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# Evaluation of endoscopic ultrasound-guided gastric botulinum toxin injections in the treatment of obesity

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## Abstract

**Background:** Obesity is rapidly emerging as one of the greatest challenges of human health. Many randomized trials and open-label human studies described conflicting results of gastric intra-muscular injections of botulinum toxin type A (BTA). Endoscopic ultrasound (EUS) guidance can assure BTA injection into the subserosal layer and muscularis propria of the gastric wall which may optimize the efficacy of injection. The aim of the study is to assess the efficacy and safety of EUS-guided gastric BTA injections in weight reduction for obese subjects.

**Results:** The present study included 25 patients (2 males and 23 females with mean age  $35.84 \pm 7.776$ ). For nutrient drink tests, median maximum tolerated volumes (MTVs) decreased from 720 cc (range 480–1680) as a baseline value 2 weeks before BTA injection to 360 cc (range 140–820) at 16 weeks after injection. Mean body weight reduction was 11.92 kg (10.8%) after 16 weeks of BTA injection. Mean body weight continued to decrease during the study period from a baseline value of 110 to 98 kg with significant reduction of mean BMI from baseline value of 41.2 to 36.7 at 16 weeks after BTA injection ( $p < 0.001$ ). The study was completed without major adverse events.

**Conclusion:** EUS-guided BTA injection into the antral subserosa and muscularis propria could be an effective technique for weight reduction, or as a bridge for surgery, which can be done safely with minimal complications.

**Trial registration:** NCT03901040

**Keywords:** Botulinum toxin, Obesity, EUS

## Background

Obesity is rapidly emerging as one of the greatest challenges of human health owing to increased risk of associated morbidities including diabetes mellitus and cardiovascular and cerebral disorders [1]. The pharmacological, dietary, and behavioral therapies have shown limited efficacy and duration [2]. The endoscopic Bioenteric Intragastic Balloon (BIB) has also shown partial and transient results [3]. Surgical interventions (gastric banding, sleeve gastrectomy, and gastric by-pass), though

they are valuable in many patients, especially those with morbid obesity, are invasive techniques and may have some fatal complications [4]. In view of the above, searching for novel methods for weight reduction is entirely justified.

In 2000, Gui et al. published a study showing significant reduction of food intake and body weight of laparotomized normal-weight rats after gastric intra-muscular injections of botulinum toxin type A (BTA) [5]. Subsequently, three small randomized trials and many open-label human studies described conflicting results, with many studies showing no or little weight reduction after injection of BTA into the gastric wall [6–11] and one randomized controlled trial showing significant

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reduction in body weight and gastric emptying [12]. In these studies, different doses of BTA (100 to 300 U) were used, and different sites (antrum only versus antrum, body, and fundus) were injected. However, the depth of injection into the gastric wall was mostly unidentified in these studies.

In 2008, Topazian et al. published a study suggesting that endoscopic ultrasound (EUS) guidance can assure BTA injection into the subserosal layer and muscularis propria of the gastric wall which may optimize the efficacy of injection [13].

In this study, we assess the efficacy and safety of EUS-guided gastric BTA injections in weight reduction for obese Egyptian subjects.

## Methods

This is an open label prospective study conducted on twenty-five overweight (BMI < 30), healthy subjects over 14 months study period from October 2017 to December 2018 at our endoscopy unit. Subjects with known peptic ulcer disease, gastroparesis, diabetes mellitus, previous gastric or small intestinal surgery, frequent symptoms of nausea or upper abdominal pain, patients with contraindication for anesthesia (ASA Class 3 or more), or patients who refused to be involved in the study were excluded. Females in childbearing period underwent urinary pregnancy tests before endoscopy. The study protocol was approved by our ethical committee, and written consents were taken from all subjects before the procedure.

