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Research Article

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The Impact of Endoscopy on Intragastric Balloon Placement

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Abstract

Introduction: *The intragastric balloon is a temporary, non-surgical device placed in the stomach to aid in weight loss. Endoscopy is essential in the placement of intragastric balloons because it guarantees that the procedure is performed safely and effectively, however there are no studies that support this.*

Methods: *This study was designed as a retrospective analysis of 460 patients who underwent gastric balloon placement for weight management at Centro Medico Noreste from July 2016 to October 2022. They underwent an endoscopy prior to balloon placement to evaluate the existence of any endoscopic findings that would contraindicate placement.*

Results: *A total of 460 patients were included, 367 (79.78%) were females with an average age of 34.8 +/- 9.2 years. A total of 438 balloons (95.22%) were placed, while the decision was made not to place 22 balloons (4.78%). Among the balloons that were not placed, it is noteworthy that the majority were related to endoscopic findings: peptic acid disease associated with gastric or duodenal ulcers in 9 cases (40.91%), submucosal lesions suggestive of GIST, ampulloma, or malignant lesions in 5 cases (22.73%), Grade C-D esophagitis of Los Angeles classification in 3 cases (13.64%), hiatal hernia > 4 cm in 2 cases (0.09%), and cricopharyngeal stricture preventing endoscope passage in 1 case (4.55%).*

Conclusion: *The endoscopy plays an important role in the placement of intragastric balloons. It helps in identifying contraindications and ensures patient safety by detecting pre-existing conditions.*

Keywords: Intragastric Ballon, Endoscopy, Bariatric Endoscopy, Obesity Treatment, Patient Outcomes, Non-Surgical Obesity Management.

Introduction

The gastric balloon is a minimally invasive method for managing obesity that involves the implantation of a space-occupying silicone device in the stomach, promoting effective and safe weight loss . It serves as an alternative for overweight or obese patients who prefer not to undergo surgery or are ineligible for surgical intervention. There are multiple types of balloons classified based on their shape, material, capacity, content, duration, method of placement, and removal [1-2].

Traditionally, gastric balloons are placed under endoscopic guidance, ensuring constant visual control and procedural safety. However, there is ongoing debate regarding the necessity of pre-placement endoscopy and its role in balloon insertion. Some argue that endoscopy is costly, time-consuming, and offers limited advantages, leading to the development of swallowable balloons that can be placed in an office-based setting, supported by X-rays, providing a quick, safe, and cost-effective alternative [3].

One such example is the Elipse balloon (Allurion Technologies Inc, Natick, MA, USA), which can be placed without the need for endoscopy and degrades naturally within four months, eliminating the requirement for balloon removal procedures. The Elipse balloon offers advantages such as easy, fast, safe, and inexpensive placement, making it an appealing option for patients .

In contrast, the Spatz balloon (Spatz Medical, Great Neck, NY, USA) is the only adjustable-volume gastric balloon currently available. It offers superior durability and weight loss outcomes compared to traditional balloons. However, its placement, adjustments, and removal must be performed using endoscopy, limiting its distribution to experienced centers [4].

While there is no consensus on the preferred method of gastric balloon placement, guidelines from the American Gastroenterological Association suggest that neither fluoroscopy nor endoscopy is necessary for balloon placement . However, the Brazilian consensus on intragastric balloons in 2017 recommends placing the balloon using an adult gastroscopy, with pediatric gastroscopy as the second alternative (only 3% of respondents) and double-channel endoscopy at 0%. For removal, it is recommended to use an adult gastroscopy (40.6%), while 31.3% prefer double-channel endoscopy, and 25% believe that either equipment can be used, with only 3.1% preferring pediatric gastroscopy [5-6].

Also, they give recommendations about the contraindications of placement that included: Absolute contraindications: Active gastric ulcers in the body or fundus, without signs of bleeding (83.3%), active gastric ulcers in the antrum, without signs of bleeding (75.0%), ulcers in any other location without signs of bleeding (71.9%), previous gastric surgery (93.8%), esophageal varices (84.4%), gastric varices (90.6%), hiatal hernia 4-5 cm (71.0%), use of anticoagulant (87.5%); The relative contraindications includes angioectasias without signs of bleeding (75.0%), eosinophilic esophagitis (81.3%), HIV positive (immunocompetent) (96.9%), psychiatric disorders without control or treatment (75.8%).

