International Journal of Advances in Engineering and Management (IJAEM)
Volume 2, Issue 5, pp: 721-727 www.ijaem.net ISSN: 2395-5252

A critical review on the intragastric balloon therapy for treatment of obesity

Dhanashree Kavhale[1], Darshana.Lahoti[1], Jaya Ambhore[*1], Shital Gandhi[1]
[1]*Department of Pharmacy, Dr. Rajendra Gode College of Pharmacy, Malkapur, Maharashtra, India 443101*
Address to correspondence: Jaya Prakash Ambhore*

Date of Submission: 30-08-2020 Date of Acceptance: 09-09-2020

ABSTRACT: There are, now, one billion overweight as well as obese persons worldwide. Only some of those patients express the desire or are able to undergo surgical operation. At present there is no medical cure for obesity. And the some dietary treatments. In patients with first degree obesity, the intragastric balloon interrupts the on-going and in exorable weight gain, and improves the relevant co-morbidities. In super-obese patients, where there are numerous co-morbidities, the weight loss obtained with the balloon represents a chance to reduce the surgical and anesthesiologic complications deriving from bariatric surgery.
The present review aims to provide an updated overview on history, types, uses and mechanism of intragastric balloon treatment for obesity. With the detail review on information about Obalon® Gastric Balloons (OBG), their operating procedure, removing steps and impact on weight reduction with adverse effects.
Keywords: Obesity, BMI, Intragastric balloons (IGB), Obalon,

I. INTRODUCTION:

Obesity is a medical condition in which excess body fat has accumulated to an extent that it may have a more side effects on health. People are generally considered to be obese when their body mass index (BMI) is more according to calculation. Body mass index (BMI) calculated as weight in kilograms divided by the square of height in meters of 30 kg/m^2 or greater.[1] Overweight is mostly defined as a BMI between 25.0 and 29.9 kg/m^2, and extreme obesity is defined as a BMI of 40 kg/m^2 or greater. International points of view the body mass index are also used to assess overweight (BMI>= 23.00kg/m^2) and obesity (BMI>= 25.00kg/m^2) [Figure.1].Obesity increases the simultaneously developed various diseases and conditions, particularly cardiovascular diseases, type 2 diabetes, sleep problems, types of cancer, osteoarthritis, and depression. [2][3]

Obesity is most commonly caused due to excessive intake of food, lack of exercise, and genetic problems.[4] A few people obesity are caused by other reasons like genes, endocrine disorders, medications, or mental disorder.[5] The view that obese people eat little yet gain weight due to a slow metabolism is not medically supported.[6] On average, obese people have greater energy expenditure than their normal counterparts due to the energy required to maintain an increased body mass. [7]

Obesity is a combination of social changes and personal choices. Changes may relate to diet and exercising are the main treatments. Diet quality of obese people can be improved by reducing the intake of high in fat or sugars, and by increasing the consumption of dietary fiber. Drugs can be used, along with a suitable diet, to reduce appetite or decrease fat absorption. If some people diet, exercise, and medication are not effective, a gastric balloon or surgery may be performed to reduce stomach volume or length of the intestines, leading to feeling full earlier or a reduced ability to absorb nutrients from food. [8]

Obesity is a leading preventable cause of death worldwide, with increasing rates in adults and children.[9][10] Obesity is more common in women than men. According to literature view obesity is the one of the most serious public health problems of the 21st century.[11] Obesity characterized in much of the modern world (particularly in the Western world), though it was seen as a symbol of wealth and fertility at other times in history and still is in some parts of the world.[12]

International Journal of Advances in Engineering and Management (IJAEM)
Volume 2, Issue 5, pp: 721-727 www.ijaem.net ISSN: 2395-5252

