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Clinical characteristics and therapeutic outcomes of obesity treated by endoscopic intragastric balloon placementi

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Abstract

Objective: *To describe clinical characteristics and evaluate treatment outcomes of obesity using endoscopic intragastric balloon placement.* ***Subject and method:*** *A prospective cross-sectional study was conducted on 86 obese patients who underwent Orbera and Spatz balloon placement from October 2010 to December 2023.* ***Result:*** *The study of 86 obese patients revealed a female predominance (68.6%) and a majority aged <30 years (53.5%), with a mean BMI of 36.0±4.5 kg/m². Following intragastric balloon placement, statistically significant reductions in weight and BMI were observed at all follow-up intervals (p<0.001), with mean weight decreasing from 95.1 kg to 77.3 kg at 6 months and %FWL reaching 47.6±6.1%. Both technical and clinical success rates were 100%. Significant improvements in blood pressure, glucose, and lipid profiles were documented at 6 months (p<0.01).* ***Conclusion:*** *The typical obese patient in this study was female, under 30 years old, with fatigue and anxiety as predominant symptoms. Endoscopic intragastric balloon placement effectively promoted weight loss, improved BMI, and ameliorated metabolic disorders, achieving all therapeutic objectives.*

Keywords: *Obesity, endoscopic intragastric balloon, orbera balloon.*

I. Introduction

Overweight and obesity have become a global pandemic, affecting over 2.1 billion people and imposing serious health consequences and medical burdens [1]. In Vietnam, the combined prevalence of overweight among adults was 20.3% over the past three decades, with a notable upward trend observed between 1998 and 2020 [2]. Intragastric balloon (IGB) placement is an effective endoscopic treatment for obesity, offering significant weight reduction and improvement in associated comorbidities [3]. Studies have reported an average weight loss ranging from 13 to 20.9 kilograms within six months. IGB therapy yields the best results when combined with strict dietary and exercise regimens [4]. While IGB alone often leads to only short-term weight loss, its combination with definitive bariatric surgery may provide more sustainable outcomes [5]. In Vietnam, although several epidemiological studies have been conducted, research focusing on the clinical characteristics and therapeutic outcomes of endoscopic IGB placement remains limited. Obesity not only deteriorates quality of life but is also a major risk factor for chronic conditions such as hypertension, type 2 diabetes, and dyslipidemia. Therefore, we conducted this study titled: “Clinical Characteristics and Treatment

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Outcomes of Obesity Managed by Endoscopic Intragastric Balloon Placement", with the objectives to: (1) Describe the clinical characteristics of obese patients undergoing IGB therapy; and (2) Evaluate the treatment outcomes of obesity using the endoscopic intragastric balloon method.

2. Subjects and methods

2.1. Study Subjects

This study included 86 obese patients who underwent intragastric balloon (IGB) placement with Orbera or Spatz systems between October 2010 and December 2023.

Inclusion criteria:

Age between 18 and 60 years.

BMI ≥ 30 kg/m² with at least one comorbidity such as hypertension, diabetes, hypercholesterolemia, joint pain; or BMI ≥ 35 kg/m².

Patients who previously attempted conventional weight loss methods (diet, physical activity, anti-obesity medications) without success and who consented to undergo endoscopic IGB placement.

Exclusion criteria:

History of abdominal surgery, esophageal diverticula, or large hiatal hernia.

Alcohol or drug addiction, chronic use of medications such as corticosteroids or NSAIDs.

Congenital gastrointestinal strictures.

Comorbid conditions such as heart failure, liver cirrhosis, renal failure, or psychiatric disorders.

Pregnant or breastfeeding women.

Contraindications to upper gastrointestinal endoscopy.

Patient refusal to participate in the study.

2.2. Study methods

Study design:

A cross-sectional descriptive study with longitudinal follow-up before and after treatment.

Sampling method:

A convenient sampling approach was used. All patients diagnosed with obesity who underwent Orbera or Spatz balloon placement between October 2010 and December 2023 and met the inclusion and exclusion criteria were recruited. A total of 86 patients were included in the analysis.

Endoscopic balloon placement procedure: The esophagogastroduodenoscopy was performed according to the Ministry of Health (2013) guidelines for upper gastrointestinal endoscopy. Under endoscopic guidance, the balloon was inserted through the mouth into the esophagus and into the stomach. Once the balloon was confirmed to be fully positioned in the stomach, it was inflated with 0.9% NaCl solution. After injecting 200-300ml, 5-10ml of methylene blue was added, and inflation continued with NaCl until a total volume of 550ml was reached. Balloon integrity was checked by observing any leakage (presence of methylene blue on the gastric mucosa). If no leakage was observed, the catheter was detached, and the valve was sealed to complete the procedure.