## Measures

Satiation was evaluated with the nutrient drink test, using the Tack et al. method [14]. Subjects were asked to ingest 120 ml of a nutrient drink (Ensure®) every 4 min. A constant rate perfusion pump was used to fill the nutrient drink cup to keep filling rate of oral intake. Satiation was scored by subjects every 5 min via a rating scale graph graded from 0 to 5 (0 means no symptoms and 5 means maximum or unbearable fullness). Subjects stopped ingestion when they reached a score of 5, and the maximum tolerated volume (MTV) of nutrient drink was documented. After 30 min, subjects scored their symptoms of nausea, fullness, bloating, and pain via a visual analog scale (VAS) attached with the words unbearable and unnoticeable on both sides. The summation of the VAS scores for each symptom was defined as the aggregate symptom score.

Gastrointestinal (GI) symptoms were evaluated using the Gastrointestinal Symptom Rating Scale (GSRS) which is a validated questionnaire encompassed of 15 items rating GI symptoms with values ranging from 0 to 3 with a total score ranging from 0 to 45. In addition, the GSRS could be scored for five symptom subscales

(abdominal pain, reflux, constipation, diarrhea, and indigestion) [15].

## Procedures

Through the 2-week baseline period before BTA injection, subjects finished the GSRS and were weighted weekly after finishing the nutrient drink test. Then, esophagogastroduodenoscopy (EGD) was done under propofol sedation. If no retained food or ulceration was found in the EGD, EUS-guided BTA injection (Botox®, Refinex) was performed in the same session.

EUS examinations were done with Pentax linear Echoendoscope EG3870UTK (PENTAX medical, Tokyo, Japan) attached to a Hitachi Avius ultrasound system (Hitachi Medical Systems, Tokyo, Japan). BTA injections were made via a 25-gauge fine needle (Wilson-Cook Cooperation, North Carolina, USA). Five injections were done into the gastric antral subserosa or muscularis propria, 2 to 3 cm proximal to the pyloric ring (20 U for each injection with a total dose of 100 U) (Fig. 1). After recovery, subjects were followed for adverse events for 2 h and on the following day by phone.

Subjects finished the GSRS and were weighted weekly during the 16-week follow-up period after BTA injections. Nutrient drink tests were repeated at 4 and 16 weeks after BTA injection. No dietary or behavioral instructions were mentioned to study subjects.

