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Effects of botulinum toxin and factors on weight loss in patients with gastric balloon and without gastric balloon

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ABSTRACT

Introduction: In this research, it was aimed to evaluate effects of botulinum toxin (BoNT) and factors on weight loss in patients with gastric balloon (GB) and without GB.

Materials and Methods: A total of 629 patient files attempted to our clinic between December 2020 to December 2022 were subjected to the study divided by two groups as patients with (GB, n=512) and without GB (NGB, n=117).

Results: Male rate in GB group was significantly higher ($p<0.05$). Body mass index (BMI), weight, weight difference and BMI difference means were significantly higher in GB group ($p<0.05$). Ursactive rate was significantly higher in NGB group ($p<0.05$). Age, height, last weight, hormone usage, hunger, medicine, illness, and diet history differences were insignificant ($p>0.05$). Weight difference was significantly correlated with group ($r=-0.212$; $p<0.01$), gender ($r=0.161$; $p<0.01$), BMI ($r=0.305$; $p<0.01$), BMR ($r=0.268$; $p<0.01$), height ($r=0.151$; $p<0.01$), weight ($r=0.333$; $p<0.01$), and medicine usage ($r=-0.072$; 0.05). BMI difference was significantly correlated with group ($r=-0.209$; $p<0.01$), BMI ($r=0.308$; $p<0.01$), BMR ($r=0.165$; $p<0.01$), and weight ($r=0.250$; $p<0.01$). GB ($B=2.410$; $p<0.01$), BMI ($B=0.344$; $p<0.01$), and BMR ($B=0.004$; $p<0.01$) had significant contribution on weight difference.

Conclusion: BoNT is more effective in patients with GB than patients without GB.

Keywords: Botulinum toxin, gastric balloon, weight loss

Introduction

In 1989, the Food and Drug Administration (FDA) of the United States gave the botulinum toxin (BoNT) treatment for strabismus its initial approval. Since then, research on BoNT has grown significantly, leading to the creation of newer versions with a wider range of uses.[1,2] BoNT, which are protein neurotoxins, are produced by neurotoxigenic strains of anaerobic, fungal growths bacteria of the genus Clostridium.[3,4] The neurotoxic proteins known as BoNT s are produced by the gram-positive, anaerobic, rod-shaped bacterium Clostridium botulinum.[5] BoNT use over an extended period of time raises the risk that patients will develop neutralizing antibodies and stop responding to the medication. The likelihood of acquiring BoNT resistance is increased by factors such as high protein loading in some formulations, high individual and cumulative doses of BoNT, and short intervisit intervals, especially with booster injections.[6,7]

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Gastric balloon (GB) application is one of the important methods in the fight against obesity and weight control.[8,9] In particular, the fact that there is no need for a surgical intervention, that it can be applied in a short time and that it can be removed immediately when the patient's comfort deteriorates has allowed GBs to be used effectively in weight loss.[10,11] Although there are side effects such as nausea and vomiting, these effects are quite limited.[12,13] There are basically two types of balloons that are swallowed and applied endoscopically.

Although there have been studies on GB and BoNT, there have not been found any research comparing NGB and GB patients at multivariate level. Thus, it was aimed to evaluate effects of BoNT and factors on weight loss in patients with GB and without GB.

Materials and Methods

The same surgeon carried out endoscopy and botox operations. With an endoscope, the stomach was examined before the procedure to check for benign and malignant disorders. Patients with cancer, ulcers, and other chronic illnesses that might have an impact on the study's findings were not allowed to participate. The endoscopic doctor made the decision based on his or her visual experience; no manometric measurements were taken in the trial.

Under surgical sedation, Clostridium BoNT was applied to 500 units of antrum, 125 units of preploric, 125 units of cardia, and 250 units of fundus. After the procedure, the patient was kept under observation for one hour. The patients were followed up once a week for 6 months by a single dietitian. After the procedure, a liquid diet was applied for the 1st week, followed by a carbohydrate-restricted and protein-based diet. Patients were weekly followed by a single dietitian, but not weekly data collection was allowed by ethical approval. Measurements were performed by initial and at 6 months. Since a reference is not definde for all patients, excess weight loss was not calculated for patients.

A total of 629 patients were subjected to the study divided by two groups as GB (n=512) and NGB (n=117). Ethics committee approval dated December 05, 2022 was obtained from İzmir Bakırçay University Non-Invasive Clinical Research Ethics Committee. 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. Informed consents were taken from patients.

Nominal and ordinal parameters were described with frequencies and scale parameters were evaluated with means and standard deviations. Shapiro–Wilk Test was used for normality of scale parameters: Fischer's exact test and Chi-square likelihood ratio. Mann–Whitney U test was used for scale parameter differences. Spearman's rho correlation analysis and Generalized Linear Model (Logit Model) were used for relational analysis. SPSS 25.0 for windows was used for analysis at 95% confidence level at 0.05 significance level.

