



Major nutrological approaches and bariatric endoscopy using the spat3® intragastric balloon: a systematic review

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Abstract

Introduction: In the context of obesity and its comorbidities, more than 2.2 billion people are overweight or obese worldwide. By 2030, it is estimated that more than 60% of the world's population will be overweight or obese. Brazil has approximately 20 million obese people. In this context, and as a measure to mitigate this pathological scenario, nutrology combined with the use of the intragastric balloon (IGB) is an important pillar for obesity treatment. Also noteworthy is the 1-year adjustable balloon option, the Spatz3®, which offers the advantage of longer treatment with the possibility of adjustments to increase weight loss. **Objective:** the present study analyzed, through a systematic review, the main information and results of the use of the Spatz3® intragastric balloon, highlighting the volume adjustments up and down. **Methods:** The model followed for the systematic review was PRISMA. Databases such as Scopus, Embase, Cochrane, Scielo, Lilacs, Google Scholar, PubMed were used. A total of 136 clinical studies were submitted to the eligibility analysis and, after that, 20 studies were selected to compose the present study. The Risk of Bias was analyzed according to the Cochrane Instrument model. **Main findings and Conclusion:** Studies have shown that the treatment of obesity and super obesity with Spatz3® is a safe and effective procedure for weight reduction, without mortality, but with greater morbidity compared to traditional BIGs. Studies have also shown

that adjusting the Spatz3® volume upwards allowed the balloon to remain in place for a longer time. However, the effectiveness of the upward adjustment still requires further confirmation. However, it is necessary for the professional to be well trained for the implantation of the intragastric balloon, as well as to know in depth the possible complications in an attempt to control the variables and reduce the chances of these occurrences. Although it may present risks of perforations and/or obstructions, the intragastric balloon represents an important alternative for superobese patients with high surgical risk for gastroplasty.

Keywords: Calorie restriction. Precise nutrition. Healthy longevity. Lifestyle.

Introduction

In the context of obesity and its comorbidities, more than 2.2 billion people are overweight or obese worldwide [1,2]. By 2030, it is estimated that more than 60% of the world's population will be overweight or obese [3]. Brazil has approximately 20 million people with obesity [4]. In 2019, according to a survey conducted by the Ministry of Health, 52.5% of Brazilians were overweight [5].

In this context, and as a measure to mitigate this pathological scenario, the intragastric balloon (IGB) is a temporary and minimally invasive option for the treatment of obesity, leading to weight loss by

increasing satiety. Using an endoscopic approach, it is currently the most widely used endoluminal obesity therapy [6], and has already been established as a safe and effective method [6-8].

There are several types of IGB models, filled with liquid or air, with no significant difference in weight loss between them. The most popular example of a liquid-filled balloon is the Orbera®, a 6-month balloon with a 700 mL capacity [9,10]. The 1-year adjustable balloon, the Spatz3®, also offers the advantage of longer-term treatment with the possibility of adjustment to increase weight loss [11-14].

The volume of the conventional IGB is adjusted only at the time of placement. The balloon can remain in the stomach for a maximum of 180 days and must be removed by this time [15,16]. However, the Spatz3® liquid-filled adjustable balloon was approved in May 2010 in all 27 countries of the European Union for patients with a body mass index (BMI).

Those who are greater than 27 kg m⁻² and have failed previous weight loss attempts. In November 2014, the Spatz3® was approved for clinical use in Brazil [17]. Today, the Spatz3® is in its third generation [17,18]. Compared to the conventional version, the Spatz3® stands out because its volume can be controlled throughout the treatment, not just at implantation [19]. However, it does not have a completely smooth surface, as it has a "tail," the insertion site for the inflation valve. [19]. The two main differences between the Spatz3® are post-implantation volume control and a maximum treatment period of 360 days [7,18,19].

Regarding volume, the balloon can be adjusted up or down throughout the treatment. The balloon's volume can be reduced in cases of intolerance (excessive and/or persistent vomiting for more than seven days). Removing 100 to 300 mL of the Spatz3® volume improves symptoms and allows the patient to continue treatment. The balloon volume can also be increased during treatment, at a predetermined date, or when the patient reports decreased satiety. Adjusting the balloon volume upwards may enhance the balloon's weight loss effect due to increased satiety and greater restriction of food intake [19].