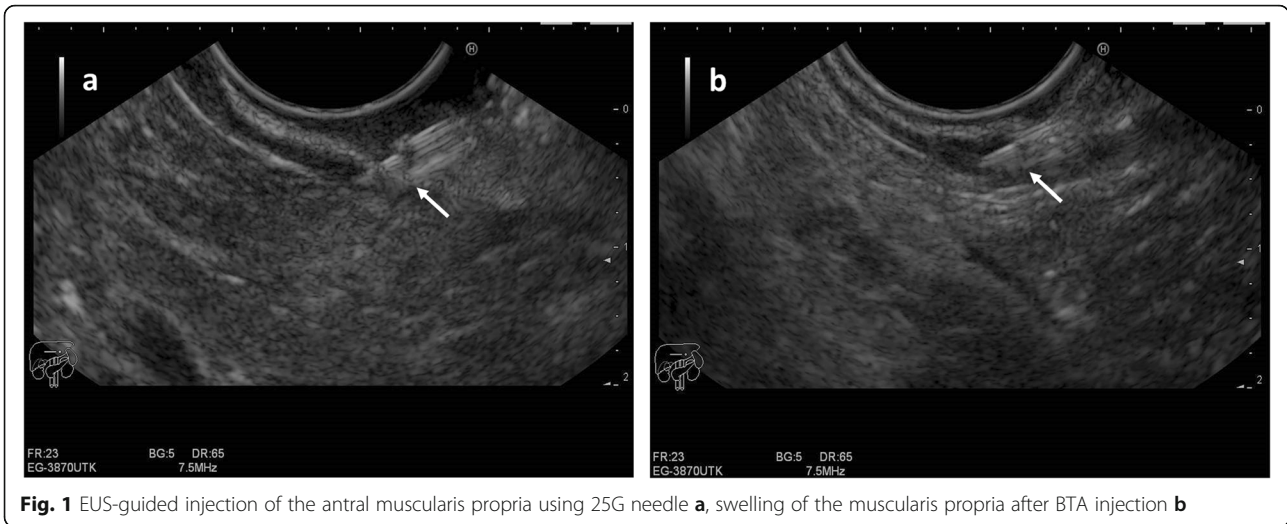
## Statistical analysis

Analysis of data was done by IBM computer using SPSS (version 15) as follows: quantitative variables expressed as mean, SD, and range; qualitative variables expressed as number and percentage; unpaired *t* test was used to compare two groups for quantitative variable in parametric data (SD < 25% mean). Mann-Whitney-Wilcoxon test was used to compare two groups for non-parametric data (SD > 50% mean). Repeated measures ANOVA was used to analyze data measured more than once for same subjects.

Sample size was calculated using the G Power software (version 3.19.4). Based on a previous study by Topazian et al. [16], we anticipate a medium body weight change (effect size:  $d = 0.55$ ). Accordingly, a sample size of 25 achieves 85% power to detect this medium effect size with a significance level (alpha) of 0.05 using one-sided one-sample *t* test assuming that actual distribution is normal.

## Results

The present study included 25 patients (2 males and 23 females with mean age  $35.84 \pm 7.776$ ), who visited our Specialized Medical Hospital between October 2017 and December 2018. The demographic and clinical data of subjects are shown in Table 1.



**Fig. 1** EUS-guided injection of the antral muscularis propria using 25G needle **a**, swelling of the muscularis propria after BTA injection **b**

**Satiation**

For nutrient drink tests, median MTVs decreased from 720 cc (range 480–1680) as a baseline value 2 weeks before BTA injection to 360 cc (range 120–720) at 4 weeks, and 360 cc (range 140–820) at 16 weeks after injection (Fig. 2).

**Body weight**

Mean body weight reduction was 11.92 kg (10.8%) after 16 weeks of BTA injection. Mean body weight continued to decrease during the study period from a baseline value of 110 to 98 kg with significant reduction of mean BMI from baseline value of 41.2 to 36.7 at 16 weeks after BTA injection ( $p < 0.001$ ) (Figs. 3 and 4).

**Symptoms**

Mean GSRS scores decreased from baseline value of 8 (0–17) to 5 (0–11) at 16 weeks after BTA injection. Mild elevation of GSRS score occurred in two subjects who experienced mild abdominal pain and diarrhea (Fig. 5).

**Table 1** Demographic and clinical data of the subjects

Variable	Statistics
Gender M/F (frequency)	2/23
Age (year)	35.84 ± 7.77
BMI (kg/m <sup>2</sup> )	41.28 ± 5.30
Weight (kg) median with IQR	109.96 (86–138)
Waist circumference (cm)	118.08 ± 12.63
Hip circumference (cm)	132.64 ± 9.12
Waist hip ratio	0.89 ± 0.09

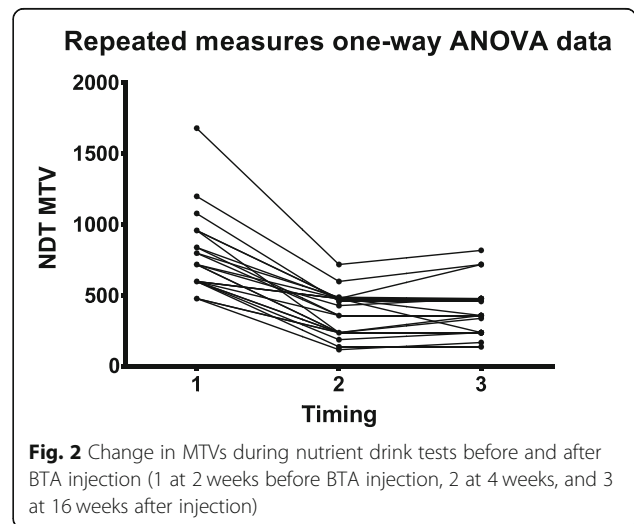
Data are presented as mean ± SD unless otherwise stated

