

## ORIGINAL RESEARCH

# Comparative Analysis of Patients Undergoing Balloon Therapy- Alone vs Patients undergoing Balloon Therapy with Medical Management

<sup>1</sup>Dr. Darshan Agrawal, <sup>2</sup>Dr. Vinod Bhandari, <sup>3</sup>Dr. Manoj Kela, <sup>4</sup>Dr. Mohit Bhandari

<sup>1,2,3,4</sup>Department of Surgery, Sri Aurobindo Institute of Medical Sciences, Indore, Madhya Pradesh, India

### Corresponding author

Dr. Mohit Bhandari

Department of Surgery, Sri Aurobindo Institute of Medical Sciences, Indore, Madhya Pradesh, India

Received: 14 January, 2023

Accepted: 18 February, 2023

### ABSTRACT

**Background:** The present study was conducted for comparing Patients Undergoing Balloon Therapy Alone versus Patients undergoing Balloon Therapy with Medical Management.

**Materials & methods:** A total of 60 patients scheduled to undergo bariatric surgery were enrolled. Complete details of all the patients were recorded. All the patients were divided into two study groups as follows: SB Group- 30 patients in which balloon therapy was done alone while, SB+S Group- 30 patients undergoing Balloon Therapy with Medical Management Outcome was recorded separately. Assessment of all the results was done using SPSS Software.

**Results:** Mean age of the patients of the SB group and SB + S group was 42.7 years and 42.3 years respectively. 43.3 percent of the patients each of the SB group and SB + S group were females. Mean height of the patients of group SB and SB+S was 166.7±9.8 cm and 166.7±12.8 cm respectively. Mean total weight loss among the patients of SB group and SB+S group at 4 months interval was 15.6 percent and 20.9 percent respectively. Significant results were obtained while comparing the mean total weight loss among the patients of the two study groups. At less than 1 week, nausea and vomiting was seen in 23.3 percent of the patients of the SB group and 30 percent of the patients of the SB+S group.

**Conclusion:** Combination therapy of balloon with semaglutide is well tolerated over 4-months period and showed clinically relevant better weight loss and reduction in comorbidities with all doses as compared to balloon therapy alone.

**Key words:** Balloon therapy, Medical, Management

---

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-Non Commercial-Share Alike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

---

### INTRODUCTION

Obesity is a complicated metabolic condition brought on by an excessive buildup of body fat that can have detrimental effects on health. Obesity raises the risk of developing a number of disorders, including non-alcoholic fatty liver disease, hypertension, coronary heart disease, sleep apnea, stroke, gastroesophageal reflux disease, and gall bladder disease. Also, it significantly harms your health in a preventable way. Lifestyle modifications, pharmacological treatment, and bariatric surgery are the current therapeutic options for treating obesity. Although extensive lifestyle change was allegedly only partially connected with weight loss, when combined with long-term use weight-loss medications, an additional weight loss of 3%–9% can be achieved within a year.<sup>1-3</sup>

Although it is claimed that these medications reduce a number of cardiometabolic risk factors, they are also

associated with negative side effects. Despite the fact that new drugs for treating obesity have just been approved and made available, they are expensive and have safety concerns. The most long-lasting and efficient therapeutic option for obesity is weight-loss surgery. The adjustable gastric band, the Roux-en-Y gastric bypass, or the sleeve gastrectomy are accessible procedures. Despite the surgical procedure's demonstrated success, just 1% of obese people who are eligible for it opt to have it. Surgery has considerable accessibility problems, high prices, patient disinterest, and high morbidity and fatality rates. The complication rate in the early and late stages of the bariatric procedure remains around 17% (95% CI: 11%-23%), despite a significant decline in its related mortality.<sup>4-6</sup> The present study was conducted for comparing Patients Undergoing Balloon Therapy Alone versus Patients undergoing Balloon Therapy with Medical Management.

**MATERIALS & METHODS**

The present study was conducted for comparing Patients Undergoing Balloon Therapy Alone versus Patients undergoing Balloon Therapy with Medical Management. A total of 60 patients scheduled to undergo bariatric surgery were enrolled. Complete details of all the patients were recorded. All the patients were divided into two study groups as follows:

SB Group- 30 patients in which balloon therapy was done alone while,

SB+S Group- 30 patients undergoing Balloon Therapy with Medical Management

Outcome was recorded separately. Assessment of all the results was done using SPSS Software. Student t test along with chi-square test was used for evaluation

of level of significance. P-value of less than 0.05 was taken as significant.

