



## Innovative Strategies for Treating Obesity by Using a Gastric Balloons

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### ABSTRACT

There are currently one billion overweight and obese people in the globe. The frequency of obesity has sharply increased worldwide. For the healthcare system, this results in extremely high expenses. Due to the poor compliance characteristic of adolescents, dietary restrictions and meticulous programmes to change their lifestyle are frequently ineffectual in managing the specific group of patients. In order to address obesity, a number of strategies, including medical treatments and surgical procedures, have been developed. Some people say they would like to lose weight surgically or are able to do so. Many people view bariatric surgery as risky and think that maintaining their current weight is safer than having the procedure. There are several novel laparoscopic and endoscopic procedures available to help with weight loss, with intragastric balloons among the most recent developments. The weight loss achieved with the balloon is an opportunity to lower the surgical and anaesthesiologic consequences resulting from bariatric surgery in super-obese individuals with various comorbidities. A novel swallowable intragastric balloon has been tested for safety and efficacy in reducing excess weight. Utilising intragastric balloons, the review's major focus is on helping patients lose weight while improving their co-morbidities.

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### Introduction

Obesity is a complicated illness and the second most prevalent cause of avoidable mortality<sup>(1)</sup>. Each person's obesity range and symptoms may be unique<sup>(2)</sup>. Throughout, 500 million people are affected by the astounding rise in obesity rates throughout the world<sup>(3)</sup>. By 2035, 5.2% of adults in India would be obese, making up around 11 percent of the population. According to the statistics, the following nations have the highest prevalence: 1. USA 2. China 3. India 4. Brazil 5. Mexico 6. Russia 7. Egypt 8. Turkey<sup>(4)</sup>. The commitment of who members to stop the growth in obesity demonstrates a tremendous health system vision. It might be used as an invasive or conservative therapy strategy. The first line of treatment for obesity is lifestyle changes. However, for a variety of reasons, these methods are ineffective. Various therapies have been developed in the past decades to combat this. For a lot of people, losing weight requires more than just food and exercise. The process of making it happen is tedious. Current weight loss methods include non-invasive, bariatric surgery, and endoscopic methods. Effective weight loss and concomitant condition resolution have been demonstrated with bariatric surgery. The limitations of bariatric surgery are related to patient problems, excessive costs, and metabolic dysfunction<sup>(5)</sup>. Therefore, a significant number of obese individuals were unable to lose weight. Endoscopic procedures are becoming a substitute for traditional weight-loss methods<sup>(6)</sup>. It overcame the shortcomings of bariatric procedures and produced long-lasting and fruitful weight loss. Endoscopic treatments for weight loss have been developed to be less intrusive. It involves introducing an intragastric balloon, an endoscopic

method for weight loss in the pathophysiology of restriction. Such devices have been researched and developed for years; the Garren Edwards gastric bubble cylindrical device commercialised them in the 1980s. Owing to patients' reports that the gadget was causing gastric erosion or ulcers. In 1992, it was taken off the market. After that, Edward redrew it, and a number of goods were created<sup>(7)</sup>.



ref (8)

Within the first three months, each balloon is positioned separately. Six months after the first balloon was inflated, all three balloons were removed. There are no tools or drugs needed for the administration process. The patient ingests the capsule. Between the capsule and the ezfill dispenser, the catheter is fastened. A container of gas for filling the balloon

is inside the ezfill dispenser. With a moderately intense diet and lifestyle changes, balloon treatment is utilised to lose weight.

### Types of balloons

The characteristics of the balloons, such as filling and administration style vary. Each IGB has unique characteristics and a distinct procedure. There are several types of IGB balloons;

#### 1. Orbera

Bioentrics balloon is another name for Orbera. In 1991, the first new generation of balloons debuted. Apollo Endosurgery is the manufacturer of Orbera. A saline solution is used to inflate the balloon with fluid<sup>(9)</sup>. It is made up of just one balloon. The balloon's volume ranges from 500 to 750 ml. The procedure might take up to six months. The balloons are inserted into the stomach fundus endoscopically via an oral route. Fluid is inflated using a closed infusion circuit. In the stomach, it floats freely. Deflation and removal necessitate an endoscopy and sedation technique. The reduction in weight might be 16.9 kg. The FDA approved Orbera in 2015<sup>(10)</sup>.

Orbera 365 is the 2nd generation with comparable qualities to Orbera, which is accessible from the previous 2 years. It remains in situ for 12 months.