Also, a maximum balloon stay of 360 days may result in sustained weight loss for a year, providing more time for the patient to undergo dietary reeducation [20]. Although the adjustable IGB appears to have several potential benefits compared to conventional balloons (better patient tolerability, gradual effective weight loss, and longer implantation duration) [21], to date, few studies (some with small numbers of participants) have evaluated its safety and efficacy [7,19].

Therefore, this study systematically analyzed the key information and outcomes of the use of the Spatz3® intragastric balloon in combination with nutrition therapy, highlighting the upward and downward volume adjustments.

Methods

Study Design

This study followed the international systematic review model, following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) guidelines. Available at: <http://www.prisma-statement.org/?AspxAutoDetectCookieSupport=1>. Accessed on: May 11, 2025. The AMSTAR-2 (Assessing the Methodological Quality of Systematic Reviews) methodological quality standards were also followed. Available at: <https://amstar.ca/>. Accessed on: May 11, 2025.

Search Strategy and Search Sources

The literature search process was conducted from April to May 2025 and was based on Scopus, PubMed, Science Direct, Scielo, and Google Scholar, covering scientific articles from various periods to the present day. The following health sciences descriptors (DeCS/MeSH Terms) were used "Obesity. Intragastric balloon. Nutrology. Weight loss. Adjusting the balloon volume" and the Boolean "and" between MeSH terms and "or" between historical findings were used.

Study Quality and Risk of Bias

Quality was classified as high, moderate, low, or very low based on the risk of bias, clarity of comparisons, precision, and consistency of analyses. The most prominent articles were systematic reviews or meta-analyses of randomized controlled trials, followed by randomized clinical trials. Low-quality evidence was attributed to case reports, editorials, and brief communications, according to the GRADE instrument. Risk of bias was analyzed according to the Cochrane instrument by analyzing the funnel plot (sample size versus effect size), using Cohen's d test.

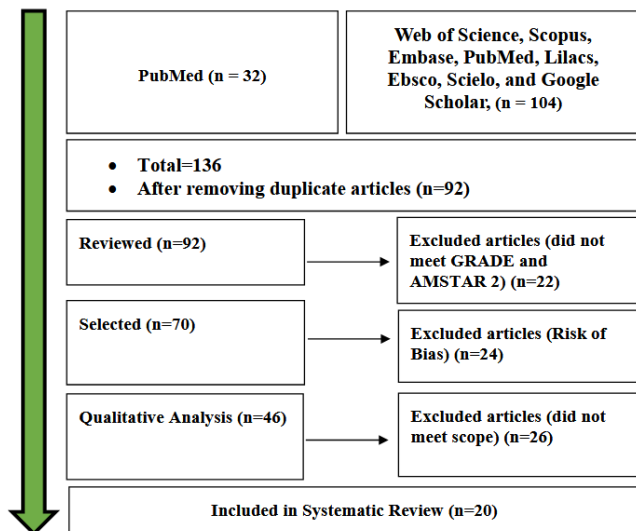
Results and Discussion

Summary of Findings

As a corollary to the literature search system, a total of 136 articles were found and submitted to eligibility analysis. Subsequently, 20 of the 39 final studies were selected to comprise the results of this systematic review. The selected studies were of medium to high quality (Figure 1), considering the level of scientific evidence of studies in meta-analysis, consensus, randomized clinical, prospective, and

observational studies. Biases did not compromise the scientific basis of the studies. According to the GRADE instrument, most studies presented homogeneity in their results, with $X^2=81.7\%>50\%$. Considering the Cochrane risk of bias tool, the overall assessment resulted in 22 studies with a high risk of bias and 24 studies that did not meet the GRADE and AMSTAR-2 criteria.

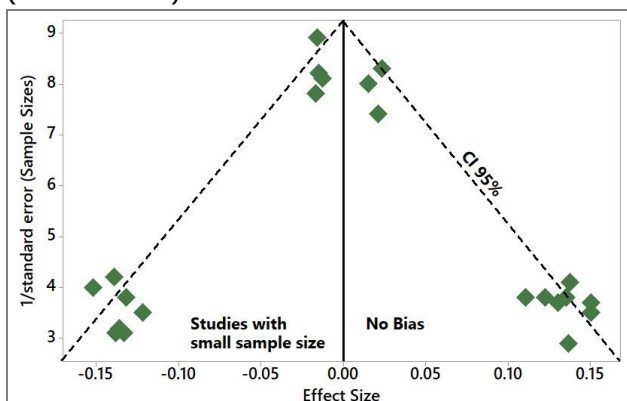
Figure 1. Flowchart of the article selection process.