**Adverse events**

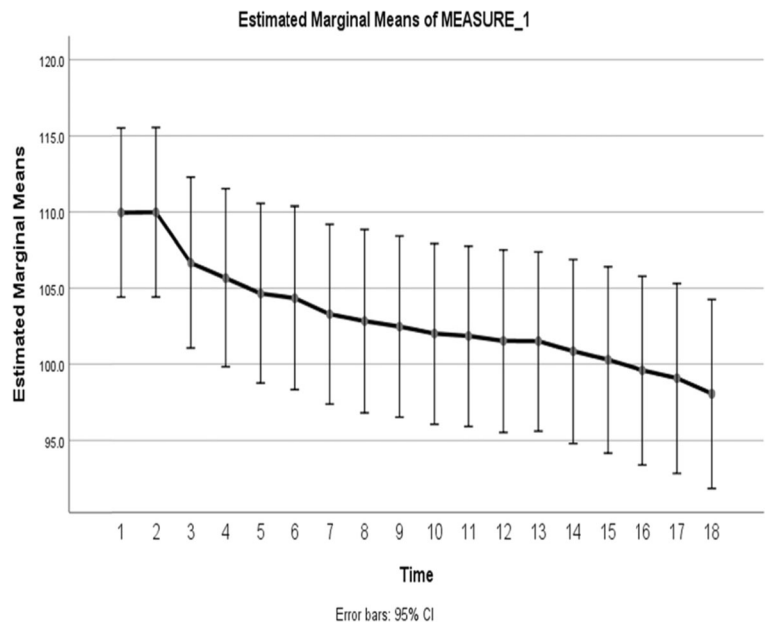
The study was completed without any major adverse events. Two subjects experienced self-limited abdominal pain and diarrhea; stool analysis and abdominal ultrasound were normal. No other adverse events happened.

**Discussion**

Obesity is a public health problem with growing prevalence worldwide [17]. Due to its serious health consequences, combined with substantial social and economic burdens, it is crucial to find an effective method to prevent and treat obesity [18]. Currently, the most effective treatment for morbid obesity is bariatric surgery [19]. However, bariatric surgery is associated with many complications and long-term problems such as nutritional deficiencies [20, 21]. There is growing interest in using endoscopic



**Fig. 2** Change in MTVs during nutrient drink tests before and after BTA injection (1 at 2 weeks before BTA injection, 2 at 4 weeks, and 3 at 16 weeks after injection)



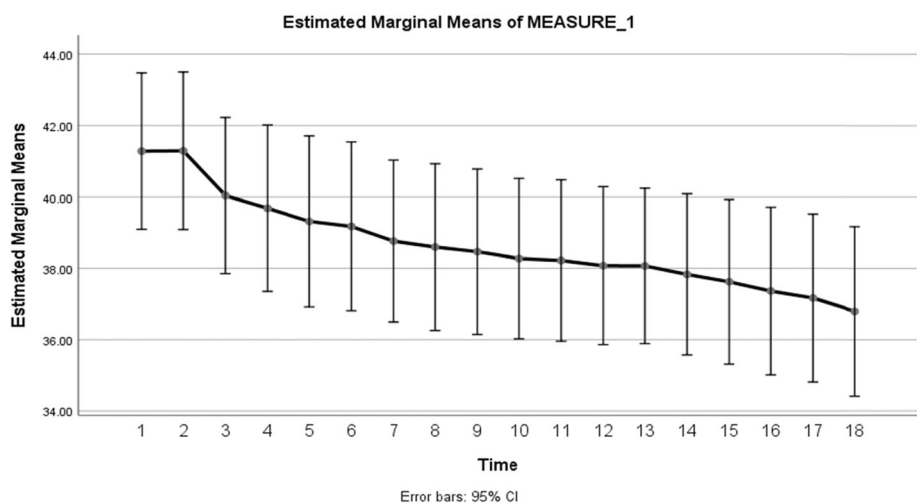
**Fig. 3** Change in body weight before and after injection (1 and 2 weeks before injection and 3–18 weeks after injection)

interventions such as space-occupying devices (BIB), malabsorptive procedures (Endobarrier), restrictive techniques (gastroplasty), and injection of materials that alter gastric emptying and motility (BTA) [22–24].

