



# Major considerations in the use of bariatric endoscopic therapy (intra-gastric balloon) and nutrological therapy in successful weight loss in patients with obesity: a systematic review

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## Abstract

**Introduction:** Obesity is a chronic and multifactorial disease that affects more than 2.2 billion people worldwide. Treatment options for obesity have expanded significantly and include lifestyle changes, pharmacotherapy, endoscopic bariatric therapies, and bariatric surgery. **Objective:** It was to carry out a systematic review to present the main considerations regarding the use of the intra-gastric balloon as bariatric endoscopic therapy and nutritional therapy in an attempt to achieve successful weight loss in patients with obesity. **Methods:** The PRISMA Platform systematic review rules were followed. The search was carried out from June to August 2023 in the Web of Science, Scopus, PubMed, Science Direct, Scielo, and Google Scholar databases. The quality of the studies was based on the GRADE instrument and the risk of bias was analyzed according to the Cochrane instrument. **Results and Conclusion:** 129 articles were found. A total of 34 articles were evaluated in full and 24 were included in this systematic review. Considering the Cochrane tool for risk of bias, the overall assessment resulted in 26 studies with a high risk of bias and 12 studies that did not meet GRADE. Most studies showed homogeneity in their results, with  $X^2 = 74.7\% > 50\%$ . In the challenges against super obesity and comorbidities, the use of endoscopic devices has been reported for many years, with the majority of positive results for patients. These devices are gaining increasing acceptance, and the Food and Drug Administration (FDA) has approved three endoscopic devices for use. Patients should be carefully assessed nutritionally and

medication-wise and advised on the most appropriate route. To promote long-term adherence, any dietary intervention must take into account patients' dietary preferences, cultural context, and food availability. Ideally, use a combination of Mediterranean and high-protein diets to promote weight loss based on the patient's preference.

**Keywords:** Nutrology. Bariatric endoscopy. Intra-gastric balloon. Therapies.

## Introduction

Obesity is a chronic and multifactorial disease that affects more than 2.2 billion people worldwide [1]. The prevalence of obesity has increased exponentially and patients living with obesity suffer its debilitating consequences. Treatment options for obesity have expanded significantly and include lifestyle changes, pharmacotherapy, endoscopic bariatric therapies, and bariatric surgery [2]. Endoscopic bariatric therapies include volume reduction procedures, such as endoscopic gastroplasty, and devices that occupy gastric space, such as intra-gastric balloons. Due to their minimally invasive nature and ease of application, endoscopic bariatric therapies are increasingly adopted as a treatment option for obesity in several centers. These procedures mainly achieve weight loss by inducing early satiety and reducing meal volume [3].

In this context, the nutritional aspects to achieve the success of bariatric endoscopic procedures stand out, including nutritional intervention in the form of a healthy low-calorie diet, physical activity planning,

behavioral changes, and psychological overcoming. Along with this, the intragastric balloon (IGB) is a temporary and minimally invasive option for the treatment of obesity, initially introduced after the observation that the presence of a gastric bezoar would lead to weight loss due to increased satiety [4]. By endoscopic approach, it is positioned between clinical and surgical treatment, currently being the most used endoluminal obesity therapy. Furthermore, IGB acts as a space-occupying device, reducing stomach capacity and inducing satiety [5]. It recently received FDA approval for use in the United States [1].

There are some types of IGB models, filled with liquid or air, with no significant difference in weight loss between them [6]. The most popular example of a liquid-filled balloon is the Orbera®, a 6-month balloon with a capacity of 700 mL [7]. On the market, there is also the option of a 1-year adjustable balloon, Spatz®, which offers the advantage of a longer treatment with the possibility of adjustment to increase weight loss [8].

Many studies have demonstrated efficacy in short-term weight loss, with significant improvements in obesity-related comorbidities [9,10]. IGB is indicated for overweight patients ( $BMI \geq 27 \text{ kg m}^{-2}$ ), obese patients who meet the criteria for bariatric surgery, and super obese patients ( $BMI \geq 50 \text{ kg m}^{-2}$ ), as preparation for bariatric surgery [11]. In this context, IGB implantation is a technique that can be used before bariatric surgery or as a single procedure in patients who do not want surgery or who remain at high operative risk, as a bridge to surgery in super obese patients and reducing the volume of the liver, when  $BMI \geq 50 \text{ kg m}^{-2}$ . On average, this method allows a total weight loss of 12.0 -15.0% [12].

Despite the non-invasive nature of the procedure, complications such as intolerance, gastric obstruction, gastric ulcer, and gastric perforations can sometimes occur. Its occurrence led to a conference in 1987, which established the basic requirements for an IGB, one of which should have a very smooth surface and little propensity to cause ulceration. Although the balloons used today are very safe, they are not completely free from the risk of complications [12].