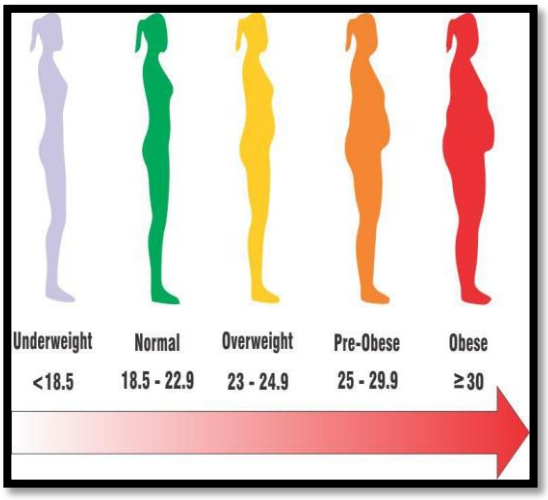

Figure 1: Representation of scale of body Mass Index

The history of pathological obese patients is changes with the repeated diet failures. The indications of surgical treatment are strictly specific and, even today, far from acceptable to the patients.[13]

In the recent year the surgical treatment of obesity has increasingly spread. Its users, as well as the operators, are constantly looking for minimally invasive for the procedure itself, complications and discomfort rate and at the same time massively effective (weight loss results) treatment [14][15]. In1986Pasulkaetal.[16] demonstrated preoperative weight loss (10–20 %) reduced surgical complications resulting from bariatric surgery. Consequently the interest has turned to the remedies which help patients to maintain restrictive diets. Those remedies make diet more effective and thus lead to greater control of the co-morbidities from the point of view of surgery.

The concept of intragastric balloon emerged in the early 1900 when patients with bezoars (partially digested agglomerates of hairs or vegetable fibers) of ten complained of post prandial fullness, nausea and vomiting. It led to the idea of contriving advice which would imitatean intragastric ricbezoar. The first intragastric balloon to be marketed was the Garren-Edwards Gastric Bubble, a cylindrical, polyurethane contrivance, inflated with air. It was then followed by number of different types of intragastric balloons, but all of them showed lack of safety and efficacy.

To the patients asking for a temporary weight loss device, especially overweight patients, still some do ubtsre main on its placement and removal due to the endoscopic approach and the post-placement discomfort. A new swallowable intragastric balloon, "Obalon," and other commercially available devices have strong safety profile and low rate of post-placement symptoms.[17]

Intragastric Balloon:

Intragastric balloon (IGB) devices are the most popular minimally invasive option for treatment of obesity. Early devices use in the1980s, however, was ineffective and potentially side effects. The first such device was the Garren-Edwards Gastric Bubble [18], an air-filled balloon. About 20,000 such devices were implanted. In practice, spontaneous deflation occurred in 31% of cases and gastric ulcers were seen in 26%.[19]Adverse effects including gastric perforations and intestinal obstructions requiring surgical extraction eventually led to the withdrawal of the device. Nevertheless, this encouraged the development of safer and more effective IGBs. The second-generation IGBs have been used outside of the United States for more than 25 years. These balloons are made of more durable silicone-based material and filled with saline or air. The most commonly used IGB worldwide is the Bioenterics Intragastric Balloon, a fluid-filled single balloon, marketed in the United States as the Orbera Intragastric Balloon System (Apollo Endosurgery, Austin, TX). More than 250,000 Orbera balloons have been placed since its introduction in 1996. It was approved for use in the United States in 2015[Figure.2]. Reshape (Reshape Medical Inc., San Clemente, CA), a dual balloon system, was approved at the same time [Figure.3]. In September 2016, the US Food and Drug Administration (FDA) approved a gastric balloon that is swallowed, the Obalon (Obalon Therapeutics, San Diego, CA). The Obalon Balloon is unique in that it allows for placement through the swallowing of a deflated balloon in the form of a capsule. Owing to the smaller overall capacity of 250 mL, up to 3 balloons can be placed in the stomach over a 3-month period. The Obalon balloons are filled with nitrogen mixed gas rather than saline through a catheter that remains attached until the balloon is fully inflated within the stomach[Figure.4]. All 3 IGBs are approved for patients with a body mass index (BMI) of 30 to 40 kg/m2 who have failed nutritional counselling and lifestyle therapy. Until recently, there was no other effective weight loss procedure available for this group, because a BMI of 40 kg/m2 is usually required for consideration of bariatric surgery.[20]

International Journal of Advances in Engineering and Management (IJAEM)
Volume 2, Issue 5, pp: 721-727 www.ijaem.net ISSN: 2395-5252

Figure.2: Orbera balloon.