Results

Most of patients were female in both groups were females, but male rate in GB group was significantly higher ($p<0.05$). Body Mass Index (BMI), weight, weight difference, and BMI difference means were significantly higher in GB group ($p<0.05$). Ursactive rate was significantly higher in NGB group ($p<0.05$). Age, height, last weight, hormone usage, hunger, medicine, illness, and diet history differences were insignificant ($p>0.05$) (Table 1).

Spearman's rho correlation analysis results showed that weight difference was significantly correlated with group ($r=-0.212$; $p<0.01$), gender ($r=0.161$; $p<0.01$), BMI ($r=0.305$; $p<0.01$), BMR ($r=0.268$; $p<0.01$), height ($r=0.151$; $p<0.01$), weight ($r=0.333$; $p<0.01$), and medicine usage ($r=-0.072$; 0.05). BMI difference was significantly correlated with group ($r=-0.209$; $p<0.01$), BMI ($r=0.308$; $p<0.01$), BMR ($r=0.165$; $p<0.01$), and weight ($r=0.250$; $p<0.01$) (Table 2).

Since BMI difference was not significantly correlated with height, weight difference was accepted as dependent variable. BMI parameter was accepted as independent variable instead of weight and height. Generalized Linear Model (Logit Model) results showed that GB ($B=2.410$; $p<0.01$), BMI ($B=0.344$; $p<0.01$), and BMR ($B=0.004$; $p<0.01$) had significant contribution on weight difference (Table 3).

BMI difference and range were higher in the GB group (Fig. 1).

Table 1. Baseline characteristics of patient groups and difference analysis results

Group	GB (n=512)	NGB (n=117)	Total (n=629)	p
Gender, n (%)				
Female	430 (84.0)	106 (90.6)	536 (85.2)	0.043[a]
Male	82 (16.0)	11 (9.4)	93 (14.8)	
Age	35.00 (16.00–72.00)	36.00 (19.00–67.00)	35.00 (16.00–72.00)	0.450[b]
Initial BMI	30.66 (22.2244.38)	30.04 (22.73–42.71)	30.55 (22.22–44.38)	0.039[b]
Height	166.50 (140.00–194.00)	167.00 (155.00–190.00)	167.00 (140.00–194.00)	0.564[b]
Weight	85.10 (58.70–141.50)	82.60 (62.50–119.10)	84.80 (58.70–141.50)	0.047[b]
Last weight	75.45 (51.20–119.30)	76.00 (58.00–117.90)	75.60 (51.20–119.30)	0.980[b]
Weight difference	8.85 (–25.60–37.60)	5.80 (–5.20–27.00)	8.30 (–25.60–37.60)	0.000[b]
Last BMI	27.12 (19.27–40.66)	27.34 (21.07–39.26)	27.23 (19.27–40.66)	0.633[b]
BMI difference	3.16 (–10.00–13.53)	2.09 (–1.44–9.68)	2.97 (–10.00–13.53)	0.000[b]
Ursactive, n (%)	3 (0.6)	22 (18.8)	25 (4.0)	0.000[a]
Hormone, n (%)	13 (2.5)	7 (6.0)	20 (3.2)	0.059[a]
Hunger, n (%)				
Moderate	174 (34.0)	28 (23.9)	202 (32.1)	0.098[c]
High	266 (52.0)	71 (60.7)	337 (53.6)	
Very high	72 (14.1)	18 (15.4)	90 (14.3)	
Medicine usage, n (%)	174 (34.0)	47 (40.2)	221 (35.1)	0.124[a]
Illness, n (%)	194 (37.9)	46 (39.3)	240 (38.2)	0.426[a]
Diet history, n (%)	368 (71.9)	87 (74.4)	455 (72.3)	0.338[a]

[a]Fischer's Exact Test; [b]Mann–Whitney U Test; [c]Chi-square Likelihood ratio; SD: Standard Deviation; BMI: Body Mass Index; BMR: Basal Metabolic Rate.

Table 2. Spearman's rho correlation between research parameters and BMI and weight difference

	Weight difference	BMI difference
Group	–0.212**	–0.209**
Gender	0.161**	0.075
Age	–0.024	0.013
BMI	0.305**	0.308**
BMR (Kcal)	0.268**	0.165**
Height	0.151**	0.012
Weight	0.333**	0.250**
Ursactive	0.060	0.069
Hormone	–0.031	–0.015
Hunger	–0.055	0.054
Medicine usage	–0.072*	–0.063
Meal	–0.056	–0.053

*p<0.05; **p<0.01.

Discussion

BoNT, which was first approved by the FDA for the treatment of strabismus in 1989, has subsequently been the subject of many clinical studies. BoNT, which is an in vitro strain of Clostridium botulinum bacteria, is protein-based and has a muscle contraction-reducing effect.[14] Due to this effect, BoNT is used effectively in many areas, especially in aesthetic interventions for wrinkle removal. The basic approach is usually the same application method. In BoNT application, due to this effect on the muscles and the effect on the volume in the area where it is applied, BoNT has been used extensively in the areas of slimming and weight loss in recent years.