Therefore, the present study carried out a systematic review to present the main considerations regarding the use of the intragastric balloon as bariatric endoscopic therapy and nutritional therapy in an attempt to achieve successful weight loss in patients with obesity.

## Methods

### Study Design

The present study followed the international systematic review model, following the rules of PRISMA (preferred reporting items for systematic reviews and meta-analysis). Available at: <http://www.prisma-statement.org/?AspxAutoDetectCookieSupport=1>. Accessed on: 07/19/2023. The methodological quality standards of AMSTAR 2 (Assessing the methodological quality of systematic reviews) were also followed. Available at: <https://amstar.ca/>. Accessed on: 07/19/2023.

### Search Strategy and Sources

The literary search process was carried out from June to August 2023 and was developed based on Web of Science, Scopus, PubMed, Lilacs, Ebsco, Scielo, and Google Scholar, covering scientific articles from various eras to the present. The descriptors (MeSH Terms) were used: "Nutrology. Bariatric endoscopy. Intragastric balloon. Therapies" (in English: Nutrology. Bariatric endoscopy. Intragastric balloon. Therapies), and using the Boolean "and" between the MeSH terms and "or" between historical discoveries.

### Study Quality and Risk of Bias

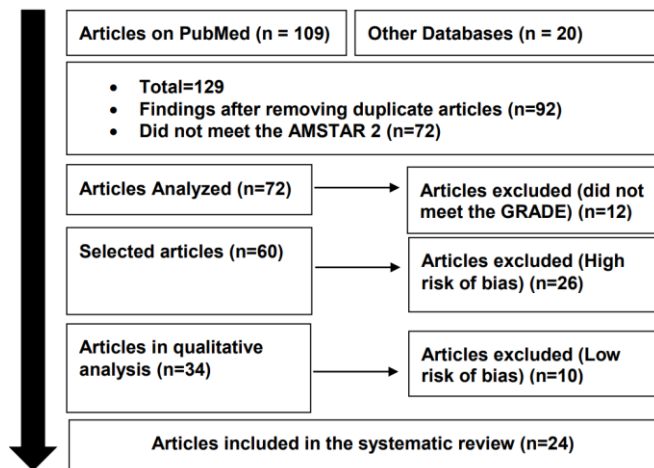
Quality was classified as high, moderate, low, or very low in terms of risk of bias, clarity of comparisons, precision, and consistency of analysis. The most evident emphasis was on systematic review articles or meta-analyses of randomized clinical trials, followed by randomized clinical trials. The low quality of evidence was attributed to case reports, editorials, and brief communications, according to the GRADE instrument. The risk of bias was analyzed according to the Cochrane instrument by analyzing the Funnel Plot graph (Sample size versus Effect size), using the Cohen test (d).

## Results and Discussion

### Summary of Findings

As a corollary of the literary search system, a total of 129 articles were found that were subjected to eligibility analysis, with 24 final studies being selected to compose the results of this systematic review. The studies listed were of medium to high quality (Figure 1), considering the level of scientific evidence of studies such as meta-analysis, consensus, randomized clinical, prospective, and observational. The biases did not compromise the scientific basis of the studies. According to the GRADE instrument, most studies showed homogeneity in their results, with  $X^2=74.7\% > 50\%$ . Considering the Cochrane tool for risk of bias, the overall assessment resulted in 26 studies with a high risk of bias and 12 studies that did not meet GRADE.

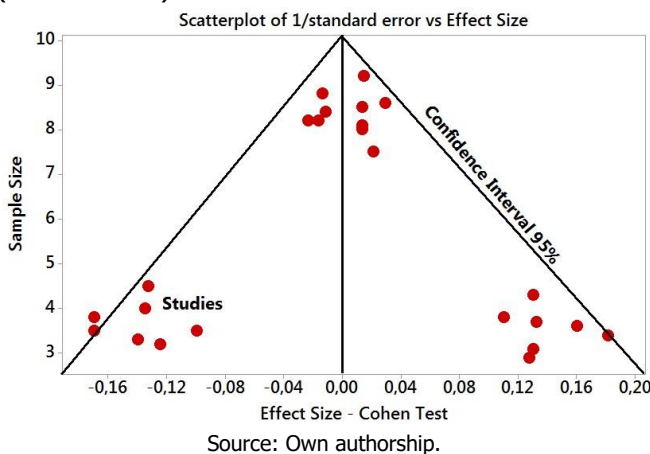
Figure 1. Flowchart showing the article selection process.



Source: Own authorship.

Figure 2 presents the results of the risk of bias of the studies using the Funnel Plot, showing the calculation of the Effect Size (Magnitude of the difference) using the Cohen Test (d). Precision (sample size) was determined indirectly by the inverse of the standard error (1/Standard Error). This graph had a symmetrical behavior, not suggesting a significant risk of bias, both between studies with a small sample size (lower precision) that are shown at the bottom of the graph and in studies with a large sample size that are presented at the top.