Orbera [ref (11)]



Spatz [ref (12)]

#### 2. Spatz

The third-generation gadget is the Spatz. Spatz FGIA is in charge of producing it. Due to its customizable volume throughout the treatment time, Spatz is an adjustable balloon system<sup>(13)</sup>. They are made out of a single balloon that can

stay in the stomach safely for 360 days. One year is spent receiving therapy. A saline solution is used to inflate the balloon with fluid. It can hold fluid with a volume of 300 to 900 ml. This small, detachable balloon has a filling catheter and a valve at the end to add or remove fluid. The balloon, silicone-covered anchor, and silicone filling tube are the three components that make up the spat. Endoscopy is used to implant it. the loss of 24 kg or more. Spatz has a CE mark from the European Union, but the FDA has not yet authorized it<sup>(14)</sup>. It is now being examined by the FDA in the United States.

#### 3. Reshape Duo

Reshape Medical is the company that makes the Reshape twin balloon system. Saline solution fills the system's fluid spaces. The balloon has a 500–750 cc fluid capacity. The therapy time is six months.<sup>(15)</sup> It has flexible silicone spheres that are connected by a small, non-communicating central shaft. This kind of balloon reduces the possibility of intestinal balloon migration. It enhances the stomach balloon's effects by taking up space. The balloon follows the stomach's natural shape. In 2015, the FDA approved Reshape Duo. The decrease in weight may be 25.1 kg. Endoscopic methods are used for implantation, inflation, deflation, and removal<sup>(16)</sup>. Apollo Endosurgery will phase out this type of balloon in December 2018 and replace it with an Orbera balloon.



Reshape Duo [ref (17)]



Heliosphere [ref (18)]



Silimed [ref (19)]



Allurion [ref (26)]

#### 4. Heliosphere

Medical Implants is the company that produces heliosphere balloons. A saline solution is used to inflate this balloon with fluid. This particular fluid-filled balloon exacerbates motion sickness, nausea, and epigastric discomfort<sup>(20)</sup>. Heliosphere, a bag of air-filled balloons, was created to address this issue. It is a single, spherical, silicone-encased polyurethane balloon with a large volume capacity. The balloon can hold between 900 and 1000 ml of air. The therapy process lasts six months. It is inserted endoscopically. The decrease in weight might be 16 kg. Because of technological issues, it was carefully removed. It contains warnings for people who completely avoid scuba diving and flying in cabins without air pressure<sup>(21)</sup>.

#### 5. Silimed Balloon

Manufacturers of Silimed produce it. A thin silicone coating surrounds a spherical silicone balloon called Silimed. It is positioned in the stomach fundus and connected to an endoscope. It is a balloon filled with saline solution and liquids<sup>(22)</sup>. The balloon can hold 650ml of liquid. 10 ml of methylene blue contrast dye was added to this solution to help detect any fluid leakage or balloon deflation in the stomach.

#### 6. Obalon

Obalon Therapeutics is the company that makes the drug. It is a balloon with thin walls. The Orbera balloon and this balloon are comparable. With nitrogen gas or any inert gas, this balloon is filled with gas<sup>(23)</sup>. It consists of a three-balloon, multiple-balloon system. For each balloon, there is a capacity of 250 ml. Obalon is a delivery method for capsules that may be swallowed. Each balloon is stowed within a 6g dissolvable gelatin capsule after being squeezed, folded, and sealed. No endoscopy or anaesthesia is necessary for the course of therapy. Before inflating the balloon in the capsule, a fluoroscopy is used to check the position of the capsule in the stomach. This course of therapy lasts six months. Endoscopy is solely employed for removal and deflation. The FDA gave its approval in 2016<sup>(24)</sup>. The reduction in weight might be 5 kg.



Obalon [ref (25)]



Medsil [ref (27)]

#### 7. Allurion

Formerly known as Elipse. The company that makes it is Allurion Technologies. The only gastric balloon involved that is not endoscopic is this one<sup>(28)</sup>. Saline solution is used to inflate this balloon with fluid. It has a 550ml volume capacity in the balloon. The insertion procedure takes around 20 minutes and is comparable to the placement of Obalon in the stomach. the balloon's location after insertion as verified by an x-ray. Endoscopy is not necessary for removal. After 4 months, a valve mechanically drains the saline solution, which then goes through the digestive system. This procedure takes four months<sup>(29)</sup>. The reduction of weight is about 2.4 kg. FDA in the US has not yet authorised it; studies are ongoing.