Study variables:

General variables: Age, sex.

Clinical variables: Clinical signs, height, weight, BMI.

Outcome measures:

Technical success and clinical effectiveness were evaluated using changes in weight, BMI, and percentage of excess weight loss (%EWL) at 1 week, 3 months, 6 months, and 12 months (for Spatz balloons).

Data analysis:

Data were analyzed using SPSS version 22.0. Quantitative variables were expressed as mean ± standard deviation. Qualitative variables were expressed as percentages. Paired t-tests were used to assess differences between two means. A p-value of < 0.05 was considered statistically significant.

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III. Results

3.1. Clinical Characteristics of the Study Subjects

Table 1. Age and Gender Distribution in Obese Patients (n = 86)

Characteristic		Number (n)	Percentage (%)
Gender	Male	27	31,4
	Female	59	68,6
Age group	< 30 years	46	53,5
	30-49 years	37	43,0
	≥ 50 years	3	3,5
Mean age (years)		31,2 ± 8,7	

Comment: The table shows that the majority of obese patients were female (68.6%). The highest proportion of patients was under the age of 30 (53.5%). The overall mean age was 31.2 ± 8.7 years.

Table 2. Clinical Symptoms and BMI Indicators in Obese Patients (n = 86)

Characteristic		Number (n)	Percentage (%)
Clinical Symptoms	Sleep disturbances, increased appetite	42	48,8
	Joint pain and stiffness	25	29,1
	Fatigue, anxiety	78	90,7
	Irregular menstruation (n = 59 females)	9	15,3
	Lower back pain	22	25,6
	Limited mobility	16	18,6
BMI and Anthropometric Data	BMI Class I (30–34.9 kg/m²)	49	57,0
	BMI Class II (35–39.9 kg/m²)	21	24,4
	BMI Class III (≥ 40 kg/m²)	16	18,6
	Mean BMI (kg/m²)	36,0 ± 4,5 kg/m² (30,2 - 49,1)	
	Mean weight (kg)	95,1 ± 18,6	
	Mean height (cm)	163,5 ± 7,8	

Comment: The most common clinical symptoms among obese patients were fatigue and anxiety (90.7%), followed by sleep disturbances and increased appetite (48.8%), joint pain (29.1%), lower back pain (25.6%), and limited mobility (18.6%). Among female patients (n = 59), 15.3% reported irregular menstruation.Anthropometric measurements showed an average body weight of 95.1 ± 18.6 kg and an average height of 163.5 ± 7.8 cm. BMI distribution was as follows: Class I obesity: 57.0%, Class II: 24.4%, Class III: 18.6% with a mean BMI of 36.0 ± 4.5 kg/m² (range: 30.2–49.1 kg/m²).

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3.2. Treatment Outcomes

The study demonstrated a 100% technical and clinical success rate for endoscopic intragastric balloon (IGB) placement.

Table 3. Clinical Outcomes After Intragastric Balloon Placement

Outcome Measure	Before Intervention	Post-intervention				p
		1 Week	1 Month	3 Months	6 Months	
Weight (kg)	95,1 ± 18,6	90,1 ± 18,2	86,8 ± 17,9	81,6 ± 17,8	77,3 ± 17,9	p_{2-1}<0,001 p_{3-1}<0,001 p_{4-1}<0,001 p_{5-1}<0,001
BMI (kg/m²)	36,0 ± 4,5	34,2 ± 4,6	32,9 ± 4,5	30,8 ± 4,5	29,2 ± 4,7	p_{2-1}<0,001 p_{3-1}<0,001 p_{4-1}<0,001 p_{5-1}<0,001
%FWL	0	13,5 ± 3,2	22,8 ± 4,1	36,2 ± 5,3	47,6 ± 6,1	p_{2-1}<0,001 p_{3-1}<0,001 p_{4-1}<0,001 p_{5-1}<0,001

Comment: The results show a significant and progressive reduction in mean body weight from 95.1 ± 18.6 kg at baseline to 77.3 ± 17.9 kg at 6 months post-intervention. Correspondingly, BMI decreased from 36.0 ± 4.5 to 29.2 ± 4.7 kg/m². The percentage of excess weight loss (%FWL) steadily increased from 13.5 ± 3.2% at 1 week to 47.6 ± 6.1% at 6 months. All differences were statistically significant compared to baseline ($p < 0.001$).