Figure 2. The symmetric funnel plot suggests no risk of bias among the small sample size studies that are shown at the bottom of the plot. High confidence and high recommendation studies are shown above the graph (n=24 studies).



Source: Own authorship.

### Major Considerations - Intra-gastric Balloon and Nutrology

In the setting of bariatric endoscopy and nutrition, the literature is accumulating evidence and developing guidelines to facilitate clinical decisions [13-16]. Surgery for obesity and metabolic diseases has evolved

in light of this, resulting in better clinical practices. A multidisciplinary group of bariatric surgeons, obesity doctors, nutrition specialists, psychologists, and anesthesiologists is needed [17].

In this sense, the placement of the intra-gastric balloon (IGB) is increasingly an option as a “bridge” for the treatment of obesity with BMI greater than 27 kg m<sup>-2</sup> in Europe, or equal to or greater than 30 kg m<sup>-2</sup> in the United States. United States and Brazil in patients with failure to control weight with diet and exercise, or lack of criteria/refusal of surgery, or as a bridge to surgery in super obese patients, when BMI ≥ 40 kg m<sup>-2</sup> [11].

Furthermore, the BIG can be placed on an outpatient basis, preferably in a hospital environment, since obese patients tend to have numerous comorbidities that can put them at risk, such as sleep apnea, hypoxemia, high blood pressure, diabetes, unfavorable neck anatomy for intubation, arrhythmias, etc. Adequate sedation is a little deeper and longer, so the presence of an anesthesiologist is highly desirable, if not mandatory, especially if the BMI is greater than 40 kg m<sup>-2</sup> [12].

After endoscopy has ruled out the presence of diseases that contraindicate the placement of the balloon, such as massive hiatal hernia, ulcer, intense gastritis, intense esophagitis, neoplasia, etc., the endoscope is removed and the probe that carries the balloon is passed into its distal end. This passage is monitored by the endoscope in parallel, which will guide and assist in the proper positioning of the balloon in the stomach. The balloon is then filled with saline solution with methylene blue, in a volume that varies from 400 cc to 800 cc [12], depending on the patient's weight and the size of their stomach. At this point, a vacuum is created by suctioning the syringe, and the probe is disconnected from the balloon. Next, it is crucial to carefully observe whether there is a leak in the valve, as 50% of leaks are caused by defects in the construction of the valve [12].

Early diagnosis of the defect will save the doctor and patient from having to change the balloon in inopportune and unpleasant situations. Once a leak is detected, immediately after placement, the balloon must be removed after it has completely deflated and another balloon must be placed in its place. It is important, at this point in the procedure, to remove all excess methylene blue from the stomach so that a late leak is not misdiagnosed (the patient may present with bluish urine) [13].

As a corollary, removing the balloon is a much more complicated and risky procedure than its placement, requiring technical knowledge and adequate training, otherwise severe and even lethal complications may

occur. Therefore, it is recommended that the patient undergo a diet with clear liquids in the three days before balloon removal [14]. It is also prudent to use appropriate instruments, such as a two-channel endoscope, appropriate foreign body forceps, and needle designed specifically for balloon puncture. Furthermore, after introducing the endoscope, try to aspirate all the gastric food residue whenever possible, then puncture the balloon with a suitable needle in a frontal position, promoting the aspiration of all the liquid contained inside, as some liquid remaining in the balloon can make it difficult to remove the balloon, causing significant damage to the cardia. After firmly grasping the balloon with a strong and suitable instrument, such as a "bipod" forceps or polypectomy loop, slow and progressive traction of the balloon begins [14].

The moment the cardia is reached, strong resistance will be felt. At this point, instead of forcing the balloon to be removed, one or two ampoules of hyoscine should be injected intravenously and wait for the spontaneous opening of the cardia, which should occur in two to three minutes. Once the balloon has been removed, a new endoscopy must be performed to detect possible injuries. If another balloon is to be placed immediately, the gastric cavity must be thoroughly washed to avoid residues of methylene blue that could falsely signal a balloon leak [15].

The most common adverse effects associated with the use of the balloon are nausea, vomiting, and mild abdominal pain (in up to 33.0% of cases), which may require early removal [15]. Other possible complications include gastric ulcer, spontaneous deflation, rupture, fungal colonization, and balloon migration that can cause intestinal obstruction, esophageal laceration/perforation, or gastric perforation [16].

Furthermore, for nutritional issues, an initial nutritional assessment is performed similar to the nutritional guidelines of the American Society for Metabolic and Bariatric Surgery (ASMBS) [18,19], with anthropometric measurements and weight histories, such as failed weight loss attempts, weight, current comorbidities, food allergies, eating disorders, current/past psychiatric diagnosis, alcohol/tobacco use, dietary intake, level of physical activity, and psychosocial factors such as level of motivation, readiness to change, stress, and coping mechanisms.