#### 8. Medsil

The Medsil is a balloon filled with saline solution and liquid. It is comparable to orbera. In terms of biocompatibility of silicone compounds, the Medsil balloon excels over other balloons and is hence more tolerated by patients. It is more cost-effective. 18.4 kg of weight might have been lost<sup>(30)</sup>.

#### 9. Lexbal

Lexbal is a silicone balloon that has been filled with fluid and is coiled up in a sheath. The construction, insertion, and removal are comparable to those of a silicone balloon. The possible weight loss is 25.2kg<sup>(31)</sup>.

#### 10. End-Ball

In Korea, endballs are primarily used. It is an intragastric balloon made of elastic polyurethane that is filled with saline and air. Although they are widely tolerated, air-filled balloons have less of an impact on weight reduction. Saline-filled devices have more difficulties but are better at losing weight. The basis for this treatment is endoscopy. The possible weight loss is 14.7kg.



Lexball [ref (32)]



Endball [ref (33)]



Medicone [ref (34)]

made to survive the stomach's acidic environment and reduce the chance of damage and inflammation. Silicone is of type CSM-3930<sup>(35)</sup>. It features an outer shell with a well-sealed interior volume made of various materials. HTV silicone with a 5% phenyl substitution makes up the inner layer. An antimicrobial agent is applied to the outside layer.

## 2. Valve System

It allows for filling and emptying of balloon. It also enables Health care professionals to introduce or remove filling solutions from balloon using a syringe or other specialized device.

## 3. Filling Material

The balloon takes up space in the stomach and expands in size when filled with air or fluids. The most popular filling material is sterile saline solution, which poses little danger and is compatible with the body. Due to allergies or an inability to accept saline, it is occasionally filled with air rather than liquid. It has a comparable impact on stomach capacity reduction and fullness promotion. Through a filling tube, the balloon is filled.

## 4. Filling Tube

The filling valve is connected to a small, flexible tube by the filling tube. During the balloon insertion operation, it is used to inject air or a saline solution into the balloon. The filling tube is normally detached and taken out once the balloon has been inflated.

## 5. Tether / Retrieval System

Many intragastric balloons include tethers or retrieval devices attached for easy removal of the balloon at the end of the treatment time. It frequently extends outside of the body and helps medical professionals hold and remove the balloon.

## 6. Radiopaque Marker

It is typically incorporated into intragastric balloons. This is visible on x-ray or fluoroscopy imaging, facilitating the position and verification of balloon placement within the stomach.



Intragastric Balloon [ ref (36)]

## 11. Medicone

A balloon filled with saline solution and fluid is called a medicone. A 300–700 ml volume range is its volume range. South America used it often. The procedure used is endoscopy-based. Concerns with other balloons are the same.

### Components

#### 1. Balloon Material

A material that is soft and flexible makes up a balloon. Medical-grade, 100% fluorinated silicone or elastomer is the most commonly used substance. Due to its strength and resistance to deterioration, silicone is a biocompatible material that is frequently employed in medical devices. It is

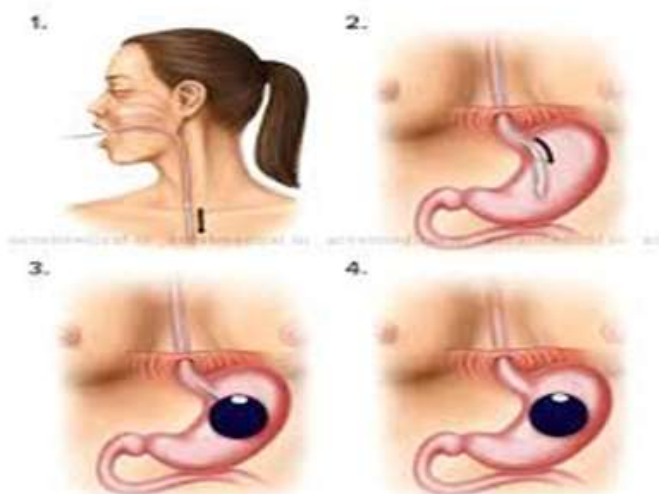
## Procedure

### ❖Pre-balloon administration

- A patient should take a placebo capsule test before receiving a balloon. The real balloon capsule may be more difficult to swallow if the test results show any swallowing difficulties.
- The patient can start receiving balloon treatment if they successfully swallow the pill and pass the exam.

