



# Effect of Consecutive Intra-gastric Balloon (BIB®) Plus Diet Versus Single BIB® Plus Diet on Eating Disorders Not Otherwise Specified (EDNOS) in Obese Patients

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## Abstract

**Background** Eating disorders are a group of conditions characterised by abnormal eating habits. Greater than 50 % of patients with eating disorders have an ‘eating disorder not otherwise specified’ (EDNOS). No specific tools exist to evaluate EDNOS, and patients are identified only with a diagnosis of exclusion from the other eating disorders. The BioEnterics® Intra-gastric Balloon (BIB®) is used worldwide as a short-term treatment option in obese patients. A new frequency score was used to evaluate the influence of double consecutive BIB® treatment compared with single BIB® treatment followed by diet on four categories of EDNOS (grazing, emotional eating, sweet-eating and after-dinner grazing).

**Methods** A prospective study allocated 50 obese patients (age range 25–35, BMI range 40.0–44.9) into two groups: BIB® (6 months) followed by diet therapy (7 months; group

A ( $N=25$ )) and BIB® placement for 6 months followed by another BIB® for 6 months, with a 1-month interval between placement (group B ( $N=25$ )). Baseline demographics were similar across both groups.

**Results** At the time of removal of the first BIB® device, EDNOS scores in both groups were not significantly different, but decreased significantly from baseline. By the end of the study, all EDNOS scores were significantly lower in patients undergoing consecutive BIB®, compared with single BIB® followed by diet therapy.

**Conclusions** The placement of an intra-gastric balloon in obese patients allows for a reduction in the intensity of grazing, emotional eating, sweet-eating and after-dinner grazing. A more significant reduction in the EDNOS score was observed with two consecutive BIBs®.

**Keywords** Intra-gastric balloon · BIB® · Eating disorder · EDNOS · Diet · Grazing · Emotional eating · Sweet-eating

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## Introduction

The World Health Organization’s latest projections indicate that approximately 2.3 billion adults will be overweight and more than 700 million will be obese by 2015 [1]. Obesity is a multifactorial condition in which several elements act synergistically, such as sociocultural, familial factors and particularly psychological aspects, such as affectivity and personality. The psychological aspect plays an important role in the treatment of obesity [2], especially for patient lifestyle and the grade of satisfaction associated with their body shape [3].

The term ‘eating disorders’ refers to a group of conditions characterised by abnormal eating habits that may involve either insufficient or excessive food intake and compensatory

behaviour (restrictive or purging) [4]. In the Diagnostic and Statistical Manual of Mental Disorders-Text Revision (DSM-IV-TR), there are three principal categories of eating disorders: anorexia nervosa, bulimia nervosa and eating disorders not otherwise specified (EDNOS) [5]. Anorexia and bulimia have received particular interest from researchers and their prevalence, aetiology, clinical features, diagnosis and treatment are well established. Despite an incidence greater than 50 % in patients with eating disorders [6], EDNOS has received less empirical attention than anorexia or bulimia, which has led to limited knowledge about its prevalence and clinical characteristics; moreover, a specific diagnosis for EDNOS is yet to be determined. Furthermore, accurate diagnosis is often difficult to achieve as patients often present with a mixture of different EDNOS. There has been considerable controversy over the diagnostic criteria used for eating behaviour diagnosis, particularly in different editions of the DSM, including the latest edition (DSM-V), which will be completed in May 2013 [7–9]. Preparation of the fifth DSM edition has led to a re-evaluation of the significance of the current classification system, with specific consideration of the EDNOS category. At the present time, the diagnosis of EDNOS is simply a diagnosis of exclusion of other eating disorders. DSM-V defines the preliminary research criteria for only one type of EDNOS [binge eating disorder (BED)] [10], yet no other criteria for EDNOS are specified.

In clinical practice, eating behaviour before surgery is considered a significant predictive factor for the post-operative course of weight loss or regain [11–13]. However, dimensions of eating behaviour, such as EDNOS and other eating disorders (especially BED), could influence post-operative outcomes and may also be influenced by the procedures performed [14–16].