Table 4. Improvement in Comorbid Conditions After 6 Months of Intervention (n = 86)

Parameter	Before Intervention	6 Months Post-Intervention	p-value
Systolic Blood Pressure (mmHg)	134,5 ± 18,7	122,1 ± 10,8	<0,01
Diastolic Blood Pressure (mmHg)	83,6 ± 9,5	78,2 ± 5,1	<0,01
Blood Glucose (mg/dL)	99,2 ± 10,3	88,7 ± 7,5	<0,01
Total Cholesterol (mg/dL)	242,3 ± 42,1	190,5 ± 25,4	<0,01
Triglycerides (mg/dL)	168,3 ± 50,2	125,4 ± 30,1	<0,01

Comment: After 6 months of intervention, all measured comorbid parameters showed statistically significant improvements ($p<0.01$). Systolic blood pressure decreased from 134.5 ± 18.7mmHg to 122.1 ± 10.8mmHg, and diastolic pressure from 83.6 ± 9.5mmHg to 78.2 ± 5.1mmHg. Blood glucose dropped from 99.2 ± 10.3mg/dL to 88.7 ± 7.5mg/dL. Lipid profile improved significantly as well, with total cholesterol decreasing from 242.3 ± 42.1mg/dL to 190.5 ± 25.4mg/dL, and triglycerides from 168.3 ± 50.2mg/dL to 125.4 ± 30.1mg/dL.

IV. Discussion

A study conducted on 86 obese patients (68.6% female; mean age 31.2 ± 8.7 years)

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demonstrated that endoscopic intragastric balloon (IGB) therapy is highly effective, aligning with international findings, though with distinct epidemiological characteristics. The predominance of female patients (female-to-male ratio of 2.2:1) and the younger age distribution (53.5% under 30 years old) differ from Ashrafian's study (mean age 44.5 ± 11.3 years) [5], reflecting the unique obesity profile in Vietnam, as also reported by Tran Thai Phuc (overweight prevalence increased to 20.3% between 1998 and 2020) [2].

Clinically, 90.7% of patients reported fatigue and anxiety, which is higher than in Argonz's study where depression was the predominant psychological symptom [6], suggesting cultural differences in symptom expression. The majority of patients had Class I obesity (57.0%, with a mean BMI of 36.0 ± 4.5kg/m²), indicating earlier intervention compared to studies targeting super-obese populations (e.g., BMI 57.3 ± 9.7kg/m² in Ashrafian's cohort) [5].

The technical success rate was 100%, exceeding the 92-98% reported by Kim [3], likely attributable to operator expertise. Mean weight decreased from 95.1 ± 18.6kg to 77.3 ± 17.9 kg over 6 months, corresponding to a 47.6 ± 6.1% fat weight loss (FWL) greater than Argonz's post-balloon removal range (14-27.2% FWL) [6] but slightly lower than the 52.8% FWL seen in Ashrafian's balloon-plus-surgery group [5].

Metabolic improvement was consistent with global findings: systolic blood pressure dropped from 134.5 ± 18.7mmHg to 122.1 ± 10.8mmHg, similar to results from the REDUCE trial [6]; improvements in glycemic and lipid profiles exceeded those reported by Kim [3]. All changes were statistically significant ($p<0.01$). Notably, the BMI reduction over 6 months (from 36.0 ± 4.5 to 29.2 ± 4.7kg/m²) surpassed the 3.8kg/m² reduction observed over 60 months in Ashrafian's balloon-only group [5], indicating greater effectiveness in Class I–II obese patients.

The complication rate of 18.1%, while lower than mortality rates seen in more invasive procedures (e.g., 1.4% in Ashrafian's study) [5], underscores the importance of appropriate patient selection. These results are also consistent with a study of 51 patients (35 of whom completed follow-up), in which the average weight loss was 11.94kg (42.16% excess weight loss, EWL) after 6 months of balloon therapy, with maintenance of an 8.25kg loss (30.27% EWL) 6-12 months post-removal. Importantly, 54.3% of patients achieved ≥ 10% initial body weight loss upon balloon removal, and 41.4% sustained this at 6-12 months, reaffirming the IGB's role as an effective intermediate option between lifestyle changes and bariatric surgery [7].

V. Conclusion

Endoscopic intragastric balloon (IGB) placement is a safe and effective treatment for obesity, particularly in patients who have not responded to lifestyle modifications and pharmacotherapy. This method can serve either as a temporary solution or as a bridging strategy prior to bariatric surgery. Weight loss outcomes depend on the type of balloon used and the inflated volume. Overall, IGB therapy represents a valuable option in the comprehensive management of obesity.

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