### ❖ Balloon Administration

- Endoscopy is not required for all types of balloons; instead, the capsule is delivered via the standard pill-swallowing technique.
- The patient should be upright when the capsule is administered.
- The patient should next drink enough water to hydrate themselves before the capsule is inserted into their stomach.
- The positioning of the balloon in the stomach has to be confirmed using an x-ray or fluoroscopy.
- In the event that ingesting the capsule presents a problem, troubleshooting techniques are performed.
- The balloon is inflated with air or a solution using a filling tube, while the catheter linked to the capsule is left outside.
- 7 kPa should be the desired air pressure.
- Up to 500–750 cc of saline were placed in the balloon.
- After inflation, use an x-ray to confirm the location of the balloons.
- Inflation causes the catheter and balloon to get separated.
- The catheter is then taken out of the stomach balloon's valve.
- Disconnect the extension tube from the catheter.
- The administration of the balloon takes 20 minutes (37).



Insertion of balloon 1. Swallowing 2. Placing of balloon 3. Inflation 4. Removal of catheter. ref (38)

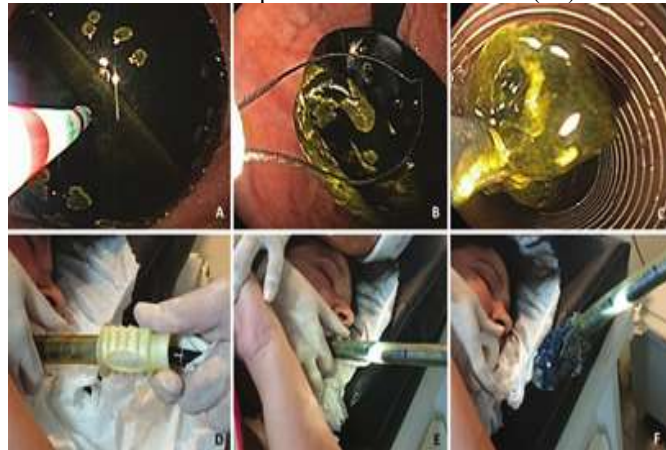
### ❖ Post administration:

- The patient is instructed to consume additional water for 24 hours following treatment. The second day is then used for soft solids.
- For three days, the patient shouldn't consume any carbonated beverages.
- They can resume their diet's solid consumption after three days.
- Vomiting and nausea symptoms might be present in the patient. Utilising medicine can reduce it.
- Any further intolerances should be disclosed to the doctor by the patient. A healthy diet should be balanced and low in calories.
- This behavioral change encourages wholesome eating practices.

### ❖ Removal of balloon

- After six months, the balloon is taken out by giving it one puncture and deflating it.
- A doctor should perform the removal operation. Before being unfastened, the patient is secured for 24 hours.

- The patient is given anaesthesia, and an endoscope is then placed in their stomach. Next, use an endoscope to introduce a needle tool.
- Find the valve, poke the balloon once with the needle, and then remove it.
- The graspers should then be immediately inserted into the tube. At the opposite end of the valve, grip the balloon with your graspers.
- Remove the balloon via the mouth after carefully pulling it up through the oesophagus. Repeat the insertion and removal steps in the event that there are three balloons involved.
- The balloon removal process takes 15 minutes (39).



ref (40)

Removal of balloon; a) insertion of needle b) puncturing of balloon c) deflation d) removal of balloon e) grasping of balloon f) deflated balloon

### Mechanism

The balloon restricts how much food the stomach can contain and induces an early sense of fullness. Weight reduction will be the effect of this decreased food consumption. The mechanism of hormonal changes in stomach emptying is performed by the balloon. The group with baseline delayed emptying may benefit from alternative weight-loss strategies. It includes hormonal adjustments that control hunger. Leptin and ghrelin levels in fasting plasma were considerably reduced while the balloon was within This indirectly reduces hunger. Hence the weight reduction brought on by balloon treatment and a balanced diet<sup>(41)</sup>.

### Side effects

#### ➤ Effects on post administration.

Several consequences that may be curable or life-threatening are induced after balloon implantation.

Nausea, vomiting, gastroesophageal reflux disease (GERD), bleeding, abdominal pain, allergic reactions, headaches or migraines, indigestion, heartburn, bloating, belching, flatulence, stomach scratches, diarrhea, sleeping disorders, abnormal esophageal function, heart attack, airway obstruction, constipation, and diarrhea (42).

#### ➤ Effects during retrieval of balloon

The following symptoms may occur:

Headache, low oxygen level, stomach ulcer, salivation, chest discomfort, vocal cord spasm (43), shortness of breath, hiccups, asthma, and hypertension (44).