Obesity causes many serious muscle and musculoskeletal diseases, from sacral stress fractures to movement problems in individuals.[15] The main purpose of the treatments used for weight loss is to provide the balance between the energy taken and the energy spent, and to

Table 3. Generalized Linear Model (Logit Model) for significantly correlated factors with weight difference

Parameter	B	SE	95% Wald Confidence Interval		Hypothesis Test	
			Lower	Upper	Wald Chi-Square	p
(Intercept)	−10.865	2.7394	−16.234	−5.496	15.731	0.000
[Group=GB]	2.410	0.5921	1.250	3.571	16.576	0.000
[Group=NGB]	0[a]					
[Gender=Female]	0.489	0.9659	−1.404	2.382	0.257	0.612
[Gender=Male]	0[a]					
[Medicines=No]	0.551	0.4833	−0.396	1.498	1.299	0.254
[Medicines=Yes]	0[a]					
BMI	0.344	0.0682	0.211	0.478	25.513	0.000
BMR (Kcal)	0.004	0.0012	0.002	0.006	11.535	0.001
(Scale)	32.934[b]	1.8571	29.488	36.782		

[a]Null categories are reference categories.

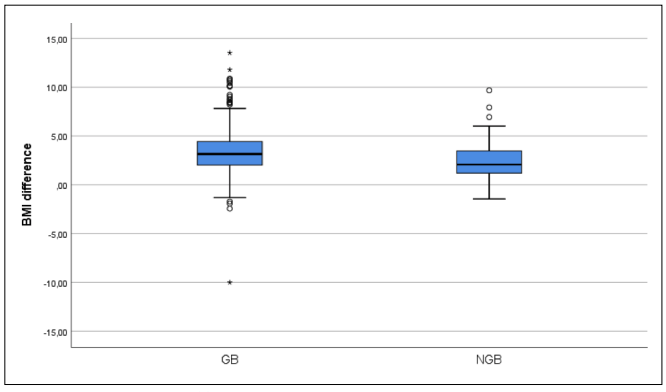

Figure 1. BMI differences between patient groups.

provide energy intake below the daily energy needed until the weight is lost and the ideal weight is reached.[16] In this way, it is to ensure that the body gets the energy, it needs from the fats, it contains and stores. The most effective way to limit energy intake is to reduce the volume of the stomach by reducing eating and drinking.[17-19] Reducing eating and drinking is a process that requires willpower and force the body. Nutrition-oriented weight loss methods, over eating and drinking, generally give slower results in weight loss.[20-24] However, gastric reduction surgery or invasive procedures allow for more effective weight loss in a shorter time. BoNT method is one of these invasive methods.

The findings of our study showed that weight loss with the BoNT method was more effective in the GB group. In our study, the differences in gender, BMI, weight, Ursactive, weight change, and BMI change between the GB and NGB groups were statistically significant. In the analysis, the differences between the two groups were examined on a multivariate basis, taking these differences into account.

The findings of the correlation study demonstrated a strong correlation between weight change and the use of GBs, gender, BMI, BMR, height, weight, and drug use. However, the findings of the multivariate analysis revealed a substantial interaction between weight loss and the use of GBs, as well as a relationship between BMI and BMR parameters and the amount of weight loss. The use of the GB was successful, and the difference in weight given was bigger in the GB group even though BMI and BMR were already expected parameters.

The most important limitation of the research is that there has not been enough work in this field due to the limitations imposed in some countries regarding BoNT. In fact, this situation provides both the limitation of the study and its being a pioneer in the field. Another limitation of the study is that the clinical parameters are limited in the application of BoNT, since the application is generally partially non-invasive. This situation shows both the limitations of the research and the non-invasive level of weight loss with the BoNT method. A retrospective characteristic of the study is also another important limitation of the study.

Since there have not been enough clinical studies in this field, despite the fact that studies and clinical data on BoNT show that the BoNT method is less invasive than surgical methods and more effective at helping people lose weight, it has not yet received worldwide approval in the field of bariatric surgery. However, the health ministries and allied agencies in numerous nations have given their approval. To be a successful and less invasive alternative in the battle against obesity and to benefit the patient, further clinical trials are required in this regard. In this regard, the research is significant because it adds to the few studies that have already been published and broadens the subject's sample size for future meta-analyses. The study also contributes to a more effective literature infrastructure for BoNT applications by revealing the impact of using GBs on weight loss.

Conclusion

Despite the fact that gender, BMI, and BMR characteristics as well as the GB have a significant impact on weight loss in the BoNT treatment at the univariate level, this impact is negligible at the multivariate level. The use of GBs is a crucial factor influencing weight loss after BoNT treatment. BoNT performs better with a GB than without one.

Disclosures

Ethichs Committee Approval: Ethics committee approval dated December 05, 2022 was obtained from İzmir Bakırçay University Non-Invasive Clinical Research Ethics Committee.

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Conflict of Interest: None declared.

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