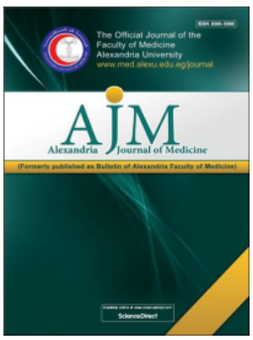

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The impact of intra gastric balloon as a treatment of obesity on pre-diabetes in obese persons

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ABSTRACT

Introduction: Obesity is arising health problem that is linked to many pathological conditions. Treatment of obesity has a beneficial effect on many health problems. Little data available about effect of weight loss on prediabetes.
Object: To evaluate the effect of intra gastric balloon (IGB) as obesity treatment on prediabetes.
Method: In a prospective study we have followed 42 obese prediabetic patients who used IGB as obesity treatment. All patients were evaluated for anthropometric measures, lipid profile, fasting blood glucose (FBG), postprandial blood glucose (PPBG) and glycosylated hemoglobin HbA1c before and 6 months after IGB insertion.
Results: There was a significant reduction in body weight, waist–hip ratio and also body mass index (BMI), as by time of balloon removal mean body weight was 86.62 ± 7.84 Kg, and mean BMI at time of removal was 29.48 ± 2.31 kg/m^2 compared to 99.10 ± 7.34 Kg and 33.61 ± 2.18 Kg/m^2 before balloon insertion ($p < 0.05$). Also, significant improvement of FBG and PPBG with mean value of FBG 93.00 ± 9.12 mg% and mean level of PPBG 133.31 ± 11.68 mg % compared to FBG 110.71 ± 12.10 mg% and PPBG 166.81 ± 18.82 mg% before balloon insertion ($p < 0.05$), likewise there was a significant reduction in HbA1c as its mean value has become 5.48 ± 0.35 compared to 6.01 ± 0.21 before balloon insertion ($p < 0.05$).
Conclusions: six months treatment with IGB for obesity improved the prediabetic condition that may prevent or at least delay type II diabetes mellitus, which needs longer follow-up.

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KEYWORDS
Obesity; gastric balloon; pre-diabetes

1. Introduction

Obesity is a morbid condition that is still major and rising health problem as more than 39% of the adult are obese [1]. Obesity is linked to many pathological conditions including hypertension, diabetes mellitus, cardiovascular diseases, obstructive sleep apnea [2]. Moreover, obesity is linked to all-cause mortality, therefore body mass index (BMI) is considered as an overall mortality predictor. [3]

Harmful effects of obesity are caused by both excess accumulation of fat and mainly by metabolic derangement from excess adipose tissue[4].

Prediabetes is a condition of impaired glucose level; however, it is not a clinical entity but still a risk factor for type II diabetes and for cardiovascular disease, early recognition and treatment of prediabetes can prevent or at least delay type II diabetes [5]. Treatment of obesity can delay the progression from prediabetes to type II diabetes [5,6].

Many modalities are available for treating obesity as lifestyle modification, pharmacological therapy, Intra gastric balloon (IGB) and bariatric surgery [6].

IGB is a simple invasive method to treat obese persons (BMI ≥30 kg/m^2). [6]

Although many studies had demonstrated the beneficial effect of weight loss on metabolic syndrome, still no enough data about the effect of weight loss after IGB on prediabetes, our study is to reveal the impact of IGB induced weight loss on prediabetes.

2. Patients and method

This prospective study was conducted at Tanta University Hospital, Gastroenterology and Endoscopy Unit, from January 2019 up to January 2020. Initially, we recruited 50 obese prediabetic patients as potentially eligible for our study. At the outpatients clinic where patients were evaluated for IGB placement for obesity treatment. Three patients were excluded due to chronic illness (one patient had chronic AF on regular anticoagulant, one patient had chronic renal impairment, one patient had psychosis) also three patients were excluded after diagnostic upper endoscopy (one patient had peptic ulcer disease, two patients had hiatal hernia, severe gastroesophageal reflux disease with severe esophagitis), two patients were excluded after IGB placement as they insisted on balloon removal within the first week due to epigastric pain and vomiting. So only 42 patients were recruited as eligible for our study including 35 males (83.3%) and 7 females (16.7%). Our inclusion criteria were, patients with obesity with BMI ≥ 30 kg/m^2, patients included were willing for weight loss by IGB and written consents were taken, also we included patients

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with prediabetes with FBG between (100 mg% and 125 mg%) or PPBG (140 mg% and 199 mg%) or HbA1c (5.7% and 6.4%). [5]

We excluded patients with secondary causes of obesity (uncontrolled hypothyroidism), patients with chronic disease as chronic liver disease or chronic renal disease, patients with chronic psychiatric illness were excluded, patients who turned out to had chronic peptic ulcer or reflux esophagitis (grade C and D) after diagnostic endoscopy were excluded from the study.

For all patient anthropometric measures including height in meters, weight in kilograms, BMI were calculated (weight divided by height square), also waist circumference was measured (midway between last rib and iliac crest), hip circumference was measured at the widest point of the hip/buttocks area with the measuring tape parallel to the floor and waist–hip ratio was calculated. Laboratory studies were taken including (renal functions, liver functions, thyroid profile, fasting blood glucose (FBG), postprandial blood glucose (PPBG), HbA1c, total cholesterol, triglyceride). All these parameters were taken before and 6 months after IGB insertion.