Not Considered as Contraindications

Esophagitis Los Angeles A or B, Gastritis, hyperplastic or benign polyps, or H. pylori positive. Concerning H. pylori infections, when upper endoscopy fails to show lesions that justify treatment, 46.9% of the participants agree that it is at the discretion of the physician to perform eradication. Among the items on which no consensus was reached are congestive gastropathy, considered a relative contraindication by 51.6% and absolute by 48.4%; familial gastric polyposis, a relative contraindication according to 62.5% and absolute according to 37.5%; the use of platelet anti aggregating agents was considered a relative contraindication by 46.9%; and grade C or D esophagitis was considered an absolute contraindication by 52.9% and a relative contraindication by 44.1% .

Although gastric balloons have demonstrated a favorable safety profile, complications can arise, including gastric perforation, esophageal perforation, and intestinal obstruction. These complications are often attributed to factors such as placement technique errors, patient behavior, or device defects. The importance of experienced personnel in balloon placement cannot be overstated, as inadequate expertise increases the risk of complications [7].

A literature review published in 2018 reported complications associated with the BIB/Orbera balloon type, including 22 cases of gastric perforation, 2 cases of esophageal perforation, and 10 cases of intestinal obstruction. Of the gastric perforation cases, 9 were related to poor placement technique, 4 cases were due to patient-related behavior, and 9 cases were attributed to balloon manufacturing defects. Cases of esophageal perforation were linked to placement technique errors, and intestinal obstruction cases were caused by patient errors in 7 cases and device errors in 5 cases. It was determined that the main risk is associated with balloon placement by inexperienced personnel. Notably, 3 of these complications were fatal, and the majority required surgical intervention .

In a review conducted by Bennett et al. involving 12,261 patients in a preoperative protocol, the proportion of changes in surgical approach after preoperative endoscopy was 7.8%, while changes in medical management accounted for 27.5%. When excluding findings related to Helicobacter pylori infection, the proportion of changes in medical management was 2.5%. The authors also concluded that preoperative endoscopy should be optional since the proportion of changes in surgical approach was low.

In our clinical practice, which has involved the placement of nearly 460 gastric balloons, we have followed a standardized approach that includes preoperative endoscopy for all candidates. Despite varying opinions on the necessity of preoperative endoscopy, we believe it plays a crucial role, especially in identifying contraindications and ensuring patient safety.

Material and Methods

This study was designed as a retrospective analysis of patients who underwent gastric balloon placement for weight management at Centro Medico Noreste from July 2016 to October 2022. The study included 460 patients who met the eligibility criteria, which include the gastric balloon procedures performed under endoscopy guidance. Before the procedure, patients underwent a comprehensive preoperative evaluation, including a thorough medical history, physical examination, laboratory tests, and multidisciplinary evaluation.

The eligibility criteria for inclusion in the study were as follows: patients of any gender, aged 18 years or older, scheduled for intragastric balloon placement, and with sufficient information available for this study. All patients who met these criteria were included in the study. Informed consent was obtained from all individual participants included in the study.

The insertion technique involved a diagnostic endoscopy to assess the macroscopic characteristics of the esophagus, stomach, and duodenum, to identify any contraindications for balloon placement. The procedure was performed under sedation to ensure patient comfort. The diagnostic endoscopy provided valuable information for the decision-making process regarding balloon placement.

Patient data were collected by reviewing medical records, clinical notes, and endoscopic reports. The necessary information was extracted and recorded using data collection sheets specifically designed for this study. All data were then entered into an electronic database created specifically for this study using the SPSS statistical software version 25. Descriptive statistics will be used to summarize the characteristics of the study population. Continuous variables will be presented as means and standard deviations or medians and minimum-maximum values, depending on their distribution. Categorical variables will be presented as absolute frequencies and percentages.

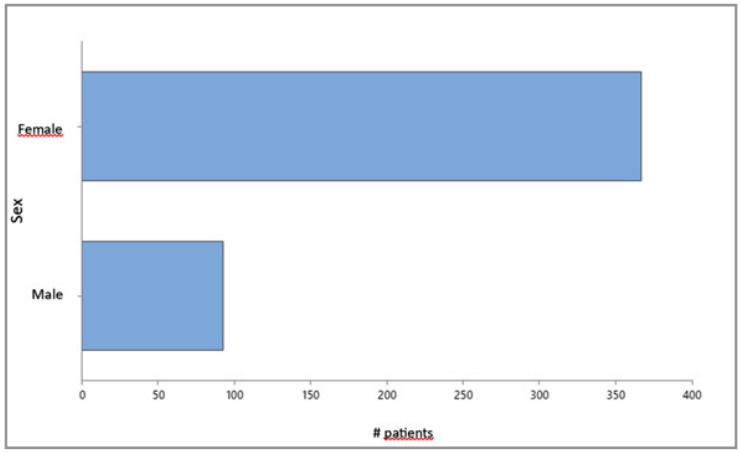
Results

A total of 460 patients scheduled for intragastric balloon placement between July 2026 and October 2022 were identified, and their medical records were reviewed along with clinical follow-up. All patients were included in the analysis.

