



Analysis of Long-Term Weight Regain in Obese Patients Treated with Intra-gastric Balloon

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Abstract

Background and Aims: Obesity is a global disease and its management includes pharmacological therapy, surgery and Intra-gastric Balloon (IGB). IGB has gained popularity recently, however, studies addressing long-term weight loss IGB are scarce in the current literature. This study aimed to assess the weight regain in a large cohort of patients treated with IGB. The objective is to communicate the results based on our experience with the percutaneous treatment of this complication.

Methods: Patients treated with IGB for a six-month, who underwent balloon removal at least two years before the collection of data, were invited to participate in the study. Patients were interviewed and medical records were analyzed, after were stratified based in length of follow-up after IGB removal on date of interview (2, 3 and 4 years).

Results: During the use of IGB patients lost a mean of 66% of excess weight. Between 2 and 4 years after removal of IGB 67% of the subjects had regained weight. The correlation between the BMI scores and the weight regain was inversely ($r = -0.20$) and significant ($p < 0.01$).

Conclusion: The percentage of weight regained after treatment for obesity with IGB is high but within the standards described in the literature.

Keywords: Intra-gastric Balloon; Weight Gain; Obesity; Endoscopy

Introduction

Obesity is a recurrent, epidemic and growing health problem, and its management remains a challenge. Obesity can traditionally be treated through different combination of programs involving diet control, exercises, behavioral and psychological counseling, in addition to appetite-control drugs. However, therapeutic failure of these measures are high, and even initially successful cases still show that weight maintenance over a long-term period frequently fails [1-3].

Recently, the intra-gastric balloon (IGB) has become a popular alternative to manage obese patients, because it is a relatively safe and minimally invasive endoscopic method that has been recognized by the National Institutes of Health (NIH) [4] and FDA as an option to manage obese individuals potentially reducing mortality [5]. In Brazil, the IGB is indicated for patients with BMI equal or greater than 27 kg/m.

Many studies [1,4-8] show successful weight loss after the use of IGB for approximately 6 months. However, no studies have reported long-term follow-up concerning weight regain among these patients after removal of the IGB. This study aimed to assess the long-term weight regain in a large cohort of patients treated with

IGB, with a time span from two to five years after the removal of the device.

Methods

Ethical aspects and delineation

This study was approved by the Ethical and Research Committee (Brazilian equivalent to an Internal Review Board) of Federal University of Minas Gerais (CAE number 42995915.4.0000.5132), as part of the postgraduate program in Adult Health Sciences. All eligible participants signed the consent form.

The subjects were selected from a population treated at a private obese outpatient medical center. All patients were contacted by phone and invited to participate in the study. The inclusion criteria in the study were: use of IGB for at least 5 months, no bariatric surgical procedure after removal of the IGB and no history of pregnancy after IGB removal.

We analyzed the medical data recorded during the whole follow-up period, as well as a semi-structured interview was personally obtained by trained professionals for physical anamnesis and qualitative evaluation of the treatment. A total of 219 patients were recruited and divided into groups according to post-discharge follow-up time, 2 years ($n = 28$), 3 years ($n = 114$) and 4 years ($n = 77$).

Concepts and procedures

In the study, the term “comorbidities” was defined as presence of metabolic or respiratory diseases. The term “diagnosis of a disease” refers to any disease related to obesity. The term “undergone a surgery” refers to any kind of surgery, except bariatric ones. The term “sedentary” refers to patients who did not practice any kind of physical activity on any day of the week. The term “use of medicines” refers to patients who made use of medication to control chronic diseases such as diabetes and arterial hypertension.

Statistical analysis

Data were analyzed using Stata statistical package (version 13.0). Comparisons of explicative variables concerning the positive or negative group of weight regain were performed by using the chi-squared test for qualitative variables and the Student t test for quantitative variables. All associations were considered significant at $p \leq 0.05$.

Results

It is a predominantly female sample (81.2%), of young adults (mean age: 37.29 ± 9.07 years), with no significant difference between the mean age according to the annalistic groups ($p=0.56$). During the use of IGB, patients lost an average of 15% of their total body weight; representing a mean of 66% of excess weight loss (the mean weight loss during treatment was 15.3 ± 6.9 kg). Between 2 and 4 years after removal of IGB, 67% of the subjects had regained weight (2 years: 4.66 ± 4.91 kg; 3 years: 8.66 ± 6.97 ; 4 years: 9.99 ± 8.44). Most patients (62%) regained 10% to 19% of total weight loss during treatment (Table 1).

