeding. No adjustments were made to any patient who underwent Spatz®.

Patients were observed in the endoscopy unit before discharge for 30 to 60 minutes after they emerged from sedation after the procedure for both procedures. Patients were referred to a dietitian immediately after the endoscopic procedure. At discharge, a proton pump inhibitor (PPI), an anti-emetic, and antispasmodic pills were prescribed. The first week's nutrition mainly consisted of a liquid diet, which was later followed by a reduced-calorie diet supported by a high-protein, low-carbohydrate, and low-fat supplement advised by the dietician (1100–1250 kcal/ day). The patients were advised to exercise daily for 30 to 45 minutes. The patients were reviewed in the bariatric outpatient clinic every month to assess their progress, including weight loss and any adverse side effects, for six months.

Statistical Analysis

Statistical evaluation was performed using SPSS 20 statistical software. The Kolmogorov-Smirnov test was used to assess the normality of continuous data. Descriptive statistics are presented as mean, standard error, minimum and maximum values for continuous variables, and frequency (n) and percentage (%) for categorical variables. Fisher's Exact test was used to compare categorical data, and the Mann-Whitney U test and independent samples t-test were used for comparisons of continuous variables between groups, based on distribution characteristics.

To assess the changes in weight-related parameters (TWL, %TWL, BMIL, %EWL) over time and between treatment groups, a mixed-design ANOVA (also known as split-plot ANOVA) was applied. This approach allowed us to evaluate both within-subject effects (changes over time within the same group) and between-subject effects (differences between the IGBTI and IGBP groups). Where appropriate, post-hoc pairwise comparisons were conducted with Bonferroni correction. Statistical significance was set at $p<0.05$.

Results

Patient Demographics

The average age was 36.39±0.89 years (range: 18–61) for the IGBTI group and 38.42±1.65 years (range: 18–62) for the IGBP group. Of the 165 patients, 90.2% (n=111/123) in the IGBTI group and 86% (n=36/42) in the IGBP group were female. Baseline mean weight, BMI, excess BMI, and excess weight were significantly higher in IGBP patients compared to IGBTI patients ($p<0.001$). The average balloon placement duration in the IGBP group was 9.54±3.14 months. Demographic characteristics are summarized in Table 1.

Overall Weight Loss Outcomes

In both groups, weight, BMI, excess BMI, and excess weight showed significant reductions from baseline at all follow-up intervals ($p<0.001$). Compared to the IGBTI group, IGBP patients had significantly greater reductions

Table 1. Distribution of demographic and anthropometric data of patients

	IGBTI (n=123) Mean±S.E (Min-Max)	IGBP (n=42) Mean±S.E (Min-Max)	p
Gender			
Female, n (%)	111 (90.2%)	36 (86%)	0.446¥
Male, n (%)	12 (9.8%)	6 (14%)	
Age (years)	36.39±0.89 (18-61)	38.42±1.65 (18-62)	0.177*
Height	164.78±0.62 (152-189)	166.52±0.62 (152-189)	0.097£
Body Weight	86.29±1.21 (65-136)	100.28±4.61 (72-270)	<0.001£
BMI	31.71±0.36 (24-48)	36.07±1.39 (29-88)	<0.001£

Normally distributed numerical data are presented as mean±standard deviation with range values, categorical data are presented as number (percentage) values. IGBP: Intragastric Balloon Placement; IGBTI: Intragastric Botulinum Toxin-A Injection; BMI: Body Mass Index. *Independent sample t test, ¥Fisher's Exact test, £ Mann-Whitney U test.

in weight and BMI, and higher BMIL and %TWL values across most follow-up points (p=0.003 for weight, p=0.006 for BMI, p<0.001 for BMIL, p<0.001 for %TWL). Exceptions included BMIL between 3 and 6 months (p=0.313) and %TWL in the first month (p=0.051), which did not differ significantly.

At 12-month follow-up, 37.3% (n=46/123) of IGBTI patients had not lost any weight, compared to only 19% (n=8/42) in the IGBP group.