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 Cohen's d Test. Precision (sample size) was determined indirectly by the inverse of the standard error (1/Standard Error). This graph showed symmetrical behavior, suggesting no significant risk of bias, either among studies with small sample sizes (lower precision), which are shown at the bottom of the graph, or among studies with large sample sizes, which are shown at the top.

Figure 2. The symmetrical funnel plot suggests no risk of bias among the small-sample size studies shown at the bottom of the graph. High-confidence and high-recommendation studies are shown above the graph (n=20 studies).



Source: Own Authorship.

Major Outcomes and Discussion

IGB placement combined with nutritional care is strongly recommended as a "bridge" option for the treatment of obesity with a BMI greater than 27 kg m⁻² in Europe, or equal to or greater than 30 kg m⁻² in the United States and Brazil, or as a bridge to surgery in super-obese patients, when BMI ≥ 40 kg m⁻² [22,23]. In this scenario, the balloon can be placed on an outpatient basis, preferably in a hospital setting, since obese patients often have numerous comorbidities that can put them at risk, such as sleep apnea, hypoxemia, arterial hypertension, diabetes, neck anatomy unfavorable for intubation, arrhythmias, etc [24].

Adequate sedation is slightly deeper and longer lasting, so the presence of an anesthesiologist is highly desirable, if not mandatory, especially if the BMI is greater than 40 kg m⁻² [25]. In this sense, the mechanism of action of IGB is multifactorial and is not yet fully understood [26,27]. Theoretically, IGB affects stretch receptors and gastric capacity, increases satiety while decreasing the residual volume available for food, as well as increases gastric emptying time and, therefore, can be considered a restrictive procedure to treat obesity [28].

Other proposed mechanisms include changes in appetite-regulating hormones (decreased ghrelin and leptin and increased CCK concentrations) [26,27]. However, the best results with IGB occur when treatment is associated with behavioral changes [7,8,29,30]. Furthermore, it is not possible to define the ideal balloon size for a specific patient, as the threshold for nausea, vomiting, and abdominal pain is not measurable or predictable [19].

Traditional IGB has some limitations, such as decreased efficacy in promoting weight loss after 2 to 3 months, a maximum treatment duration of 6 months, and a significant rate of complications during the initial implantation period (nausea, vomiting, and discomfort), leading to balloon extraction in 4-5% of patients [29-32]. Thus, the introduction of the Spatz3® adjustable balloon system offers features that address these limitations. The main complication can be identified as early balloon removal, within nine months after implantation. However, most cases were not due to adaptation symptoms, but rather to various other reasons, such as a desire to discontinue treatment, weight loss considered insufficient by the patient, and psychological intolerance [34].

Also, with the use of the Spatz3®, removals due to severe symptoms (excessive vomiting) in patients who did not wish to undergo downward adjustment and decided to discontinue treatment are rare [34]. The incidence of early removal is low, as demonstrated by studies conducted by Machytka et al. (2014) [17],

who observed a rate of 7.79%, and Brooks et al. (2014) [31], who observed a rate of 5.47%. However, this rate is higher than that observed in studies conducted with conventional IGB. Genco et al. (2005) [7] observed a rate of 0.44%, Lopez-Nava et al. (2011) [21] observed a rate of 0.8%, and Sallet et al. (2004) [6] observed a rate of 3.4%.

In addition, in general, patients who undergo downward adjustment typically complete the minimum nine-month treatment period [17,31]. Thus, it appears that downward adjustment of the balloon may contribute to better adaptation and a lower removal rate. There is a low rate of spontaneous emptying before nine months post-implantation, the minimum time established for treatment, with immediate replacement of the defective balloon and continued treatment, as presented by Machytka et al. (2011) [17] who used first and second generation Spatz® balloons. However, the Spatz3® may present easier implantation and extraction procedures, being less complicated with fewer steps.