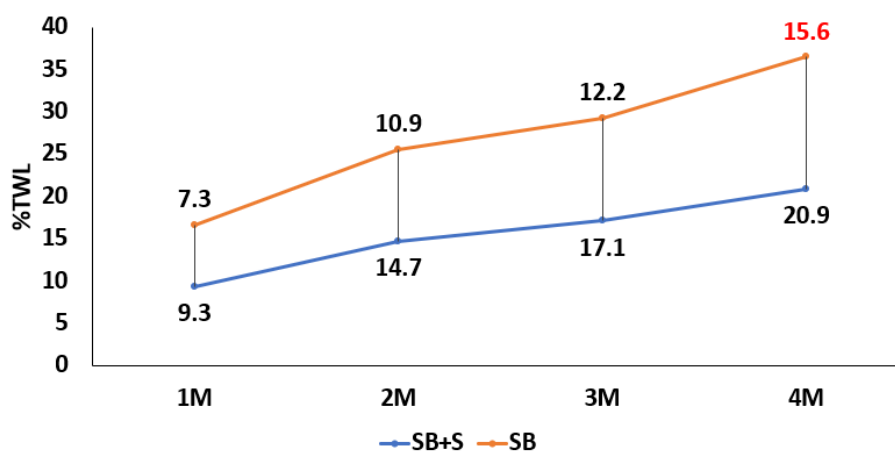
**RESULTS**

Mean age of the patients of the SB group and SB + S group was 42.7 years and 42.3 years respectively. 43.3 percent of the patients each of the SB group and SB + S group were females. Mean height of the patients of group SB and SB+S was 166.7±9.8 cm and 166.7±12.8 cm respectively. Mean total weight loss among the patients of SB group and SB+S group at 4 months interval was 15.6 percent and 20.9 percent respectively. Significant results were obtained while comparing the mean total weight loss among the patients of the two study groups. At less than 1 week, nausea and vomiting was seen in 23.3 percent of the patients of the SB group and 30 percent of the patients of the SB+S group.

**Table 1: Demographic variables**

Variable	SB (n=30)	SB+S(n=30)	p-value
Age	42.7±12.3	42.3±13.3	0.132
Gender (Female)	13(43.3%)	13(43.3%)	1
Height	166.7±9.8	166.7±12.8	0.315
Weight	110.5±18.2	113.0±29.4	0.628
BMI	39.2±4.3	39.9±10.4	0.441
T2DM	9(30%)	9(30%)	1
HTN	8(26.6%)	8(26.6%)	1

**Graph 1: Comparison of total weight loss (TWL%)**



**Table 2: Incidence of nausea and vomiting**

Nausea and Vomiting	SB	SB+S
<1 week	23.3%	30%
>1 week	None	None

**DISCUSSION**

Intragastric balloons have offered a less invasive alternative to surgery for overweight and obese individuals. Although more effective than drugs, diet, and exercise, balloon uptake has been limited due to the need for endoscopy for placement and removal. In morbidly obese patients, it is recommended as a less invasive treatment than bariatric surgery. Although

commercially available intragastric balloons are all somewhat different, in general they have been shown to have comparable weight loss results.<sup>6- 9</sup>The intragastric balloon (IGB) probably set the starting point of endoscopic bariatric therapy. Depending on the system, an empty balloon is introduced into the stomach by means of a gastroscopy or by just swallowing a capsule. The balloon is then inflated with air or saline to varying volumes. This reduces the

stomach volume, resulting in a feeling of satiety which shall then lead to weight loss. The treatment is limited to 6 months for most systems. Ideally the procedure is imbedded in a continuous weight loss program, and the patient is supported by an interdisciplinary team of healthcare professionals.<sup>8-10</sup>Hence; the present study was conducted for comparing Patients Undergoing Balloon Therapy Alone versus Patients undergoing Balloon Therapy with Medical Management.

Mean age of the patients of the SB group and SB + S group was 42.7 years and 42.3 years respectively. 43.3 percent of the patients each of the SB group and SB + S group were females. Mean height of the patients of group SB and SB+S was 166.7±9.8 cm and 166.7±12.8 cm respectively. Mean total weight loss among the patients of SB group and SB+S group at 4 months interval was 15.6 percent and 20.9 percent respectively. Ribeiro da Silva, et al assessed the safety, tolerance, and kinetics of IGBs (Intragastric balloons) in weight loss. The study included 51 patients who had undergone Orbera® IGB placement between September 2014 and February 2016. Inclusion criteria were age between 18 and 65 years; body mass index (BMI) 28–35 with severe obesity-related disorders; or BMI 35–40. The IGB was removed 6 months later. All patients were followed for a minimum period of 6–12 months. Of 51 patients, 16 were excluded (7 due to intolerance) and 35 patients entered the study, of which 83% were followed for more than 6–12 months. The average weight loss (WL) and % excess WL (%EWL) after 6 months of treatment were 11.94 kg and 42.16%, respectively. At 6–12 months, after removal of the IGB, the mean WL was 8.25 kg and %EWL was 30.27%. Nineteen patients attained a WL of ≥10% the baseline value at IGB removal and 12 maintained their weight below this threshold during the 6–12 following months. After temporary IGB implantation in overweight or obese individuals, a WL that was ≥10% of weight at baseline was achieved in 54.3% and sustained at 6–12 months in 41.4% of participants.<sup>11</sup>