The %EWL values also differed significantly between groups at the 1st, 3rd, and 6th months (p=0.002 for each interval), but not at the 12th month (p=0.088). Additionally, there was no significant difference in %EWL change between groups over time (p=0.987). Full details of the weight-related parameters are provided in Table 2.

Subgroup Analysis by Balloon Type

Among patients treated with IGBP, MedSil® remained in the stomach for an average of 5.94±1.43 months, while Spatz® remained in place for 12 months (p<0.001, Table 3). At the 6-month follow-up, there were no significant differences between the two balloon types in TWL, %TWL, %EWL, or BMIL. However, by the 12th month, Spatz® significantly outperformed MedSil® in all these parameters (TWL: p<0.001, %TWL: p<0.001, %EWL: p=0.002, BMIL: p<0.001). Patients with MedSil® also showed significant decreases in all weight-related parameters between months 6 and 12 (p<0.001), indicating weight regain following removal.

Correlation Analyses

There was a weak positive correlation between patients' initial weight, excess weight, and BMI and their weight loss outcomes. In contrast, a strong positive correlation was observed between weight loss and the duration of IGB placement. A moderate positive correlation was also found between %EWL and balloon duration (Table 4).

In the IGBTI group, almost no correlation was found between the amount of BTxA administered and most weight loss parameters, except for TWL and BMIL at the 6-month interval, where significance was observed (p=0.002 for both). However, the percentage of BMI loss (%BMIL) did not differ significantly between the 250 IU and 500 IU dosing groups at any time point (Table 5).

Discussion

This study is one of the few studies comparing IGBTI and IGBP for weight loss. IGBP was superior to IGBTI in the amount and duration of weight loss, but IGBTI was also effective for weight control in different degrees of obesity. However, almost 40 % of the patients did not lose weight after IGBTI. Another interesting finding was the absence of a consistent correlation between the amount of BTxA applied and the weight loss outcomes in different intervals.

The frequency of proceeding to further obesity treatments, such as bariatric surgery, after failed lifestyle interventions and pharmacological therapy is low, with only 1% of these individuals undergoing weight-loss surgery.[19] Therefore, there is a significant unresolved problem for

Table 2. Comparison of weight parameters in consequent follow-up intervals of IGBTI and IGBP groups. Data are given as Mean±S.E (Min-Max)

	IGBTI		IGBP		p£		IGBTI		IGBP		p£
Weight						BMI					
0	86.29±1.21	(65-136)	100.28±4.61	(72-270)	p<0.001	0	31.71±0.36	(24-48)	36.07±1.39	(29-88)	p<0.001
1 m	81.35±1.14[a]	(59-128)	93,14±4,59[a]	(65-263)		1 m	29.92±0.36[a]	(23-44.6)	33.41±1.42[a]	(25.4-85.9)	
3 m	79.66±11.11[a,b]	(56-122)	89.28±4.54[a,b]	(63-257)		3 m	29.31±0.35[a,b]	(21.9-40.6)	32.02±1.40 [a,b]	(24.6-83.9)	
6 m	79.69±1.08[a,b]	(58-121)	87.09±4.49[a,b]	(60-252)		6 m	29.32±0.35[a,b]	(23-42.5)	31.21±1.37 [a,b]	(23.4-82.3)	
12 m	82.76±1.18[a,c,d]	(59-128)	88.73±4.35[a,b]	(57-244)		12 m	30.43±0.36[a,c,d]	(23-42.5)	31.79±1.33 [a,b]	(22.3-79.7)	
p*	p<0.001		p<0.001			p*	p<0.001		p<0.001		
TWL						%TWL					
1 m	4.93±0.35	(0-20)	6.97±0.62	(0-22)	p<0.001	1 m	5.65±0.40	(0-25)	7.30±0.64	(0-18)	p<0.001
3 m	6.62±0.49[b]	(-4-20)	10.74±0.77[b]	(0-27)		3 m	7.51±0.54[b]	(-5-25)	11.28±0.77 [b]	(0-23)	
6 m	6.59±0.59[b]	(-8-28)	12.88±0.95[b,c]	(0-27)		6 m	7.30±0.63[b]	(-9-25)	13.45±0.90 [b]	(0-25)	
12 m	3.52±0.56[c,d]	(-1.-40)	11.27±1.23[b,c]	(-2-26)		12 m	3.89±0.59[b,c,d]	(-11-33)	11.61±1.22 [b]	(-2-27)	
p*	p<0.001		p<0.001			p*	p<0.001		p<0.001		
BMIL						%EBMIL					
1 m	1,80±0,13	(0-8)	2.48±1.35	(0-6)	p<0.001	1 m	45.82±4,41	(0-400)	50.30±3,62	(0-93)	p<0.001
3 m	2,41±0,18[b]	(-2-8)	3.88±1.70[b]	(0-8)		3 m	60.43±5,95[b]	(-27-500)	63.45±4,40 [b]	(0-107)	
6 m	2,38±0,21[b]	(-3-11)	4.09±2.97[b]	(-1-9)		6 m	56.43±6,31[b]	(-54-454)	60.16±5,74	(-5-178)	
12 m	1,27±0,21[c,d]	(-4-16)	4.17± 2.93[b]	(-1-9)		12 m	75,94±9,64	(-100-500)	97.45±22,23 [b,c,d]	(-36-404)	
p*	p<0.001		p<0.001			p*	p<0.001		p<0.001		