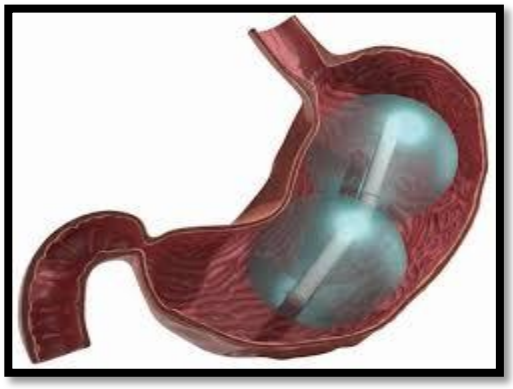

Figure.3: Reshape Duo balloon.

Figure.4: Obalon balloon(s).

Types of Intragastric balloons Approved for use

There are three types of intragastric balloons approved for use in marketed summarised in Table.1

1. Orbera [21]

- Mostly Saline-filled single balloon system
- Having capacity fill volume of 500 to 750 mL
- Generally placed endoscopically
- Implanted for up to 6 months
- It requires endoscopy for deflation and removal

2. Reshape Duo [22]

- It is the Saline-filled double balloon system
- It fill volume of 450 mL/balloon for total of 900 mL
- Mostly placed endoscopically
- Implanted for up to 6 months
- It requires endoscopy for deflation and removal

3. Obalon [18]

- It is the Gas-filled multiballoon system
- It fill volume of 250 mL; up to 3 balloons may be placed
- It is swallowed capsule delivery device
- Does not require endoscopy or sedation for placement; placement in the stomach is confirmed with fluoroscopy before inflation
- Implanted for up to 6 months
- It requires endoscopy for deflation and removal

Table1: Types of Intragastric balloons with specifications

IGBs Devices	FDA Approval	Volume	Implant/ Removal	Fillings	Duration of Treatment
Orbera	Approved in 2015: BMI 30–40 kg/m2	400–700 mL	Endo/Endo	Liquid	6 months
Reshape Duo	Approved in 2015: BMI 30–40 kg/m2	900 mL (450 mL×2)	Endo/Endo	Liquid	6 months
Obalon	Approved in 2016: BMI 30–40 kg/m2	250 mL	Swallow / Endo	Gas	6 months

International Journal of Advances in Engineering and Management (IJAEM)
Volume 2, Issue 5, pp: 721-727 www.ijaem.net ISSN: 2395-5252

Mechanism of Action

IGBs lead to weight loss by performing the mechanism of action like promote weight loss by decreasing the stomach's potential volume .Due to this manner, the total caloric intake for the day may be minimizing with adherence to nutritional counselling. Again IGBs device performed additional mechanisms include changes in hormonal changes and gastric emptying. According to some research study on IGBs it was observed that that gastric emptying rates are reduced at 1 and 4 months after balloon insertion, and return to normal 1 month after balloon removal. On this above study some recent experiments give the additional observation to the role of delayed gastric emptying in promoting weight loss after IGB placement.[23]a subset of patients with normal or increased gastric emptying times before balloon placement experienced greater weight loss with IGB therapy compared with patients with baseline delayed emptying. The group with baseline delayed emptying may benefit from different mechanistic methods to achieve weight loss other than IGBs. Other mechanisms of IGBs include changes in hormones which is regulating the appetite. Mostly fasting plasma ghrelin and leptin were minimizes significantly when the balloon was in the stomach, due the minimizing level of ghrelin and leptin indirectly decreased hunger.[24]However; there are some reports of observed hormonal changes in other studies. It is likely that many of these factors together contribute to the overall weight loss achieved.

Obalon Balloon:

The first swallowable balloon system is Obalon® (Obalon Therapeutics, Inc.), in this system allows up to three balloons to be put in place without any endoscopy. [25] Obalon treatment is weight-loss procedure without any surgery. Obalon therapy mostly approved by FDA for people having BMI of 30 to 40. According to FDA the Obalon Balloon is not a cure for obesity but It helps to control weight. In this therapy a 250 ml gas filled gelatin capsule having a weight around 6gm. [Figure.5].[26]swallowed under fluoroscopic guidance, and once in place, it is inflated with a nitrogen-sulphur hexafluoride gas. It consists of up to 3 intragastric balloons placed over the first 3 month. The patient swallows the catheter-balloon capsule, which also contains a radiopaque marker assisting in confirming its position under the gastroesophageal junction with fluoroscopy or X-ray. Once this is achieved, the catheter is used to inject gas (nitrogensulfur hexafluoride mixture) into the balloon. Each balloon has a volume of approximately 250 cc, totalling 750cc with 3 balloons.[27]

Figure.5: Obalon Balloon Capsule view

Figure .6: Comparison of size with vitamin E Gel capsule.