This was demonstrated by Brooks et al (2014) [31], who obtained a spontaneous deflation rate of 1.66% of cases. Furthermore, upper gastrointestinal bleeding without hemodynamic repercussions can also occur, caused by rupture of the gastroesophageal junction due to excessive vomiting after upward adjustment of the balloon. Machytka et al. (2014) [17] also reported one case (1.29%) of upper gastrointestinal bleeding, but due to a gastric ulcer.

Despite this, the incidence of ulcers is higher in studies using Spatz3® (Machytka et al (2014) [17] - 1.29% and Brooks et al. (2014) [31] - 2.73%) than in studies using traditional balloons (Genco et al (2005) [2] - 0.2% and Sallet et al. (2004) [6] - 0%). This can be explained by the fact that Spatz3® does not have a completely smooth surface, as it has a tail, which acts as a point of compression on the gastric mucosa, creating a pressure ulcer [19].

In this context, however, weight loss has traditionally been the main outcome measure of the efficacy of Spatz3® treatment, being observed in most patients [7,17,19]. Furthermore, the percentage of excess weight loss is similar in several studies [34-37]. Regarding upward volume adjustment, Genco et al. (2013) [20] reported that the final mean BMI of patients who underwent upward volume adjustment was higher than that of Spatz® patients who did not. In addition, long-term treatment (one year) allows for more prolonged nutritional counseling to increase patient adherence and reinforce the need for behavioral changes from the early stages of treatment. Patients should be aware that it is important not only to lose weight but also to maintain a sustained weight

loss, as described by various authors [18-20].

In this regard, the use of Spatz3® does not represent a definitive treatment for obesity and must be associated with permanent behavior changes and likely a second balloon treatment. Currently, there are no contraindications to using Spatz3® for sequential therapy like traditional IGB [20]. Spatz3® treatment is an effective procedure for weight reduction without mortality.

Besides, IGB offer a safe and effective weight loss option for patients. Downward adjustment reduces the incidence of early withdrawals due to intolerance. However, it is unclear whether upward adjustment is effective in promoting additional weight loss, since all parameters analyzed showed no statistical difference between the two groups [12,38].

Further clinical studies are needed to understand the difficulties and problems with the use of Spatz3® and the effectiveness of upward adjustment. In this regard, a recent prospective randomized study of one hundred and eighty patients analyzed the results regarding weight loss and complications related to Spatz3® in Brazil. Patients had a minimum BMI of 27 kg m⁻². The study examined complications of Spatz3® treatment and BMI reduction, percentage of total weight loss (% TWL), and percentage of excess weight loss (% EWL). Patients were randomly divided into a group in which Spatz3® was maintained at the same volume (600 mL) throughout treatment (Control Group) and another group adjusted to a volume 250 mL higher. The complication rate was 16.14%, with no deaths. Mean BMI decreased from 39.51 to 32.84 kg m⁻², body weight from 111.87 to 90.28 kg, and excess weight from 41.55 to 22.99 kg. Upward adjustment resulted in a greater mean weight loss of 4.35 kg (-8 to 17.6 kg), and the mean procedure time was 7.12 ± 1.63 months. This procedure also allowed the balloon to remain in place longer. However, the efficacy of upward adjustment still requires further confirmation [39].

Limitations

Few clinical studies, mainly randomized ones, were found on the use of the Spatz3® balloon in conjunction with nutritional care. Further studies are also needed to corroborate the clinical effects of upward adjustment of the Spatz3®.

Conclusion

It was concluded that studies have shown that the treatment of obesity and superobesity with Spatz3® is a safe and effective procedure for weight reduction, with no mortality, but with higher morbidity compared

to traditional IGB, especially from a nutritional perspective. Studies have also shown that upward adjustment of the Spatz3® volume allowed the balloon to remain in place longer. However, the effectiveness of upward adjustment still requires further confirmation. However, the professional must be well-trained in intragastric balloon implantation, as well as have in-depth knowledge of possible complications, in an attempt to control variables and reduce the chances of these occurrences. Although it may present risks of perforations and/or obstructions, the intragastric balloon represents an important alternative for super obese patients with a high surgical risk for gastroplasty.

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No additional data are available.

Conflict of Interest

The authors declare no conflict of interest.

Similarity Check

It was applied by Ithenticate®.

Application of Artificial Intelligence (AI)

Not applicable.

Peer Review Process

It was performed.

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