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Intragastric Balloon vs. Endoscopic Sleeve Gastroplasty: A review of the efficacy and safety of both procedures

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ABSTRACT

The increasing prevalence of obesity worldwide has made it a global pandemic. In recent years, endoscopic bariatric therapies (EBTs), such as the intragastric balloon (IGB) and the endoscopic sleeve gastroplasty (ESG), have gained recognition for their effectiveness. This literature review compares IGB vs ESG, analyzing their relative efficacy in achieving weight loss and improving metabolic outcomes. It also assesses their safety profile parameters like procedure-related risks, adverse events, and long-term patient outcomes. Studies conducted between January 2015 and December 2022 that assessed parameters such as percentage total body weight loss (%TBWL) and body mass index (BMI) over a 12-month post-operative period were included in this review. The results indicate that while both procedures promote weight loss and enhance the patient's quality of life, ESG is more effective in achieving sustainable weight loss and reducing comorbidities with low incidence of adverse events in comparison to intragastric balloons. The literature suggests that ESG is a comparatively safer and more effective alternative to IGBs for the treatment of obesity.

Keywords: Obesity, weight loss, Endoscopic Sleeve Gastroplasty, Intragastric Balloon.

1. INTRODUCTION

Obesity is a complex disease with considerably high morbidity and mortality rates. Morbid obesity (Class III) is defined as having a BMI of 40 or higher (Kitahara et al., 2014). Morbid obesity predisposes patients to several complications, such as hypertension, ischemic heart disease, sleep apnea, diabetes mellitus type 2, as well as certain types of cancers (Evans and Scott, 2001). Today, obesity affects 2.3 billion children and adults worldwide, making it

a significant public health concern. If the current trend continues, 1.35 billion and 573 million individuals, could be overweight and obese respectively by 2030 Kelly et al., (2008) making it crucial to refine and improve treatment methods.

Surgery is often needed to treat severely obese patients. Endoscopic bariatric treatments (EBT) like intragastric balloon (IGB) and endoscopic sleeve gastrectomy (ESG) are one of the most widely used treatments for obesity (Rapaka et al., 2022). They are practical and minimally invasive, producing sustainable weight loss while significantly reducing the risk of post-operative complications and improving the quality of life of a patient (Kozłowska-Petriczko et al., 2023). IGB implants are one of the most widely used and well-established EBTs. The procedure involves endoscopically inserting a balloon into the stomach, where it occupies space, reducing the stomach volume and promoting early satiety.

According to Kozłowska-Petriczko et al., (2023) this causes reduced caloric intake, resulting in sustained weight loss. Moreover, based on a study conducted by Bazerbachi et al., (2019) IGBs offer a more suitable alternative to bariatric surgery for patients with class I and class II obesity since many of the current guidelines only allow patients with class III obesity and significant comorbidities to undergo surgery. IGBs can be liquid-filled, air-filled, or adjustable and are inserted and inflated under endoscopic supervision. In ESG, another EBT procedure, the formation of a gastric sleeve that follows the greater curvature of the stomach from the distal portion of the pre-pyloric antrum to the proximal gastroesophageal junction allows a reduction of the stomach volume (Rapaka et al., 2022).

This method creates a tubular gastric lumen with an approximate 80% reduction in stomach volume. As a result, overall calorie intake is reduced, leading to sustainable weight loss. While both IGB and ESG are effective and safe procedures, data comparing their methods across multiple factors remains limited. The choice between them is based on cost, patient preference, and physician expertise (Singh et al., 2020). This review aims to consolidate the available data comparing the safety and efficacy of IGB versus ESG.

2. METHODS

A comprehensive literature search was conducted from January 2015 and December 2022 across PubMed/MEDLINE, Embase, Web of Science, and Google Scholar. The search strategy included keywords such as intragastric balloon, endoscopic sleeve gastroplasty, obesity, and weight loss. Inclusion criteria were Randomized Controlled Trials (RCTs), observational studies, and cross-sectional studies involving adults with a BMI greater than 30 kg/m^2, comparing the efficacy and safety of IGB and ESG. Exclusion criteria consisted of studies involving participants with a history of gastric surgery, gastroesophageal varices, acute gastric pathology, hiatal hernia larger than 5 cm, or pregnancy.

Data extraction involved study characteristics (author(s), year of publication, study design), participant characteristics (age, sex, weight, BMI), intervention details (type of procedure, duration of follow-up), and outcome measures, including the comparison of the percentage of total body weight lost (%TBWL), percentage of excess weight lost (%EWL), and mean BMI loss between IGB and ESG at 1, 3, 6, 9, and 12 months, with patients' excess weight (EW) calculated as the difference between their baseline weight and ideal body weight (using a BMI of 24.9 kg/m^2).