### Contra-Indications

In order to avoid the following complications, the IGB therapy also has certain limitations:

- A patient who has had weight-loss surgery.
- Untreated *Helicobacter pylori* infections.
- Allergy to pig-derived food.
- Anatomical conditions that might make it difficult for food to enter the GIT or to be swallowed.

- Proton pump inhibitors are not being taken by the patient when the device is being inserted.
- Diseases associated with GIT inflammation (45).
- Patients who abuse drugs or alcohol and binge consume large amounts of liquid calories.
- Patients on antithrombotic drugs.
- Diseases causing GIT blockage.
- Variations in stomach emptying may have an influence on patients who take medications at certain hourly intervals (46).

#### Advantages

- The time it takes to insert and remove a balloon is shorter.
- There is no surgery necessary.
- Additionally, it encourages us to adopt healthy eating habits.
- If they are not tolerated, the balloons can be removed.
- Co-morbidities in medicine are improving.
- The gut-brain axis controls the complicated process of increasing satiety.

#### Disadvantages

- The price of the intragastric balloon treatment is high, at US \$8150.
- It should have a BMI between 30 and 40 kg/m<sup>2</sup>.
- The age restriction is 22 to 40.
- The course of therapy is lengthy.
- There are no long-term evaluations of weight reduction in the data.
- To treat it, a doctor with the necessary training is needed.
- Life-threatening problems might arise.
- After the balloon has been removed, the diet should be continued for two years<sup>(47)</sup>.

#### Comparison of different methods Ref (48)

	Endoscopic method	Swallowable/non-endoscopic method
Insertion	Balloon is inserted using endoscopy with sedation.	Swallowed with a glass of water.
BMI	30-50 kg/m <sup>2</sup>	27-50 kg/m <sup>2</sup>
Implantation	6 or 12 months	4 or 8 months (new)
Hospital stay	3-4 hours for day case procedure	None, 20 mins appt only
After care support	12 or 18 months	10 or 16 months
Removal	Via endoscopy under sedation	None, balloon passed naturally
Type of Balloons	Orbera, spatz, Reshape duo, Heliosphere bag, Silimed balloon	Elipse (Allurion), Obalon.



Endoscopic method [ref (49)]



Swallowable method [ref (50)]

#### Effects on Co-Morbidities

An extensive retrospective study from an Italian group for lap-band surgery has demonstrated that weight loss brought on by an intragastric balloon can improve or treat the majority of co-morbidities, including respiratory disorders, hypertension, type 2 diabetes mellitus, osteoarthritis, dyslipidemia, heart disease, stroke, and some cancers<sup>(52)</sup>.

#### Conclusion

According to a safe, effective, and minimally invasive procedure, intragastric balloons improve the quality of life for obese patients<sup>(53)</sup>. In patients with an initial BMI greater than 65 kg/m<sup>2</sup>, this demonstrates the use of a balloon system as an additional therapy to **promote** weight reduction and act as a bridge to bariatric surgery. It guarantees a noticeable weight loss, especially in kids and teenagers with BMIs under 35 kg/m<sup>2(54)</sup>. Patients with obesity and associated metabolic co-morbidities are also managed by it.

#### Randomised Controlled Trial Reports of Igb [Ref (51)]

S.no	Type of balloon	Study design	Number of subjects	Bmi(kg/m <sup>2</sup> )	% ewl
1.	Orbera	Prospective, Randomised multicentre	125	35.2±3.2	26.5
2.	Obalon	Prospective, Randomised multicentre	198	35.1±2.7	24.1±19.2
3.	Spatz	Prospective	73	36.6	45.7
4.	Elipse	Prospective, Observational open label	34	34.8±3.7	10.0% of total weight
5.	Reshape duo	Prospective, Randomised multicentre	187	35.3±2.8	27.9±21.3
6.	Heliosphere bag	Prospective	84	39.1±5.8	33.2
7.	Medsil	Prospective	301	36.2±5.2	12.48±5.2 kg
8.	Medicone	Post-hoc analysis	23	40.8±11.4	21.7
9.	Silimed	Preliminary	52	34.7±5.2	46.5±36.7
10.	Lexbal	Prospective	63	58.3±10.5	26.8±12.3
11.	Endball	Retrospective	114	33.5	39.2

- BMI- Body Mass Index
- % EWL-Excess Weight Loss

With a larger absolute value seen in higher BMI groups, the average weight reduction was  $17.8 \text{ kg/m}^{2(55)}$ . The intragastric balloon therapy acts as a significant way to lose weight despite being complex in a number of patients, according to the review on IGB.

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