The parameters were analyzed within each group over time (comparing different follow-up points) and between the two groups at the same follow-up time points [m - months]. The p* value compares the same group's follow-up periods . The p£ value represents the comparison between the two groups at the exact follow-up times. IGBP: Intragastric Balloon Placement; IGBTI: Intragastric Botulinum Toxin-A Injection; BMI: Body Mass Index, TWL: Total Weight Loss; %TWL: Percentage Total Weight Loss, BMIL: Body Mass Index Loss; %BMIL: Percentage Body Mass Index Loss. Mixed Design ANOVA. Letters represent p values of different time intervals' comparisons within each other. a) p<0.05 compared to baseline, (b) p<0.05 compared to first month, (c) p<0.05 compared to third month, (d) p<0.05 compared to sixth month.

Table 3. Comparison of patients in terms of devices that occupy space in the stomach. Data are given as Mean±S.E (Min-Max)

	TWL		%TWL		%EWL		BMIL		%EBMIL	
6th Month										
Spatz®	14.00±4.34	(0-23)	14.00±4.56	(0-25)	53.24±29.76	(0-144)	5.20±0.32	(0.1-8.60)	55.27±7.17	(9-140)
Medsil®	11.33±8.05	(0-27)	11.94±7.81	(0-23)	51.83±33.87	(0-93)	4.10±0.64	[(-0.2) - 9.20]	51.47±6.17	[(-3.33) - 108]
p	0.169*	0.284*	0.886*	0.105*	0.690*					
12th Month										
Spatz®	15.84±6.65	(0-26)	15.72±6.54	(0-27)	59.36±36.80	(0-144)	5.86±0.47	(0.1-9.20)	56.05±9.50	[(-2) - 168]
Medsil®	4.94±5.22	[(-2) - 13]	5.27±5.56	[(-2) - 16]	24.44±28.96	(0-93)	1.82±0.42	[(-0.5) - 5.20]	36.68±6.34	[(-10) - 115]
p	<0.001£	<0.001£	0.002*	<0.001*	0.085*					
IGB duration (months)										
Spatz®	12.00±0.00	(12-12)								
Medsil®	5.94±1.43	(3-8)								
p	<0.001£									

%EWL: Percent Excess Weight Loss; TWL: Total Weight Loss; %TWL: Percent Total Weight Loss; IGBP: Intragastric Balloon Placement; IGBTI: Intragastric Botulinum Toxin-A Injection; BMIL: Body Mass Index Loss. *Independent samples t-test; £ Mann-Whitney U test.