Balloon Insertion:

Obalon Balloon is inserting to stomach by swallowing a large capsule, this capsule is generally made with gelatin that comes from pigs. The balloon is made of plastic that is folded neatly into capsule that is slightly larger than a vitamin pill [Figure.6] that is connected to a small bendable tube, called catheter.[28]A manometer connected to the catheter for the purpose of recording the pressure inside the Obalon. When dissolution of the gelatin capsule, the pressure drops below 7 KPa, it indicates that the balloon has properly unrolled in the stomach. It is mandatory to performed fluoroscopic control before balloon inflation. After complete balloon inflation and stabilization of internal pressure at about 8.3Kpa to 17.2Kpa, the catheter is detached and removed. Fluoroscopy is used to define the location of the intragastric balloon, and the gelatin capsule disintegrates and releases the balloon. The balloon is then inflated using a gas-contained canister. The catheter is separated from the balloon and removed after

International Journal of Advances in Engineering and Management (IJAEM)
Volume 2, Issue 5, pp: 721-727 www.ijaem.net ISSN: 2395-5252

balloon inflation. Each balloon inflated to 250cc in volume, which is about the size of a small orange. The balloon will be free floating and will move inside in stomach [Figure.7] [29]

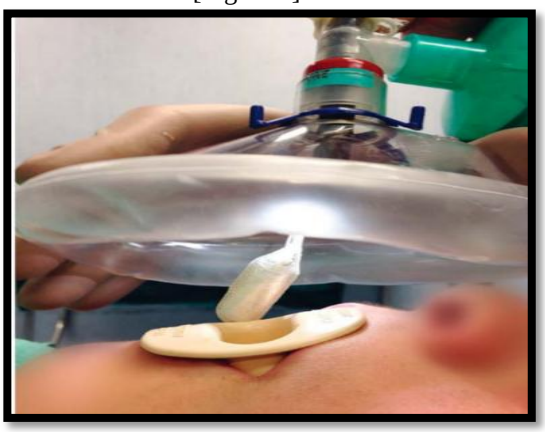

Figure.7: Insertion of Obalon Capsule.

Balloon Removal:

There is no need inserted Obalon balloon endoscopically. It does, however, require endoscopic removal at the end of 12 or 24 weeks. The first Obalon balloon will be in your stomach around 6 months. A second balloon can be placed in stomach at the end of 4 weeks, and a third at the end of 8 weeks. These balloons will take up more space in your stomach to help you lose weight. All balloons are taken out 6 months after the first balloon capsule is swallowed. By medication in vein that causes conscious sedation (light anesthesia). By puncture all the balloons get deflated one by one. Taking all three balloons out of stomach typically takes less than 20 minutes [Figure.8].[30]

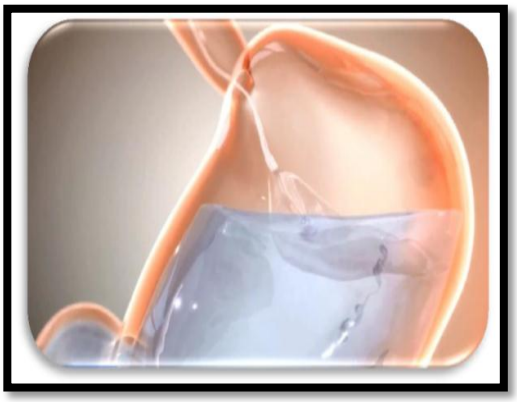

Figure 8: Deflated Obalon Balloon removal.