3. RESULT

Overview of Intragastric Balloons

IGBs have been a mainstay in the treatment of obesity since its introduction as a therapy over 30 years ago. Stavrou et al., (2021) demonstrated that these treatments offer a more suitable alternative to bariatric surgery, as current guidelines typically recommend surgery only for patients with a BMI of 30-35 or higher, and significant comorbidities. IGBs therefore offer a minimally invasive, non-surgical option for weight loss management in obese patients, which is sustained alongside diet and lifestyle modifications.

IGBs can either be liquid-filled or air-filled and are inserted and inflated under endoscopic supervision (Alsabah et al., 2018). The idea and application of an insert lodged in the stomach that could cause insidious weight loss without other associated symptoms were first described in 1982 by (Bazerbachi et al., 2019). Currently, there are eight different types of balloons available on the market, but only three are FDA-approved: The Orbera Intragastric Balloon (OIB), the Obalon IGB, and the ReShape Duo (Bazerbachi et al., 2019).

Intervention

The patient is first positioned in a supine or left lateral decubitus position. Xylocaine spray is then applied to the oropharynx to provide local anesthesia and reduce the gag reflex, as is standard for all endoscopic procedures. Intravenous sedation with propofol or general

anesthesia is administered under the supervision of an anesthesiologist. An endoscopic evaluation of the upper gastrointestinal tract is performed to identify any contraindications to balloon placement. Following the evaluation, an empty balloon is inserted into the gastric cavity as an orogastric tube using a guidewire, alongside an endoscope serving as a facilitator (Falcão et al., 2020; Fittipaldi-Fernandez et al., 2020).

For liquid filled-balloons

The balloon is gradually inflated with a saline solution, with methylene blue optionally added to detect leakage. It should be inflated to a capacity of 500-700 ml. Throughout the inflation process, the stomach is insufflated with air to facilitate smooth and even balloon expansion (Scarparo et al., 2020).

For air-filled balloons

Once the balloon is inserted and properly positioned in the gastric cavity, the polypropylene thread securing the protective layer is cut and fully removed, releasing the protective coating. The balloon is then prepared for inflation and filled with 650-750 ml of air (Falcão et al., 2020).

For adjustable balloons

Once positioned in the stomach, the balloon is filled with 400-700 ml of saline solution tinted with methylene blue to detect potential leaks. A blue plug with a nylon thread loop is attached to the valve of the facilitator, enabling the valve to be reintroduced into the balloon with an endoscope if necessary. The insertion tube is then carefully withdrawn from the stomach by gently pulling the balloon against the cardia, allowing the tube to disconnect from the balloon. The balloon is then left to float freely within the stomach (Fittipaldi-Fernandez et al., 2020).

Post-operative care

Post-procedure, the intravenous administration of omeprazole (20 mg), dexamethasone (4 mg), scopolamine (20 mg), ondansetron (8 mg), and dimenhydrinate (100 mg) is recommended to minimize post-implantation symptoms. Additionally, anti-emetics like aprepitant (125 mg) may be administered to manage nausea and vomiting. A liquid diet is advised for up to 10 days following the procedure. A multidisciplinary approach addressing nutritional and psychological aspects is essential for optimal patient care and long-term success (Falcão et al., 2020; Fittipaldi-Fernandez et al., 2020).

Overview of Endoscopic Sleeve Gastroplasty

ESG is a minimally invasive, incision-less procedure used as a non-surgical weight loss therapy for patients with class I and II obesity (BMI > 30 kg/m2). It involves creating a gastric sleeve by suturing the stomach from the distal pre-pyloric antrum to the proximal gastroesophageal junction, running along the greater curvature of the stomach.

Intervention

Patients receive prophylactic antibiotics (Cefotaxime 2 g IV, or Levofloxacin 500 mg IV) and antiemetics (scopolamine transdermal patch and aprepitant 80 mg PO) before the procedure. They are then positioned in the left lateral decubitus position and placed under general anesthesia via endotracheal intubation (Lopez-Nava et al., 2017). An overtube is placed to facilitate the passage of the endoscope, and the suturing device is subsequently inserted. Various suturing techniques have been described for the tubulization` of the gastric lumen, namely:

Z-line sutures: An interrupted Z-line suture is used to create an invagination in the greater curvature of the stomach, forming the sleeve. This is followed by a running stitch that brings the anterior and posterior suture sites together, which is then tightened to achieve plication. Each suture consists of six bites in the sequence of the anterior wall → greater curvature → posterior wall, followed by cinching. A second layer of interrupted sutures is then placed along the sleeve for reinforcement.