this large group of patients who cannot lose weight with conservative methods. Offered as an outpatient endoscopic procedure, IGBs are intended to fill this gap effectively and safely.[20] IGBs increase satiety by affecting both stomach capacity and stretch receptors and are, therefore, a non-surgical procedure to treat obesity. IGB may be attractive to patients compared to surgical treatment because it is less invasive, repeatable, and reversible. Additionally, IGBP is a temporary method, as the prosthesis remains in the stomach cavity for a limited time.[21]

In our study, two different balloon brands —MedSil® and Spatz®—were used, and the anthropometric data of the patients were evaluated in the first, third, sixth, and twelfth at 1-, 3-, 6- and 12-months post-procedure. The corresponding TWLs were 7.14 (7.30%), 11.00 (11.28%), 13.19 (13.45%), and 11.54 (11.61%) kg, while BMILs were 2.54, 3.80, 4.19, and 4.19 kg/m^2, respectively. Although initial weight loss efficacy did not differ between the two brands, patients in the MedSil® group began to regain weight after balloon removal around 6 months, whereas those with Spatz® maintained weight loss for up to 12 months—the duration of balloon implantation. This outcome was expected, as weight regain is common once the device is removed, particularly in patients who fail to adopt lasting lifestyle changes.

Several studies have reported comparable results following IGB placement. Ribeiro da Silva et al.[21] reported a TWL of 11.94 kg and %EWL of 42.16% at 6 months. Fuller et al.[22] reported a TWL of 9.4 kg, Gaur et al.[23] and Sallet et al.[24] found a TWLs of 18.3 kg and 17.4 kg, respectively. Doğan et al.[25] documented an average TWL of 9.5 kg at the balloon removal, and 7.6 kg one-year post-removal. Similarly, Lee et al.[26] observed a mean TWL of 9.95 kg (10.76%), BMIL of 3.72 kg/m^2, and %EWL of 43.67% with a mean implantation time of 251.4 days. The 13.45% TWL observed in our IGBP group at 6 months is with the 13.16% TWL reported in the meta-analysis by Dayyeh et al.[12] According to established standards, a ≥10% reduction in total body weight maintained for one year is considered a successful outcome.[27] By the end of our study, %TWL was 15.72 in the Spatz® group and 5.27 in the MedSil® group, supporting the notion that Spatz® IGBP offers superior long-term control due to its extended residence time in the stomach.

IGBTI has also emerged as a minimally invasive endoscopic option for obesity treatment. Originally used for motility disorders such as oropharyngeal dysphagia, achalasia, esophageal spasms, anismus, rectocele, and anal fissure.

Table 4. Correlation of weight loss with some parameters

	TWL		%EWL	
	r	p	r	p
Baseline Weight	0.268	<0.001	-0.127	0.104
Excess Weight	0.206	0.008	-0.141	0.070
Baseline BMI	0.188	0.016	-0.141	0.070
Amount of BTxA	-0.034	0.706	-0.170	0.061
Age	0.002	0.976	-0.085	0.276
IGB placement duration	0.681	<0.001	0.450	0.003

(r) Pearson correlation coefficient, %EWL: Percent Excess Weight Loss; TWL: Total Weight Loss; BMI: Body Mass Index; IGB: Intragastric Balloon; BTxA: Botulinum Toxin A.

[28,29] BTxA was later applied intragastrically to target the body, fundus, and antrum, which play key roles in mechanical digestion, satiety signaling, and gastric emptying.[30,31] By impairing these functions via IGBTI, recent studies aimed to promote early satiety and delayed gastric emptying, resulting in weight loss.[32] Gui et al.[33] reported a 37.8% reduction in food intake and a 14% weight loss in rats following BTxA injection into the antrum. The first human case of IGBTI was published by Rollnik et al.[34] who observed an 8.9% weight reduction and 6.5% BMI decrease at 4 weeks post-injection Sánchez et al.[35] reported an average weight loss of 4.6 kg after 24 weeks in 52 obese patients treated with IGBTI. Similarly Albani et al.[36] found that patients lost about 4 kg at one month after receiving 500 IU of BTxA. A meta-analysis of seven studies administering 100–500 IU of BTxA found weight loss ranging from 4.9% to 9.0% over 5 to 24 weeks.[18] However, not all studies support its efficacy. Bustamante et al.[37] in a meta-analysis of four randomized controlled trials, found BTxA was not superior to placebo. Similarly, de Moura et al.[38] concluded that IGBTI was ineffective for preoperative weight loss in patients with super-obesity.