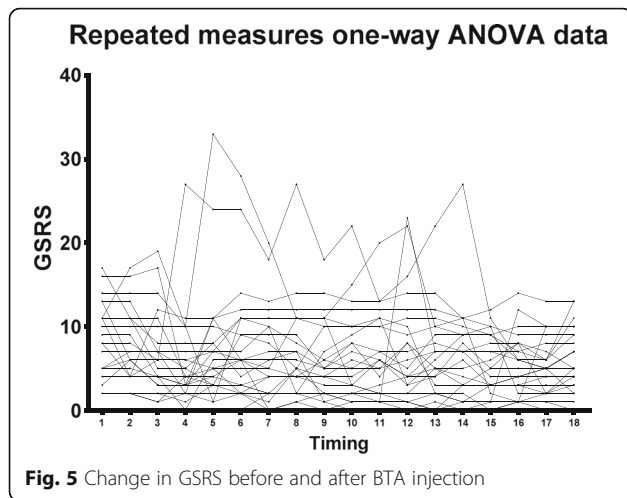
Previous studies verified the effect of antral contractility on the normal gastric emptying of solid food [25]. Decreased gastric antral contractility is associated with delayed and prolonged half-time (T1/2) of gastric emptying, prolonged lag time, and a slower post-lag gastric-emptying stage [26]. BTA decrease contractility through inhibition of cholinergic transmission which is essential for stimulation of contractility of the gastrointestinal

tract [3]. Therapeutic applications of BTA injection in gastrointestinal disorders include achalasia, diffuse esophageal spasm, anal fissure, and anismus, with different doses ranging from 100 to 300 U [27]. Also, it has been reported that symptoms of gastroparesis improve after injection of BTA into the pyloric ring without complications [28].

The available data regarding the use of gastric BTA injection in obese subjects are conflicting. Two randomized trials and most open-label studies showed little or no effect of gastric BTA injections with different doses ranging from 100 to 300 U [6, 7, 9, 10, 29]. However,



**Fig. 4** Change in BMI before and after injection (1 and 2 weeks before injection and 3–18 weeks after injection) ( $p < 0.001$ ).



another randomized controlled trial showed decrease in maximal gastric capacity, delayed gastric emptying, increased satiety, and increased weight reduction in comparison to saline control [12]. A large meta-analysis that included 8 studies and a total of 115 patients showed that weight reduction was achieved with wide areas of injections (fundus or body rather than antrum alone) and with multiple injections (10 injections) rather than higher doses of BTA [30]. Possible explanation for these conflicting results includes not only the dose of BTA but also the injection depth into the gastric wall, as none of these studies have confirmed that injections were done into subserosa or muscularis propria.

The first published study that used EUS guidance, to assure BTA injection into the subserosal layer or muscularis propria of the gastric wall, showed similar reduction in mean body weight in subjects injected with 100 or 300 U BTA (5 versus 4.8 kg, respectively) [13]. Another study that evaluated the efficacy of EUS-guided BTA injection in super obese patients as a bridge for surgery showed no significant weight reduction of EUS-guided injection in comparison to the control group [31]. In our practice, targeting the antral subserosa or muscularis propria under EUS guidance was technically challenging as the EUS needle either stopover in the submucosal layer or pass through the muscularis propria and serosa outside the gastric wall. This difficulty of delivering BTA to the subserosa or muscularis propria may explain the variable data in the literature.