Significant results were obtained while comparing the mean total weight loss among the patients of the two study groups. At less than 1 week, nausea and vomiting was seen in 23.3 percent of the patients of the SB group and 30 percent of the patients of the SB+S group. Haddad, A. E et al analyzed the long-term results regarding the effectiveness, tolerability, and patient satisfaction in a cohort of patients undergoing the IGB insertion. Ninety-nine eligible patients were contacted, and 65 consented to the study. The average weight loss achieved at the end of the treatment period (3 to 10 months) was approximately a 12% decrease from the baseline. Only 39% of patients were satisfied with the procedure, and less than 50% were satisfied with the weight loss achieved. When assessing the long-term follow-up, years after the IGB removal (3.3±1.76

years), the vast majority of patients (78.7%) regained weight or resorted to further bariatric measures. IGB leads to weight loss among most patients, but it does not appear to fulfill patients' expectations. Further, the initial weight loss is not sustainable over time.<sup>12</sup>

## CONCLUSION

Combination therapy of balloon with semaglutide is well tolerated over 4-months period and showed clinically relevant better weight loss and reduction in comorbidities with all doses as compared to balloon therapy alone. Long term multicentric studies are required for further validation of study.

## REFERENCES

- Mitura K, Garnysz K. In search of the ideal patient for the intragastric balloon - short- and long-term results in 70 obese patients. *WideochirInne Tech Maloinwazyjne*. 2016;10:541–547.
- Ginsberg GG, Chand B, Cote GA, Dallal RM, Edmundowicz SA, Nguyen NT, Pryor A, Thompson CC. A pathway to endoscopic bariatric therapies. *GastrointestEndosc*. 2011;74:943–953.
- Mathus-Vliegen EM, de Groot GH. Fasting and meal-induced CCK and PP secretion following intragastric balloon treatment for obesity. *Obes Surg*. 2013;23:622–633.
- Forestieri P, De Palma GD, Formato A, Giuliano ME, Monda A, Pilone V, Romano A, Tramontano S. Heliosphere Bag in the treatment of severe obesity: preliminary experience. *Obes Surg*. 2006;16:635–637.
- De Castro ML, Morales MJ, Del Campo V, Pineda JR, Pena E, Sierra JM, Arbones MJ, Prada IR. Efficacy, safety, and tolerance of two types of intragastric balloons placed in obese subjects: a double-blind comparative study. *Obes Surg*. 2010;20:1642–1646.
- Giardiello C, Borrelli A, Silvestri E, Antognozzi V, Iodice G, Lorenzo M. Air-filled vs water-filled intragastric balloon: a prospective randomized study. *Obes Surg*. 2012;22:1916–1919.
- Dumonceau JM. Evidence-based review of the Bioenterics intragastric balloon for weight loss. *Obes Surg*. 2008;18:1611–1617.
- Phillips RJ, Powley TL. Gastric volume rather than nutrient content inhibits food intake. *Am J Physiol*. 1996;271:R766–R769.
- Kojima M, Hosoda H, Date Y, Nakazato M, Matsuo H, Kangawa K. Ghrelin is a growth-hormone-releasing acylated peptide from stomach. *Nature*. 1999;402:656–660.
- Genco A, Balducci S, Bacci V, Matera A, Cipriano M, Baglio G, Ribaudo MC, Maselli R, Lorenzo M, Basso N. Intragastric balloon or diet alone? A retrospective evaluation. *Obes Surg*. 2008;18:989–992.
- Ribeiro da Silva, J., Proença, L., Rodrigues, A., Pinho, R., Ponte, A., Rodrigues, J., Sousa, M., Almeida, R., & Carvalho, J. (2018). Intragastric Balloon for Obesity Treatment: Safety, Tolerance, and Efficacy. *GE Portuguese journal of gastroenterology*, 25(5), 236–242. <https://doi.org/10.1159/000485428>
- Haddad, A. E., Rammal, M. O., Soweid, A., Shararra, A. I., Daniel, F., Rahal, M. A., & Shaib, Y. (2019). Intragastric balloon treatment of obesity: Long-term results and patient satisfaction. *The Turkish journal of*

gastroenterology : the official journal of Turkish Society of Gastroenterology, 30(5), 461–466.