% weight regain	Follow up		
	2 years	3 years	4 years
<10%	20	15,6	18,5
Between 10 e 19%	70	62,7	59,3
Between 20 e 29%	10	14,5	14,8
Between 30 e 39%		2,4	1,9
Between 40 e 49%		1,2	5,6
Between 50 e 59%		2,4	
Between 90 e 99%		1,23	

Table 1: Total weight loss during treatment.

A higher percentage of individuals with a weight regain was observed for those who started BMI <30 kg/m² when compared to BMI scores (BMI <30 kg/m: 71.4%; 30 – 40kg/m: 67.1%; 40 – 50 kg/m: 62.9%; > 50 kg/m: 50%), but with no difference in follow-up times. The correlation between the BMI scores and the weight regain was inversely ($r = -0.20$) and significant ($p < 0.01$) (Figure 1-A). The correlation was stronger and more significant with patients with a 2year follow-up ($r = -0.59$, $p < 0.01$) (Figure 1-B) followed by the 4-year follow-up sample ($r = 0.23$; $p = 0.03$) (Figure 9-C). For the 3-year follow-up group, the correlation was weak and nonsignificant ($r = -0.06$, $p = 0.53$) (Figure 9-D).

Discussion

To our knowledge, this study is the largest population of patients treated with IGB aiming to investigate long-term efficacy of this device in overweight and obese patients.

Studies about long-term weight regain in patients who underwent an IGB procedure are still limited in the literature [1,4-7,9,10], many studies report on the failure of isolated treatments such as diet, physical exercise and bariatric surgery or even a combination of these interventions [3,11-13]. Those procedures are efficient for weight loss during treatment, but weight regain is prevalent after all these interventions. IGB also can result in a transitory effect if the patient is not involved in re-education about diet and life style modifications. It is important to emphasize that permanent medical care should not be restricted to the period of IGB use, and that treatment must provide conditions for patients to lose weight, receive re-education about their diet habits and improve their health status so that, after IGB removal, the patients be prepared to benefit and maintain the weight reached.

The peak increase in weight regain occurred within 2 years after treatment; it practically doubled in the third year and stabilized in the subsequent year. This fact shows that the first 2 years are of paramount importance to avoid weight regain. One possible explanation is the social environment acquired after treatment. Weight loss gives back to patients a social environment that favors an increased caloric consumption.

It is important to note that weight regain in 53% of the sample of the study remained between 10% and 20% of the percentage of weight lost during treatment. Less than 1% of the sample regained all the weight lost, and no patients had weight regain greater than the weight lost during treatment. Also add the fact that although 66% of the total sample had some weight regain, this regrowth was 30% of the weight lost during the treatment, showing a promising long-term result. In studies describing long-term results of patients undergoing bariatric surgery for obesity, there are significant reports of weight regain like in a study conducted by Catalano., *et al.* [14], after 18 years on average of follow-up, patients had regained 28kg.

There is no consensus in the literature regarding the minimum BMI for the patient to be admitted as eligible for the procedure. Based on national studies, each institution set a cutoff point.

Thus this work contributes to establishing the fundamentals of obesity treatment guidelines with IGB. The data presented indicate that patients with BMI <30 kg/m² do not benefit in the long term compared to weight regain regimen, when compared with patients with BMI > 30 kg/m². Studies with metabolic approaches need to be performed to identify the likely causes of increased weight regain

in this group and other methods of weight loss should be prioritized whenever possible.

When there is consensus that these variables are involved in different ways in weight regain, it is necessary to determine and measure risk for each variable in order to support new tools and follow-up strategies for treatment of obesity in patients who used IGB.

This study has limitations associated with its investigation process. First, this sample was analyzed during a 2- to 4-year follow-up period; however, we could not measure the weight gain in parametric form on the sample. This has implications because time and variation of long-term weight regain have an impact in such a way that data extrapolation must consider these issues.

We conclude that the percentage of weight regained after treatment for obesity with IGB is high but within the standards described in the literature; however, the percentage of weight regained in this sample was, in most cases, between 10% and 20% of weight lost during treatment.

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