The BioEnterics® Intra-gastric Balloon (BIB®) is used worldwide as a short-term treatment option in obese patients who refuse or are unsuitable for weight loss surgery [17, 18]. The BIB® can also be used prior to weight loss surgery to reduce obesity-related co-morbidities [18]. When associated with diet therapy, the BIB® is more effective for losing weight and reducing co-morbidities than diet alone [19, 20]. Recently, we reported a prospective randomised study of 100 patients comparing the efficacy of BIB® followed by diet versus BIB® followed by another BIB®, and demonstrated that 1-year treatment (two consecutive balloons) was more effective than a single treatment (6 months) as it allows patients to continue to lose weight and achieve better final results [20]. However, the influence of the BIB® on eating disorders, in particular on EDNOS, has been not yet been evaluated. Additionally, the influence of 1 year's treatment with the BIB® device is also unknown. The aim of this study is to evaluate the influence of double consecutive BIB® treatment versus single BIB® treatment followed by dietary interventions on EDNOS.

## Methods and Procedures

From June 2009 to June 2010, a homogeneous group of 50 obese patients were enrolled and randomly allocated to two different groups: group A ( $N=25$ ) patients underwent BIB® placement (6 months) followed by dietary intervention (7 months) and group B ( $N=25$ ) patients underwent BIB® placement (6 months) followed by another BIB® (6 months), with a 1-month interval between placement.

All patients signed a specific informed consent. The study was approved by the local ethical committee. Baseline demographics were similar in both groups (group A 15 M/35 F, mean age  $31.0\pm 2.9$ , mean weight  $105.7\pm 15.6$  kg, mean BMI  $41.2\pm 2.1$  kg/m<sup>2</sup>; group B 13 M/37 F, mean age  $32.9\pm 3.0$ , mean weight  $106.3\pm 13.9$ , mean BMI  $42.8\pm 2.6$ ).

All patients had a diagnosis of EDNOS. The diagnosis of another eating disorder or Axis I Disorder was excluded following the diagnostic criteria of DSM-IV-TR, using the Structured Clinical Interview for DSM-IV Axis I Disorder [21]. As BED is at present the only eating behaviour with specific diagnostic criteria, BED patients were excluded from the study. Four dimensions of eating behaviour, defined as 'inappropriate eating habits', were investigated and evaluated by a structured obesity diagnostic interview specifically designed by an expert psychologist for this purpose and performed by the same. The psychologist was blinded to the patients' treatment. The inappropriate eating habits investigated were defined as follows:

1. 'Grazing', patients who tend to consume small amounts of food frequently throughout the day and outside of the five main meals (breakfast, mid-morning snack, lunch, afternoon snack, dinner);
2. 'Emotional eating', patients who eat in response to emotional arousal states, such as fear, anger, anxiety, etc.;
3. 'Sweet-eating', patients who prefer to consume hypercaloric sweets, either in solid or liquid form, such as sweets, soft drinks, etc.;
4. 'After-dinner grazing', patients who graze after dinner (but not during the night).

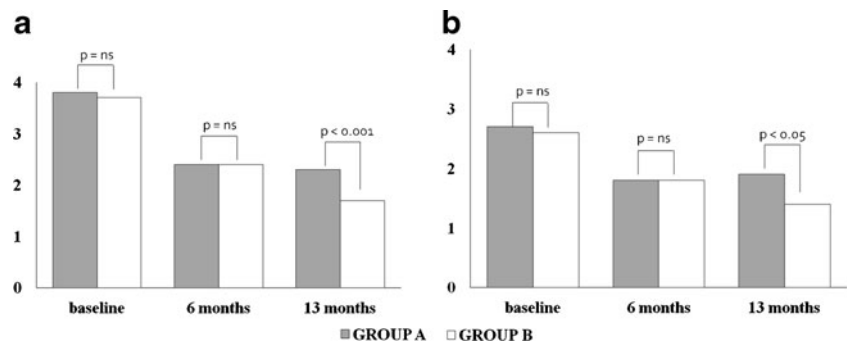
In both patient groups, the evaluations were performed before BIB® placement (baseline), after BIB® removal (6 months) and at 13 months.

Statistical analysis was performed using the STATA 7.0 Package, by means of Student's *t* test for numerical variables and  $\chi^2$  test or Fisher's exact test for categorical variables;  $p<0.05$  was considered significant.

### Structured Obesity Diagnostic Interview

The psychodiagnostic interview included obtaining clinical data through personal interviews, medical history, past and present personal and family psychological/psychiatric

**Fig. 1** Results on grazing (a) and emotional eating (b) scores at baseline, 6 and 13 months in group A (single balloon treatment) and group B (double balloon treatment). The results are expressed as mean score based on the frequency of the improper eating behaviour scale



anamnesis, personal and family history of the patient with particular reference to the onset of obesity, history of eating habits, diet attempts, evaluation of the current food habits and preferences, motivation, weight loss and change of any abnormal eating behaviours. The purpose of the interview was to exclude the presence of major psychiatric disease and identify improper eating behaviours. For the detection and evaluation of improper eating behaviours (grazing, emotional eating, sweet-eating, after-dinner grazing), a direct clinical interview and food diary were used. In particular, the patient was asked to quantify the frequency of the improper eating behaviour over the previous 3 months, expressed as the number of days during a week, using a scoring scale: ‘never’ = 0 (0/week), ‘sometimes’ = 1 (1–2/week), ‘often’ = 2 (3–4/week), ‘very often’ = 3 (5–6/week), ‘always’ = 4 (7/week).