In our study, IGBTI was applied to 123 patients. The dose started at 250 IU and was later increased to 500 IU. TWL at 1, 3, 6, and 12 months was 4.93 (5.65%), 6.62 (7.51%), 6.59 (7.30%), and 3.52 (3.89%) kg, respectively. Corresponding BMIL values were 1.79 (5.64%) kg/m^2, 2.4 (7.56%) kg/m^2, 2.39 (7.53%) kg/m^2, and 1.28 (4.03%) kg/m^2, respectively. Altunel et al.[39] reported higher TWL values—7.6 kg at 3 months and 9.8 kg at 6 months—after 500 IU of BTxA, likely due to higher baseline BMI in their cohort.

BTxA is often preferred for its technical simplicity and minimal side effects,[40] though its effect typically diminishes within 3–6 months without causing permanent damage.[41] In our cohort a substantial proportion of IGBTI patients failed to respond. Specifically, 17% (n=21) did not lose weight in the first month, 23.6% (n=29) in the third month (including 5 who gained weight), and 31.7% (n=39) in the sixth month (8 of whom gained weight). By the end of the 12-month follow-up, 37.3% (n=46) of patients in the IGBTI group had not lost weight. This lack of response was not statistically associated with BTxA dose. In contrast, only one in five IGBP patients failed to lose weight, suggesting that IGBTI may carry a significantly higher risk of treatment failure. These findings highlight the critical limitation of IGBTI's clinical efficacy, especially in light of its nearly 40% non-responder rate. This underscores the need for improved patient selection and further investigation into predictors of treatment success.

Many studies have attempted to determine the superiority of different obesity treatment methods; however, few directly compare IGBTI and IGBP. Tayyem et al.[42] found that initial weight, excess weight, and BMI were higher in the IGBP than the IGBTI group. After 6 months, TWL was 9.6kg in the IGBTI group and 15.6 in the IGBP group. BMIL was 5.6 kg/m² for IGBP versus 3.2 kg/m² for IGBTI. Interestingly, %EWL was higher in the IGBTI group (59.1%) compared to IGBP (42.2%).[42] In another study, Kanlioz et al.[43] reported BMILs of 3.95 kg/m² and 1.6 kg/m² at six months for IGBP and IGBTI, respectively. Al et al.[44], showed similar trends: patients in the IGBP group lost 9.0 kg (5.0–12.0) in the first month and 19 kg (13.0–30.0) by month six, while the IGBTI group lost 6.0 kg (2.0–8.0) and 13 kg (1.0–19.0), respectively (p<0.001).

Consistent with these findings, our study demonstrated that initial weight, excess weight, and BMI were signif-

Table 5. Comparison of weight parameters of patients who had BTxA dose of 250 IU and 500 IU. Data are given as mean±S.E (Min-Max)