U-shaped sutures: Using non-absorbable sutures, the procedure begins at the angularis incisura distally and concludes at the proximal body of the stomach. U-shaped sutures are placed through the anterior wall, across the greater curvature, and through the posterior wall, then passed back again without reinforcement.

Triangular stitch pattern: Once again, the pattern starts from the distal angularis incisura and extends proximally to the fundus. The sutures are placed along the anterior wall, greater curvature, and posterior wall, after which the pattern reverses direction. Each suture consists of three to six bites, which are then cinched.

Following the placement of the sutures, a gastric sleeve is formed and thoroughly washed with gentamicin (80 mg in 60 cc saline) to reduce the risk of infection. The suturing device and endoscope are then withdrawn (Sharaiha et al., 2017; Neto et al., 2020).

Post-operative care

Postoperatively, the patient is given 2 liters of saline to maintain hydration (Neto et al., 2020). Patients are started on a clear liquid diet and, during hospitalization, are provided with analgesics (metamizole IV) and other medications (omeprazole 20 mg every 12 hours IV). Anti-emetics (prochlorperazine 25 mg per rectum or ondansetron IV) are also administered as needed (Sharaiha et al., 2017).

Comparison

Today, there are a variety of IGB designs, including fluid-filled, air-filled, swallowable, and adjustable ones, with only very slight variations between them. Although many of these are currently used in clinical settings, only few have received FDA approval (Stavrou et al., 2021). Based on data collected from multiple studies (Fittipaldi-Fernandez et al., 2020; Sullivan et al., 2018; Ponce et al., 2015; Agnihotri et al., 2018; Schwaab et al., 2020). Table 1 highlights the slight difference in the efficacy of various IGBs used in clinical practice, using factors like BMI, percentage excess weight loss (%EWL), and percentage total body weight loss (%TBWL) as metrics to preserve the homogeneity of expression (Moore et al., 2020; Espinet-Coll et al., 2019).

Table 1 Comparative study on the efficacy of IGBs

Reference	Type of Study	Cases	Type of Balloon	Months	Mean BMI loss (kg/m2)	Mean BWL (kg)	% TWL	% EWL
Fittipaldi-Fernandez et al., 2020	Observational	5874	Air-filled	6	-	19.13 ± 8.86	18.42 ± 7.25	65.66 ± 36.24
Sullivan et al., 2018	RCT	185/181	Obalon/sham	6	-	-	6.6 ± 5.1/3.4 ± 5.0	-
Ponce et al., 2015	RCT	187/139	ReShapeDuo diet/exercise	6	-	-	-	25.1 ± 1.6/11.3 ± 1.9
Agnihotri et al., 2018	Observational	202	ReShapeDuo	6	-	11.7 ± 7.3	11.4 ± 6.7	29.9 ± 18.2
Schwaab et al., 2020	Cross-sectional	360/144	Orbera/Spatz3	6-12	-	-	15.4 ± 7/15.5 ± 9.6	-

BMI - body mass index; % TWL – percentage total weight loss; % EWL – percentage excess weight loss; RCT -Randomized controlled trial.

A comparison of the efficacy of IGB and ESG is based on data from two studies Agnihotri et al., (2018), Sarkar et al., (2022) which compared 202 patients who underwent IGB insertion with 91 patients who underwent ESG. Table 2 provides an overview of the baseline characteristics for each patient group. The average weight loss for patients who underwent IGB insertion varied at different time points: 4.9 kg ± 2.6 kg at 1 month, 8.9 ± 4.8 kg at 3 months, 11.7 ± 7.3 kg at 6 months, 13.3 ± 7.8 kg at 9 months, and 15.8 ± 14 kg at 12 months. Significantly more weight was lost in the first three months (8.9 4.8 kg) than in the following three to six months (3.3 3.8 kg). Compared to the baseline, the BMI significantly decreased after six months. At three months, the percentage of total body weight lost (%TBWL) was 8.8 4.3%, and at six months, it was 11.4 6.7%.

There were no appreciable variations in %TWBL, %EWL, or mean BMI at 12 months compared to 6%. Seventeen patients (8.4%) had esophageal rips after IGB insertion, but no treatment was necessary. Furthermore, 13 patients (6.4%) had to have their IGBs removed

before the 6-month treatment period was over (Agnihotri et al., 2018). As for patients who underwent ESG, the mean BMI reduction after 1, 3, 6, 9, and 12 months was 34.5 (25.9–56.6), 31.3 (25–54.6), 29.4 (23–54.6) and 30.1 (20.4–53.9) respectively, and the mean %TBWL after 1,3, and 6 months post-ESG was 7.2%, 11.2%, and 17.4% respectively (Sarkar et al., 2022). Table 3 summarizes the weight loss changes between the two patient groups.