Impact on weight reduction:

The Obalon (orally ingestible intragastric balloon) showed median weight losses after 4 weeks, 8 weeks, and 12 weeks as 2.2 kg, 4.0 kg, and 5 kg, respectively .According to SMART trial, a multi-canter U.S. pivotal trial of 387 patients, showed result that TWL of 6.81%±5.1% with just one episode of gastric ulcer as an adverse effect. They also noted significant changes in fasting glucose as well as some important parameters like low-density lipoprotein cholesterol, systolic blood pressure and triglycerides at the 24-week mark. In the majority of cases (82%), patients were able to swallow it without sedation and general anesthesia was required only at the end of treatment during balloon removal. Furthermore, the Obalon device can be used starting at a lower threshold BMI (>30) respect to BIB or other intragastric balloons because of its minimum side effect and complication rates. Obalon device can be easily administered without anesthesia in the majority of patients (83%) and within 3 months it induces significant weight loss. Obalon® will prevent nausea and vomiting while being also efficient in terms of weight loss. A study including 17 patients with BMI ranging from 27 to 35 kg/m2 reported that 98% of balloons were swallowed successfully. Among the FDA approved IGBs the Obalon balloon is having significant weight loss with lower rate of complications.[31-32]

Adverse Effects:

Adverse events after IGB placement are common and similarly seen with all systems that are currently used. The rate of adverse events reported It is clear, however, that the majority of patients carrying a gastric balloon suffer from nausea and vomiting.[33]

II. CONCLUSION:

The long-term solution to cure obesity is basically diet and exercise to be continued on regular basis which is time consuming and it is not possible in today's run. The medication available for cure of obesity are not so healthy option and does not continue their effect for long time, so Obalon It offers a minimally invasive and effective method for managing obesity and associated conditions with moderate weight loss and minimum side effects. Obalon can be administered easily without complications, inducing an appreciable weight loss with a statistically significant reduction in BMI and an improvement in associated comorbidities. As more IGBs for obesity become available and multidisciplinary programs are developed to offer long-term follow-up, the treatment of obesity will continue to evolve. It shows promise in improving the quality of life and health status for obese patients, as for safety, efficacy, and cost effectiveness.