Furthermore, micronutrient deficiencies are frequently found among patients with obesity due to excessive consumption of low-nutrient, high-calorie foods before bariatric endoscopic therapy [19]. Deficiencies of iron, B vitamins, vitamin D, and folic acid have been reported. In this regard, malabsorption

procedures such as Roux-en-Y gastric bypass are known to exacerbate micronutrient depletion of vitamin B12 and other B vitamins, iron, and calcium. Bariatric endoscopic therapies do not induce malabsorption, however, poor dietary choices, food intolerance, and restricted portion sizes can contribute to micronutrient deficiency.

Added to this, the ASMBS has taken the position that there is a lack of evidence to support insurance-required pre-operative weight loss (time-based) as there is no association with morbidity or mortality [20]. Similar to this recommendation, routine weight loss pre-endoscopic therapy is not suggested. However, it may be considered to provide time to assess patients' motivation and willingness to adhere to nutritional counseling and follow-up. Therefore, it is a challenge to lose weight without reaching a negative energy balance, which is determined by energy intake and expenditure. Energy balance is regulated by a complex interplay of endocrine, metabolic, and nervous system signals to control food intake in response to the body's dynamic energy needs and environmental influences [21].

Therefore, a change in body weight occurs when energy expenditure is greater than intake over a certain period, resulting in the loss of body fat mass. When designing a dietary intervention, an individualized diet that achieves a state of negative energy balance should be prescribed. Various dietary approaches are available based on the inclusion and restriction of different food components to achieve and maintain weight loss. These include modifying the macronutrient formulation of foods (low-carbohydrate diet; low-fat diet; high-protein diet), inclusion of different food groups (Mediterranean diet – based on foods rich in vegetables and moderation of refined grains, red meat, and dairy), restriction of specific foods (paleo diet, vegan diet and gluten-free diet) and time-restricted eating [22].

In scientific support of this, a network meta-analysis of randomized trials on 14 popular macronutrient diets showed that most diets resulted in modest weight loss and improved blood pressure over six months. At 12 months, weight loss had slowed and improvements in blood pressure had largely disappeared. Similarly, a randomized trial comparing time-restricted eating to a daily low-calorie diet showed no difference in reducing body weight, body fat, or metabolic risk factors in patients with obesity [22].

Limited evidence focuses on the use of the Mediterranean diet or high-protein diet [23]. The Mediterranean diet (carbohydrates – 53%, proteins – 22%, and fats – 25%) is characterized by an abundance of plant foods, a moderate intake of fish and dairy products, a low intake of red meat, and the use of extra



virgin olive oil as the main source of dietary fat. The anti-inflammatory and antioxidant properties of the Mediterranean diet have been postulated to promote weight loss and improve comorbidities. Short-term studies (3 months) demonstrated the superiority of the Mediterranean diet over the high-protein diet in inducing weight loss in obesity.

Despite this, the protein-based model of Cambi et al. [24] described the macronutrient and micronutrient composition of daily meals to promote and maintain long-term weight loss after bariatric endoscopic therapy. This model recommends 50% proteins rich in calcium and iron, 30% vitamins, minerals, and fiber, represented by fruits and vegetables, and 20% whole carbohydrates with a low glycemic index. Lipids in the form of canola or olive oil have been suggested. Diets high in protein and fiber are believed to be associated with improved satiety, satiety, and reduced food intake. Ideally, use a combination of Mediterranean and high-protein diets to promote weight loss based on the patient's preference. Optimal micronutrient levels are essential for several biological processes, such as fat and carbohydrate metabolism, thyroid function, and glucose homeostasis.

Finally, information about nutritional management after bariatric endoscopic therapies can overwhelm patients, leading to dropout and non-adherence. To simplify daily adherence to healthy eating practices, a visual description of how to plan the meal and design its composition would be useful. The bariatric plate model can be an easy tool for patients to prepare their meals [24].

## Conclusion

It was concluded that in the challenges against super obesity and comorbidities, the use of endoscopic devices has been reported for many years, with the majority of positive results for patients. These devices are gaining increasing acceptance, and the Food and Drug Administration (FDA) has approved three endoscopic devices for use. Patients should be carefully assessed nutritionally and medication-wise and advised on the most appropriate route. To promote long-term adherence, any dietary intervention must take into account patients' dietary preferences, cultural context, and food availability. Ideally, use a combination of Mediterranean and high-protein diets to promote weight loss based on the patient's preference.

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Not applicable.

## Informed consent

Not applicable.

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## Data sharing statement

No additional data are available.

## Conflict of interest

The authors declare no conflict of interest.

## Similarity check

It was applied by Ithenticate@.

## Peer review process

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