In our study, EUS-guided BTA injection into the subserosa and muscularis propria of the antral wall resulted in increased satiety. Probable explanations for increased satiety include reduced antral capacity, delayed gastric emptying, BTA-induced inflammation, modification of secretion of some gastric hormones (as gastrin and ghrelin), or a placebo effect. We also noticed that

the reduction of the body weight continued gradually through the 16-week follow-up period, which is more than the supposed duration of action of BTA on skeletal muscle [32]. Probable mechanisms explaining this extended effect may include relative prolonged effect on gastrointestinal smooth muscle compared to its effect on skeletal muscle, BTA-induced inflammation, persistence of the behavioral effect after resolution of the BTA pharmacological effect, or a placebo effect. Further studies are required to confirm these explanations.

Studies that evaluated the efficacy of BIB placement for obese patients showed short-term weight reduction ranging from 14 to 18 kg in 6 months, and non-significant weight reduction in about 20 to 40% of patients [33]. Nevertheless, BIB placement as a bridge for surgery was associated with lower intraoperative complications [34]. Patients with significant weight reduction showed a lower incidence of metabolic syndrome, reduced insulin resistance and hemoglobin A1c levels, and improvement in obstructive sleep apnea and hepatic steatosis [35–40]. However, many complications of BIB were reported in a meta-analysis including nausea and vomiting in the first week of placement, esophagitis (1.27%), gastric outlet obstruction (0.76%), balloon leak or rupture (0.36%), gastric perforation (0.21%), peptic ulcer (0.2%), and death (0.07%) [41]. Other reported complications of BIB include perforation of the esophagus [42], small intestinal obstruction requiring surgical intervention [43–45], and cardiac arrest after BIB insertion, which was explained by vagal nerve stimulation secondary to gastric wall stretching [46].

When compared to BIB, EUS-guided BTA injection in our study showed short-term weight reduction of 11.92 kg which is comparable to that reported for BIB placement (14–18 kg). For obese patients refusing surgery or when used as a bridge for surgery, EUS-guided BTA injection showed potential advantages. First, no nausea or vomiting was reported in any subject, which are common complications for BIB placement. Second, there is no need for another endoscopic procedure compared to endoscopic BIB removal after 6 months. Finally, this technique can be done in patients with large hiatus hernia, which is a contraindication for BIB insertion.

The strength of this study is the use of EUS as a standardized injection method for the precise targeting of gastric muscularis propria not the conventional upper endoscopic approach. Despite this strength, there are some limitations. First, the number of subjects enrolled in the study was relatively small. Second, the long-term follow-up was not included in our study. Third, there is lack of control group. Finally, there are no standards about the best injection needle gauge or the preferred distance between injection points.

## Conclusion

EUS-guided BTA injection into the antral subserosa and muscularis propria could be an effective technique for weight reduction, or as a bridge for surgery, which can be done safely with minimal complications. Larger studies with longer follow-up duration are required to confirm these findings.

## Abbreviations

BIB: Bioenteric Intragastic Balloon; BTA: Botulinum toxin type A; EUS: Endoscopic ultrasound; BMI: Body mass index; MTV: Maximum tolerated volume; VAS: Visual analog scale; GI: Gastrointestinal; GSRS: Gastrointestinal Symptom Rating Scale; EGD: Esophagogastroduodenoscopy; SD: Standard deviation

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None

## Authors' contributions

AG made substantial contributions to the design of the work, analysis, and interpretation of the data. MB, SS, and MH made substantial contributions to the design of the work, supervising the work, and in doing the statistical analysis of the data. MA had major contribution in revising the work. AA is the corresponding author, has a major role in collecting the data and the endoscopic procedure of the patients in the study, and had a major role in writing the manuscript. All authors have read and approved the final manuscript.

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## Availability of data and materials

The data used and/or analyzed during the current study are available from the corresponding author on reasonable request

## Ethics approval and consent to participate

The study protocol was approved by the Ethics Review Board of Faculty of Medicine, Mansoura University, and informed written consent was obtained from all participants according to the Declaration of Helsinki. The committee's reference number is MD/17.08.92

## Consent for publication

Not applicable

## Competing interests

The authors declare that they have no competing interests.

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