The qualitative overeating (relative to the type of food, drinks and condiments chosen) and quantitative overeating (relative to the amount of food eaten) were not taken into account. Overeating is present in all obese patients and regulated by the presence of the BIB® and subsequent diet therapy prescribed in the post-placement period.

**BIB Placement and Removal**

All BIB® devices (Allergan, Irvine, CA, USA) were placed and removed under unconscious sedation (propofol 2 mg/kg i.v.) [22]. Placement of the device was preceded by diagnostic endoscopy to exclude possible gastric or duodenal lesions. The BIB®

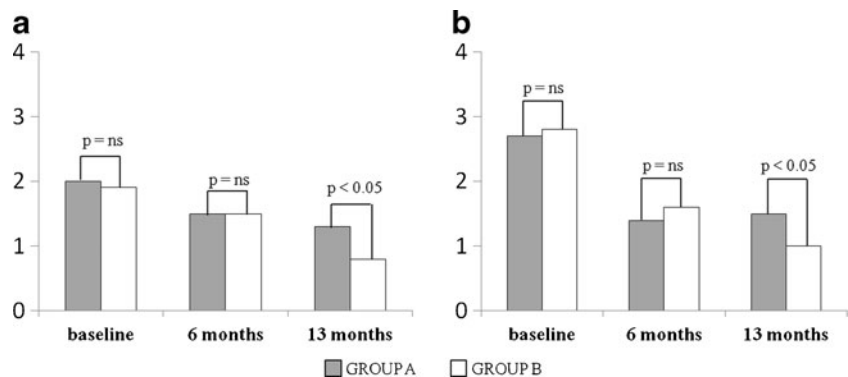
was inserted below the gastro-oesophageal junction and filled via the catheter with 500 ml of saline and 10 ml of methylene blue. A clinical examination was performed 7 days after BIB® placement in all patients. Blood tests and clinical examinations were performed every 30 days for 6 months. After placement, patients from both groups received same diet instructions with same caloric intake. After 6 months, the BIB® was removed by endoscopy following complete deflation. Due to the delayed gastric emptying achieved with the balloon, the removal procedure was preceded by a 72-h diet without roughage and by a 24-h semi-liquid diet (yoghurt, mashed potatoes, puréed vegetables).

**Results**

At the end of the first treatment (6 months), mean BMI was 32.8±2.8 kg/m<sup>2</sup> in group A and 34.7±3.0 kg/m<sup>2</sup> in group B (*p*=n.s.): BMI was reduced by 8.4 and 8.1 kg/m<sup>2</sup> in patients from group A and group B, respectively. At the end of the study (13 months), the mean BMI was 35.1±8.6 kg/m<sup>2</sup> in group A and 30.9±6.5 kg/m<sup>2</sup> in group B (*p*<0.005): BMI was reduced by 7.5 and 11.9 kg/m<sup>2</sup> from baseline in patients from group A (single BIB treatment) and group B (double balloon treatment), respectively. No major complications were observed in either treatment group.

No significant differences in eating behaviour were present between patient groups at baseline (*p*=n.s.). The mean baseline grazing scores were 3.8 and 3.7 for group A and group B, respectively; at 6 months, the mean grazing scores

**Fig. 2** Results on sweet-eating (a) and after dinner grazing (b) scores at baseline, 6 and 13 months in group A and group B



were 2.4 for both patient groups. At 13 months, grazing score frequency was significantly higher in group A compared with group B patients ( $p < 0.001$ ).

No significant differences in emotional eating score were observed at the 6-month time point, with a decrease of 1.8 from baseline in both groups. At month 13, both patient groups showed score reductions from baseline; group B demonstrated a significant reduction in emotional eating score compared with group A ( $p < 0.05$ ) (Fig. 1).

At the end of the study, scores for both sweet-eating and after-dinner grazing were significantly reduced in patients who underwent consecutive BIB® (group B), compared with single BIB® treatment followed by diet (group A) (Fig. 2, Table 1).