A total of 460 patients were analyzed for the study. Out of the total, 367 (79.78%) were females and 93 (20.22%) were males, with an average age of 34.8 +/- 9.2 years. The average age for females was 35.1 +/- 9.4 years, while for males it was 33.7 +/- 8.3 years. (Table 1) (Grafic 1)

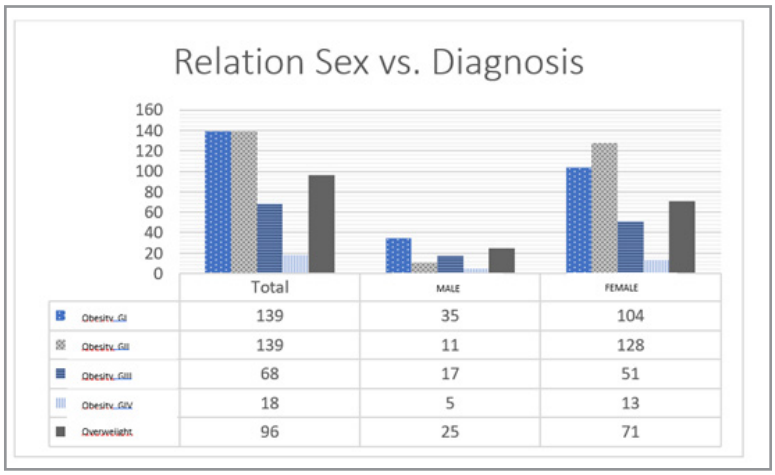
Table 1. Demographic characteristics (n=460)

Male	**93 (20.22%)**
Female	367 (79.78%)
Age	34.8 (9.2)
Male	33.7 (8.3)
Female	35.1 (9.4)
Diagnosis	
Overweight	96 (20.87%)
Obesity GI	139 (30.22%)
Obesity GII	139 (30.22%)
Obesity GIII	68 (14.78%)
Obesity GIV	18 (3.91%)
Ballon placement	
Yes	438 (95.22%)
Male	89 (95.70%)
Female	4 (4.30%)
No	22 (4.7%)
Male	4 (4.30%)
Female	17 (4.63)



Grafic 1. Grafic of Sex

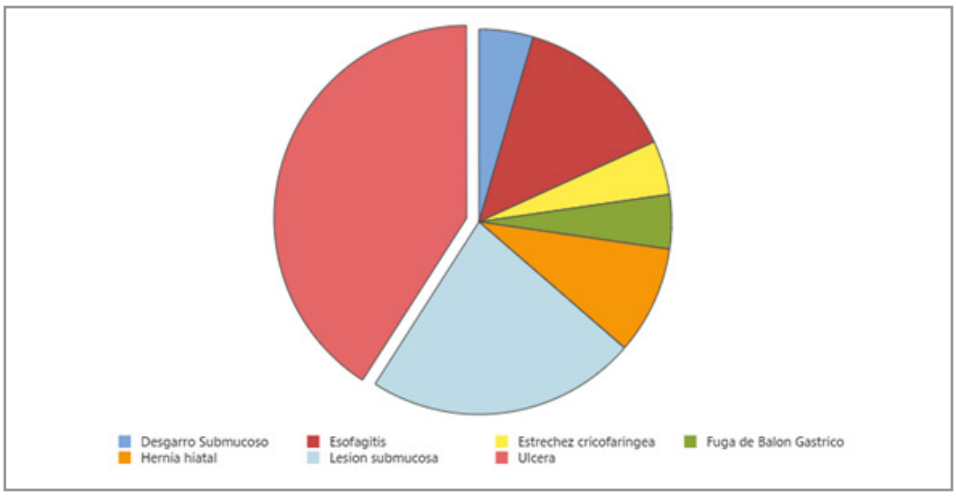
The diagnoses of the patients were described, with the following distribution: 96 (20.87%) patients with overweight, 139 (30.22%) with grade I obesity, 139 (30.22%) with grade II obesity, 68 (14.78%) with grade III obesity, and 18 (3.91%) with grade IV obesity, in which the intragastric balloon was used as a bridging therapy. (Grafic 2)