Table 2 Study population characteristics

Baseline population characteristics	IGB (12)	ESG (13)
Number of patients	202	91
Initial age, years (Mean ± SD)	47.8 ± 10.8 years	39.7 ± 11.6
BMI, kg/m2 (Mean ± SD)	36.8 ± 8.4	38.7 ± 7.3
Gender (n men/n women)	34/168	35/56

Table 3 Comparison of %TBWL, %EWL, and mean BMI loss between IGB and ESG at 1, 3, 6, 9, and 12 months.

Time period Parameter	Procedure	1 month	3 months	6 months	9 months	12 months
Mean %TBWL	ESG (13)	7.2%	11.2%	17.4%	-	-
	IGB (12)	4.8 ± 2.4%	8.8 ± 4.3%	11.4 ± 6.7%	13.3 ± 7.8%	14.7 ± 11.8%
Mean BMI (kg/m2)	ESG (13)	34.5 (25.9–56.6)	31.3 (25–54.6)	29.4 (23–54.6)	-	30.1 (20.4–53.9)
	IGB (12)	-	-	32.8 ± 6.7	-	-
Mean %EWL	ESG (13)	17.3% (p<0.000)	29.2% (p<0.000)	35.6% (p<0.000)	-	-
	IGB (12)	13.2 ± 7.2%	23.8 ± 11.8%	29.9 ± 18.2%	34.7 ± 21.4%	36.4 ± 28.1%

Adverse Effects

The use of IGBs is generally associated with mild adverse events, with very few cases linked to severe complications. The most commonly observed adverse effects are nausea and vomiting, occurring in 73.8% and 49% of cases, respectively, and typically resolving within 7-10 days. The incidence of severe adverse events is low (ranging from 0.03% to 1.3%) comprising of hyperinflation, spontaneous rupture, migration requiring surgical intervention, bleeding, and gastric ulcers (Popov et al., 2017; Neto et al., 2018). The most serious adverse event, gastric perforation, which can lead to mortality (0.08%), is extremely rare (Ribeiro et al., 2021). Immediate adverse events for patients who underwent endoscopic sleeve gastrectomy included nausea, vomiting, and bleeding (n = 2; n = 6). Stenosis was the most common extended adverse event recorded (n = 1) (Sarkar et al., 2022).

4. DISCUSSION

This study demonstrates sustained, clinically significant weight loss outcomes with both IGB and ESG. With a BMI reduction of 9.3 kg/m2 at the 6-month mark, from a baseline of 38.7 ± 7.3 kg/m2, ESG resulted in greater weight loss over 12 months compared to IGB placement (Sarkar et al., 2022). Patients who underwent IGB also experienced a reduction in BMI at 6 months, with a decrease of 4.6 kg/m2 from baseline (Agnihotri et al., 2018). There was no significant difference in %TBWL, %EWL, or mean BMI at the 12-month mark compared to the 6-month results (Sarkar et al., 2022; Agnihotri et al., 2018). Studies have shown that %TBWL tends to slow down or decrease by the 6-month mark for patients who underwent ESG and IGB, respectively (Fayad et al., 2019).

IGB has not been associated with weight regain, likely due to factors such as superior lifestyle modification techniques, continued healthcare provider contact, and the financial investment made by the patients (Sarkar et al., 2022). However, other studies have shown that weight recidivism after the removal of the IGB implant is common. One such study reported that the removal of the balloon reduced the effectiveness of IGB therapy after six months and led to weight regain (Tate and Geliebter, 2017). In contrast, patients who underwent ESG maintained consistent weight loss, as demonstrated by a 5-year follow-up study, which showed a mean weight loss of 18.7 kg and 14.5% TBWL five years after the initial procedure (Sharaiha et al., 2021).

5. CONCLUSION

ESG and IGB are both effective methods of treating obesity, but ESG is superior for sustainable weight loss. ESG had a more significant impact on TBWL and BMI than IGB. Safety profiles are comparable, although IGB had more balloon-related complications. Overall, ESG yielded higher patient satisfaction and better results after 12 months.

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Not applicable.

Informed consent

Not applicable.

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Conflict of interest

The authors declare that there is no conflict of interests.

Data and materials availability

All data sets collected during this study are available upon reasonable request from the corresponding author.

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