## Conclusion

A recent study demonstrated that EDNOS is the most common eating disorder in both adolescents and adults, representing 80.97 and 75.38 % of those with an eating disorder, respectively. It is important to note that, as EDNOS is a residual ‘umbrella classification’ for all cases that do not meet criteria for threshold eating disorders, there is the risk that such cases are perceived as less severe. However, alarmingly high numbers of adolescents and adults with EDNOS also meet criteria for co-morbid psychopathologies, such as anxiety and mood disorders. More than two thirds of both adolescent (74 %) and adult (71 %) EDNOS cases present with a co-morbid DSM-IV diagnosis [23]. The influence of EDNOS on the outcome of bariatric surgery is not yet established, but the presence of binge eating status is considered a significant predictive factor for the post-operative course of body weight [11, 13] after gastric restrictive surgery.

To our knowledge, there is only one study investigating the effects of treatment with the BIB® in patients presenting with BED [24], which demonstrated that BIB® treatment achieves significant weight loss in obese patients identified as either binge eaters (BE) or non-binge eaters (NBE). However, the degree of BMI reduction in the BE patients was significantly less than with NBE patients. Moreover, the rate of complications and failure in the BE group was statistically higher than in the NBE group, suggesting that the presence of binge eating behaviour is a negative predictive factor for treatment success. In our study, the use of the intragastric balloon for the treatment of morbid obesity demonstrated significant weight loss in both groups, with an additional positive influence on the frequency of the EDNOS. At 6 months, both patient groups demonstrated a lower EDNOS score compared with baseline levels; at 13 months, patients in the multiple treatment arm (group B) showed significant reductions in the frequency of all specific eating disorders, compared with single BIB® treatment followed by diet (group A). The results of the 1-year BIB treatment were recently reported [24]. Our study demonstrates that 1-year treatment (two consecutive balloons) is

**Table 1** Results on the eating behaviours in group A (BIB + Diet) and group B (BIB + BIB) at baseline, 6 months and 13 months on the entire (100 %) population evaluated. The mean score relates to a specific frequency of the improper eating behaviour over the previous 3 months, expressed as the number of days during a week, using a scoring scale: ‘never’ = 0 (0/week), ‘sometimes’ = 1 (1–2/week), ‘often’ = 2 (3–4/week), ‘very often’ = 3 (5–6/week), ‘always’ = 4 (7/week). The results are expressed as mean score as well as percentage differences from baseline

	Grazing		Emotional eating		Sweet-eating		After dinner grazing		<i>p</i> value
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B	
Baseline	3.8	3.7	2.7	2.6	2	1.9	2.7	2.8	ns
6 months	2.4 (–37 %)	2.4 (–35.2 %)	1.8 (–33.4)	1.8 (–30.8 %)	1.5 (–25 %)	1.5 (–21 %)	1.4 (–48.2)	1.6 (42.9 %)	ns
13 months	2.3 (–40 %)	1.7 (–54 %)	1.9 (–30 %)	1.4 (–46.2)	1.3 (–35 %)	0.7 (–64 %)	1.5 (–44.5 %)	1 (–64.3 %)	<0.05



more effective than single treatment (6 months). Thus, for patients refusing bariatric surgery but receiving BIB<sup>®</sup> treatment, it is advisable to place a subsequent BIB<sup>®</sup> for continued weight loss and improved eating disorder control, rather than patient management with dietary therapy only.

Some limitations to our study need to be considered. First, the EDNOS category for the present study was not all inclusive. Only four different dimensions of all the possible eating behaviours were investigated. Currently, tools for diagnosing eating disorders are poor and not well established, i.e. we were required to find and utilise a non-validated ‘intensity’ score. This new score was based on patient-reported information only. Therefore, further identification and diagnostic instruments specific for EDNOS are required to better evaluate the correlation between weight loss and eating behaviour. Such developments in EDNOS diagnostics will aid in identifying correct and effective treatments for improving EDNOS severity during weight loss.

It has been postulated, but not yet demonstrated, that some device or surgical operations for weight loss could improve pathological eating behaviour, which once ‘corrected’ could help maintain weight loss. This raises questions regarding whether eating behaviour could affect outcomes or be influenced by the procedures performed. Our study demonstrates that the placement of an intragastric balloon in obese patients allows for a reduction in the intensity of grazing, emotional eating, sweet-eating and after-dinner grazing. Furthermore, two consecutive intragastric balloons over a 12-month period demonstrate significant advantages over a single procedure in terms of influencing EDNOS.

**Conflict of Interest** No conflicts of interest exist for all authors.

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