	250 IU		500 IU		p		250 IU		500 IU		p
Weight						BMI					
0	83.20±10.30	(65 - 120)	88.00±14.70	(65 - 136)	0.056	0	31±5.42	(25 - 42)	31±1.14	(24 - 40)	0.151
1 m	78.20±10.50	(59 - 110)	83.10±13.50	(61 - 128)	0.064	1 m	29.4±4.35	(23 - 44.6)	30.2±3.82	(24.2 - 40.4)	0.169
3 m	77.50±10.40	(56 - 106)	80.80±13.20	(58 - 122)	0.302	3 m	29.2±4.27	(21.9 - 40.6)	29.4±3.85	(23.4 - 40.4)	0.673
6 m	78.90±10.70	(59 - 113)	80.20±12.80	(58 - 121)	0.810	6 m	29.6±4.31	(23.7 - 42.5)	29.2±3.73	(23 - 42.2)	0.648
12 m	79.90±10.30	(59 - 113)	84.40±14.20	(59 - 128)	0.109	12 m	30±4.13	(23 - 42.5)	30.7±4.02	(23.7 - 42.7)	0.400
TWL						BMIL					
1 m	5.02±5.04	(0 - 20)	4.89±5.04	(0 - 19)	0.493	1 m	1.90±1.97	(0 - 8.43)	1.75±1.09	(0 - 5.32)	0.539
3 m	5.64±6.53	[(-4) - 20]	7.18±4.79	[(-4) - 20]	0.054	3 m	2.13±2.50	[(-1.56) - 8.43]	2.58±1.65	[(-1.56) - 6.24]	0.065
6 m	4.32±7.07	[(-8) - 28]	7.86±7.07	[(-5) - 22]	0.002	6 m	1.64±2.73	[(-3.13) - 10.7]	2.82±2.06	[(-1.84) - 7.02]	0.002
12 m	3.30±8.16	[(-10) - 40]	3.66±8.16	[(-8) - 21]	0.077	12 m	1.25±3.12	[(-3.91) - 15.5]	1.32±1.77	[(-2.74) - 6.70]	0.095
%TWL						%BMIL					
1 m	6±6.05	(0 - 25.3)	5.44±6.05	(0 - 14.8)	0.718	1 m	47.80±70.4	(0 - 400)	32.5±30.50	(0 - 200)	1.000
3 m	6.63±7.5	[(-4.55) - 25.3]	7.99±7.5	[(-5) - 18.5]	0.118	3 m	52.90±85.7	[(-27) - 500]	51.00±51.59	[(-25) - 300]	0.242
6 m	5.03±7.83	[(-9.09) - 25.3]	8.64±7.83	[(-6.94) - 20.4]	0.004	6 m	41.1±73.7	[(-54) - 400]	54.30±68.00	[(-12.5) - 454]	0.052
12 m	3.67±8.42	[(-11.4) - 33.3]	4.05±8.42	[(-11.1) - 19.8]	0.101	12 m	33.2±105	[(-145) - 600]	31.80±86.80	[(-78.1) - 726]	0.131

The negative values represent gains in the related parameters. BTxA: Botulinum toxin A; BMI: body mass index; TWL: total weight loss; %TWL: percentage total weight loss; %EWL: percentage excess weight loss; BMIL: body mass index loss; %BMIL: percentage body mass index loss.)

icantly higher in IGBP patients. TWL and BMIL at 1, 3, 6, and 12 months were consistently greater in the IGBP group. After the third to sixth month—when the pharmacological effect of BTxA begins to wane—the gap in TWL and BMIL between groups widened further.

A major strength of our study is the inclusion of 12-month follow-up data comparing IGBTI and IGBP in a single cohort. However, several limitations should be acknowledged. First, the study's retrospective design and exclusion of patients under 18 or over 65 years limit the generalizability of our findings. Second, the predominance of female participants precludes a reliable gender-based comparison.

Overall, both IGBP and IGBTI were associated with significant reductions in weight and BMI. However, when comparing TWL, %TWL, and BMIL, IGBP consistently outperformed IGBTI at all follow-up intervals. In the IGBTI group, weight loss declined after the third month and reversed in some cases after the sixth month—coinciding with the waning effect of BTxA. In contrast, weight loss durability in the IGBP group was strongly linked to balloon implantation duration.

These findings support the superior efficacy and sustainability of IGBP over IGBTI in endoscopic obesity treatment. The development of longer-acting balloon systems and the identification of predictors of non-response to IGBTI could help improve individualized treatment strategies in the future.

Disclosures

Ethics Committee Approval: All procedures performed in this study involving human participants followed the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. This study was approved by the ethics committee (Date: 20/05/2024, No: TUTF-GOBAEK 2024/219).

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