Grafic 2. Relation Between Sex and Dignosis

Different types of balloons were placed, including Spatz 3, Orbera BIB, and Lexbal. Out of the total 460 patients, 438 balloons (95.22%) were placed, while the decision was made not to place 22 balloons (4.78%). (Table 1)

Among the balloons that were not placed, it is noteworthy that the majority were related to endoscopic findings. Only 2 (9.09%) of the 22 cases were related to technique or balloon-related problems, such as balloon leakage and submucosal esophageal tear during balloon displacement, leading to the decision to defer placement. (Grafic 3)



Grafic 3. Endoscopic Findings

The remaining cases with endoscopic findings included peptic acid disease associated with gastric or duodenal ulcers in 9 cases (40.91%), submucosal lesions suggestive of GIST, ampulloma, or malignant lesions in 5 cases (22.73%), Grade C-D esophagitis of Los Angeles classification in 3 cases (13.64%), hiatal hernia > 4 cm in 2 cases (0.09%), and cricopharyngeal stricture preventing endoscope passage in 1 case (4.55%).

When conducting a statistical analysis for statistical significance regarding the relationship between balloon placement and variables such as age and sex, no significance was found. The p-values for both male (p=0.8) and female (p=0.8) were not significant.

Discussion

Endoscopy plays a crucial role in identifying contraindications for balloon placement. As mentioned in the study, certain conditions such as active gastric ulcers, previous gastric surgery, esophageal varices, and hiatal hernia may pose risks and make the patient ineligible for balloon placement [8].

By conducting preoperative endoscopy, these contraindications can be detected, ensuring patient safety. Also, diagnostic endoscopy provides valuable information about the macroscopic characteristics of the esophagus, stomach, and duodenum. It allows for the evaluation of any abnormalities, such as lesions, strictures, or other structural issues that may affect balloon placement. Understanding the anatomical features helps in determining the suitability and feasibility of balloon insertion [9].

Endoscopy can reveal additional findings beyond the primary purpose of balloon placement. In the study, endoscopic findings included peptic acid disease, submucosal lesions, esophagitis, hiatal hernia, and cricopharyngeal stricture. Detecting these findings during endoscopy allows for appropriate management and treatment before proceeding with balloon placement.

This ensures constant visual control during the balloon placement procedure. This real-time visualization helps in minimizing the risk of complications such as gastric or esophageal perforation and intestinal obstruction. Experienced personnel can accurately position the balloon and detect any procedural errors that may arise.

Each patient's case may have unique considerations and potential risks. Endoscopy allows for a personalized approach, taking into account individual factors that could influence the success and safety of balloon placement. By tailoring the procedure to the patient's specific needs and characteristics, better outcomes can be achieved.

Talking about the swallowable ballons, there is no evidence from randomized studies or meta-analyses supporting the application, as the available series do not mention the complications associated with placement without prior endoscopy or intra-procedural issues, such as esophageal insufflation or perforation.

By presenting these points and supporting them with relevant evidence from the study and other literature, you can provide a strong justification for the necessity of preoperative endoscopy in intragastric balloon placement.

Conclusion

The endoscopy plays an important role in the placement of intragastric balloons. It helps in identifying contraindications and ensures patient safety by detecting pre-existing conditions such as gastric or duodenal ulcers, submucosal lesions, esophagitis, hiatal hernia, and strictures that may affect the feasibility of balloon placement.

Some argue that it is costly, time-consuming, and offers limited advantages, others emphasize its significance in preventing complications and early balloon removal. The use of swallowable balloons as an alternative to endoscopy-guided placement is mentioned, but it is important to note that these options may have their own limitations and considerations.

Complications associated with balloon placement, such as gastric or esophageal perforation and intestinal obstruction, are discussed, emphasizing the importance of experienced personnel and adequate expertise in minimizing the risk of complications. The review of complications associated with specific balloon types underscores the need for careful placement techniques and patient compliance.

In conclusion, while the debate regarding the necessity of preoperative endoscopy continues, this discussion supports the view that endoscopy plays a crucial role in ensuring patient safety, identifying contraindications, and minimizing the risk of complications during intragastric balloon placement. Further studies and evidence are needed to establish standardized guidelines and determine the optimal approach for balloon placement.

Data Availability Statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding authors.

- Conflict of interest
- The authors declare that they have no conflict of interest.
- No funding was received for this study.

Publisher's Note

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