Conflict of interest: declare none

REFERENCES

[1]. Obesity and overweight Fact sheet N°311". WHO. January 2015. Retrieved 2 February 2016.
[2]. Haslam DW, James WP (October 2005). "Obesity". Lancet (Review). 366 (9492): 1197–1209.
[3]. Luppino FS, de Wit LM, Bouvy PF, Stijnen T, Cuijpers P, Penninx BW, Zitman FG (March 2010). "Overweight, obesity, and depression: a systematic review and meta-analysis of longitudinal studies". Archives of General Psychiatry. 67 (3): 2209.
[4]. Yazdi FT, Clee SM, Meyre D (2015). "Obesity genetics in mouse and human: back and forth, and back again". Peer J. 3: 856.
[5]. Yanovski SZ, Yanovski JA (January 2014). "Long-term drug treatment for obesity: a systematic and clinical review". JAMA (Review). 311 (1): 74 86.
[6]. Colquitt JL, Pickett K, Loveman E, Frampton GK (August 2014). "Surgery for weight loss in adults". The Cochrane Database of Systematic Reviews (Meta-analysis, Review). 8(8): CD003641
[7]. Afshin A, Forouzanfar MH, (July 2017). "Health Effects of Overweight and Obesity in 195 Countries over 25 Years". The New England Journal of Medicine. 377 (1): 13–27.
[8]. Kanazawa M, Yoshiike N, Osaka T, Numba Y, Zimmet P, Inoue S (2005). "Criteria and Classification of Obesity in Japan and Asia-Oceania". Nutrition and Fitness: Obesity, the Metabolic Syndrome, Cardiovascular Disease, and Cancer. World Review of Nutrition and Dietetics. 94. pp. 1–12.
[9]. Bleich S, Cutler D, Murray C, Adams A (2008). "Why is the developed world obese?". Annual Review of Public Health (Research Support). 29: 273–95.
[10]. Oxford Handbook of Medical Sciences (2nd ed.). Oxford: OUP Oxford. 2011. p. 180.
[11]. Kushner R (2007). Treatment of the Obese Patient (Contemporary Endocrinology). Totowa, NJ: Humana Press. p. 158.
[12]. Imaz I, Martínez-Cervell C, García-Alvarez EE, Sendra-Gutiérrez JM, González-Enríquez J (July 2008). "Safety and effectiveness of the intragastric balloon for obesity. A meta-analysis". Obesity Surgery. 18 (7): 841–6.
[13]. Ogunnaike BO, Jones SB, Jones DB, Provost D, Whitten CW. Anesthetic considerations for bariatric surgery. Anesth Analg. 2002;95(6):1793–805.
[14]. ASGE Technology Committee, Kethu SR, Banerjee S, Barth BA, Desilets DJ, KaulV, Endoluminal bariatric techniques. Gastrointest Endosc. 2012;76(1):1–7.
[15]. Majumder S, Birk J. A review of the current status of endoluminal therapy as a primary approach to obesity management. SurgEndosc.2013;27(7):2305–11.
[16]. Pasulka PS, Bistrian BR, Benotti PN, Blackburn GL. The risks of surgery in obese patients. Ann Intern Med.1986;104(4):540–6.
[17]. Dumonceau JM. Evidence-based review of the Bioenterics intra- gastric balloon for weight loss. Obes Surg.2008;18(12):1611–7.
[18]. Ulicny K, Goldberg SJ, Harper WJ, et al. Surgical complications of the Garren-Edwards Gastric Bubble. SurgGynecolObstet1988;166(6):535–40.
[19]. Mathus-Vliegen E. Endoscopic treatment: the past, the present and the future. Best Pract Res ClinGastroenterol2014;28(4):685–702.
[20]. Obalon. 2016. [Online]. Available at: http://www.obalon.com/. Accessed September 17,2016.
[21]. Apollo Endosurgery. Obera managed weight loss system. 2016. [Online]. Avail- able at: www.obera.com. Accessed September 17,2016.
[22]. Reshapen on-surgical weight loss procedure. Reshape Medical; 2016 [Online]. Available at: http://pro.reshapeready.com/about-reshape/. Accessed September 17,2016.
[23]. Gomez V. Baseline gastric emptying and its change in response to diverse endo-scopic bariatric therapies predict weight change after intervention. Obesity 2016;24(9):1849–53.
[24]. Mion F, Napoléon B, Roman S, et al. Effects of intragastric balloon on gastric emptying and plasma ghrelin levels in non-morbid obese patients. Obes Surg. 2005;15(4):510-516.
[25]. De Peppo, F., Caccamo, R., Adorisio, O., Ceriati, E., Marchetti, P., Contursi, A., Nobili, V. (2017). The Obalon swallowable intragastric balloon in pediatric and adolescent morbid obesity. Endoscopy International Open, 05(01), E59–E63.
[26]. Bennett, M. C., Badillo, R., & Sullivan, S. (2016). Endoscopic Management. Gastroenterology Clinics of North America, 45(4), 673–688.

[27]. Obalon[tm] gastric balloon instructions for use fdawww.obalon.com/patents/
[28]. Kim, S. H., Chun, H. J., Choi, H. S., Kim, E. S., Keum, B., &Jeen, Y. T. (2016). Current status of intragastric balloon for obesity treatment. World Journal of Gastroenterology, 22(24), 5495.
[29]. Ulicnyksjr, goldbergsj, harper wj, korelitzjl, podore pc, fegelmanrh. Surgical complications of the garren-edwards gastric bubble. Surggyne colobstet 1988; 166: 535-540.
[30]. Mion, F., Ibrahim, M., Marjoux, S., Ponchon, T., Dugardeyn, S., Roman, S., &Deviere, J. (2013). Swallowable Obalon® Gastric Balloons as an Aid for Weight Loss: A Pilot Feasibility Study. Obesity Surgery, 23(5), 730–733.
[31]. Farina, M. G., Baratta, R., Nigro, A., Vinciguerra, F., Puglisi, C., Schembri, R., …Frittitta, L. (2011). Intragastric Balloon in Association with Lifestyle and/or Pharmacotherapy in the Long-Term Management of Obesity. Obesity Surgery, 22(4), 565–571.
[32]. Lecumberri e, krekshi w, matia p, et al. Effectiveness and safety of air-filled balloon heliosphere bag(r) in 82 consecutive obese patients. Obessurg 2011; 21:1508-12.
[33]. Vyas d, deshpande k, pandya y. Advances in endoscopic balloon therapy for weight loss and its limitations. World j gastroenterol 2017; 23(44): 7813-7817.