3. Balloon placement and removal

All patients eligible for balloon insertion underwent diagnostic endoscopy first to exclude local contraindications for IGB, then under deep sedation without endotracheal intubation still under observation of anesthesiologist nonadjustable IGB (BIB® – Orbera®) was inserted below gastro esophageal junction filled with 500 ml of normal saline and 20 ml of methylene blue solution for alerting patients in case of balloon rupture, patients kept under close observation till full recovery, patients followed a fluid diet from the second day after the procedure till the seventh day after when gradual introduction of semisolid food is allowed, after 2-weeks solid food was allowed with a regular low-calorie diet (900–1200 kcal/day). Proton pump inhibitor (esomeprazole 80 mg once daily) was given for the first month and 40 mg once daily after that, double antiemetic (metoclopramide and ondansetron) was given for 1 week, an anti-gaseous drug (simethicone) was also given. Balloon was removed after 6 months with the same procedure of balloon insertion. A prolonged fasting of at least 12 h was needed to avoid the risk of aspiration.

All patients were followed after 6 months for their anthropometric and laboratory parameters, then statistical analysis was done using SPSS 20, IBM, Armonk, NY, United States of America, quantitative data were expressed as mean ± standard deviation, paired *t*-test of significance was used when comparing between two means, Pearson's correlation coefficient (*r*) test was used for correlating data (Significant when *P*-value < 0.05).

Table 1. Demographic data of 42 patients who had intra gastric balloon.

Sex	*N*	%
Male	35	83.3
Female	7	16.7
Total	42	100
	Range	Mean ± S. D
Age	20–50 years	35.74 ± 7.89
Height	160–180 cm	171.43 ± 5.27

4. Results

BMI: body mass index, FBG: fasting blood glucose, PPBG: postprandial blood glucose, HbA1c: glycosylated hemoglobin

The demographic distribution of our patients shown in (Table 1)

Significant reduction in BMI occurred at the time of balloon removal. With the significant improvement of waist–hip ratio as mean waist–hip ratio was 0.66 ± 0.01 before and become 0.58 ± 0.01 after IGB insertion. Also, significant improvement of FBG and PPBG by the time of balloon removal. Furthermore, there was a significant reduction in HbA1c as value become 5.48 ± 0.35 compared to 6.01 ± 0.21 before balloon insertion, significant improvement of lipid profile (total cholesterol and triglyceride) as shown in Table 2.

Significant correlation was found between reduction in body weight and reduction blood glucose

Table 2. Changes in anthropometric and laboratory parameters in individuals treated with intra gastric balloon (*N* = 42).

		Pre			Post			t. test	p. value
Weight	Range	80	–	119	65	–	105	7.528	0.001*
	Mean ± S. D	99.10	±	7.34	86.62	±	7.84		
BMI	Range	30.4	–	40.1	25	–	35.1	8.422	0.001*
	Mean ± S. D	33.61	±	2.18	29.48	±	2.31		
FBG	Range	85	–	130	80	–	125	7.574	0.001*
	Mean ± S. D	110.71	±	12.10	93.00	±	9.12		
PPBG	Range	124	–	200	112	–	180	9.800	0.001*
	Mean ± S. D	166.81	±	18.82	133.31	±	11.68		
HbA1c	Range	5.5	–	6.3	4.69	–	6	8.344	0.001*
	Mean ± S. D	6.01	±	0.21	5.48	±	0.35		
Total Cholesterol	Range	110	–	300	100	–	260	2.547	0.013*
	Mean ± S. D	184.83	±	48.92	160.76	±	36.86		
Triglycerides	Range	78	–	390	70	–	280	2.584	0.012*
	Mean ± S. D	160.55	±	77.98	124.95	±	43.44		
Waist circumference	Mean ± S. D	108.42 ± 1.61			95.09 ± 1.59			4.880	<0.0001*
Hip circumference	Mean ± S. D	120.54 ± 1.08			109.99 ± 1.36			453.5	<0.0001*
Waist–hip ratio	Mean ± S. D	0.66 ± 0.01			0.58 ± 0.01			5.263	<0.0001*

*significant P < .05

Table 3. Correlation between body weight reduction and changes in body mass index BMI, fasting blood glucose FBG, postprandial blood glucose PPBG, glycosylated hemoglobin HbA1c before and after IGB treatment for 6 months.

	Weight Reduction	
	r	*p*
FBG Reduction	0.573	0.001*
PPBG Reduction	0.465	0.001*
HbA1c Reduction	0.424	0.001*

parameters including fasting, postprandial, and glycosylated hemoglobin as showed in (Table 3).

5. Discussion

Obesity is a worldwide health problem with high mortality [4,5]. We should treat obesity not only to improve the lifestyle and wellbeing of patients but also to improve major metabolic disorders that follow obesity [6]. Trying only conventional obesity treatments as (diet therapy, increased physical activity, behavior change and drug therapy) mostly patients will relapse to previous body weight [7]. So many patients will go to mild invasive treatment for obesity as IGB.

In our study, we found significant weight reduction and significant improvement of blood glucose parameters after 6 months of IGB treatment.

Many studies available about the effect of IGB on weight loss and its correlation to metabolic syndrome as Gencu A et al. found that the weight loss induced by the IGB leads to modest improvement in comorbidities associated with obesity [8,11]. Similar conclusions have been drawn by Mui [9,12], and Ricci [10,13]

Still, we thought that more concentration needed about the relation between effect of IGB-induced weight reduction and prediabetes. Our study focused on prediabetic as an important and preventable risk factor, we aimed to study the effect of IGB as treatment of obesity on weight loss and improvement of prediabetic condition, we found a significant reduction in body weight, waist–hip ratio as well as significant reduction in BMI at time of balloon removal, also a significant improvement of FBG and PPBG and glycosylated hemoglobin HbA1c, positive correlation found between weight reduction and improvement on the prediabetes parameters.

In conclusion, our study documented that the IGB is an effective method of obesity treatment for obtaining a body weight loss and improving prediabetic condition in obese persons.

Our recommendation is to carry out a long-term study for further follow-up of the effect of IGB on body weight loss and obesity-related disorders.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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