Obesity Facts

Obes Facts , DOI: 10.1159/000531459
Received: February 25, 2023
Accepted: May 23, 2023
Published online: August 14, 2023

# Efficacy of intragastric balloon vs liraglutide as bridge to surgery in super-obese patients.

Martines G, Dezi A, Giove C, Lantone V, Rotelli MT, Picciariello A, Tomasicchio G

ISSN: 1662-4025 (Print), eISSN: 1662-4033 (Online)
https://www.karger.com/OFA
Obesity Facts

**Efficacy of intragastric balloon vs liraglutide as bridge to surgery in super-obese patients.**

Gennaro Martines[a], Agnese Dezi[a], Carlo Giove[a], Valerio Lantone[a], Maria Tersa Rotelli[a], Arcangelo Picciariello[a], Giovanni Tomasicchio[a*]
[a]: General Surgery Unit "M. Rubino", Department of Precision and Regenerative Medicine and Jonic Area (DiMePRe-J), University of Bari Aldo Moro, Bari, Italy

**Running title**
Efficacy of two-stage management in super-obese patients

**Corresponding Author**:
Giovanni Tomasicchio
Department of Precision and Regenerative Medicine and Jonic Area (DiMePRe-J)
General Surgery Unit "M. Rubino", University of Bari Aldo Moro, Bari, Italy
Azienda Ospedaliero Universitaria Policlinico, University of Bari, Piazza G Cesare, 11, 70124, Bari, Italy.
Tel: +39 3335463536
E-mail address: giovannitomasicchio92@gmail.com

**Number of Tables**: 3
**Number of Figure**: 2
**Word count**: 2579

**Keywords**: obesity, intragastric balloon, liraglutide, sleeve gastrectomy, weight loss



**Abstract**
**Introduction**
Bariatric surgery is a safe and effective treatment for obesity, although in super obese patients (BMI ≥ 50 kg/m$^2$) it can become challenging for anatomical and anaesthesiologic issues. Several bridging therapies have been proposed to increase preoperative weight loss and decrease perioperative morbidity and mortality. The aim of this study was to compare the efficacy and safety of different two-stage approaches in super obese patients: laparoscopic sleeve gastrectomy (LSG) following preoperative liraglutide therapy *vs* LSG with preoperative IGB (intragastric balloon) during a 1-year follow-up.
**Methods**
Clinical records of 86 patients affected by super-obesity who underwent two stage approach between January 2019 and January 2022 were retrospectively reviewed using a prospectively maintained database. Patients were separated into two groups: those managed with preoperative IGB and those with liraglutide 3.0 mg prior to LSG. Weight (Kg), BMI (kg/m$^2$), %EWL and %EWBL were reported and compared between the two groups at the end of bridging therapy, at 6$^{th}$ month and 12$^{th}$ month postoperatively. Postoperative complications were recorded.
**Results**
Forty-four patients underwent IGB insertion prior to LSG, while forty-two were treated with liraglutide. There were no statistical differences in baseline weight and BMI. At the end of pre-operative treatment, the group treated with intragastric balloon reported a significant reduction in BMI (47.24 kg/m$^2$ vs 53.6 kg/m$^2$; $p$<0.391) compared to liraglutide group. There were no differences recorded between the two groups concerning post-operative complications. At 6 months the liraglutide group had lower %EWL (15.8 *vs* 29.84; *p<0.05*) and %EWBL (27.8 *vs* 55.6; *p<0.05*) when compared to intragastric balloon group. At 12 months the intragastric balloon preserved the with higher %EWL (39.9 *vs* 25; *p<0.05*) and %EWBL (71.2 *vs* 42; *p<0.05*).
**Conclusion**

A two-stage therapeutic approach with intragastric balloon prior to laparoscopy sleeve gastrectomy in super-obese patients could be considered an attractive alternative to liraglutide as bridging therapy before bariatric surgery.

**Introduction**

The worldwide prevalence rates of obesity have approximately doubled since 1980 to an extent that over one-third of the world's population is now classified as overweight or obese [1]. Obesity is closely linked to multiple disease conditions: type 2 diabetes, hypertension, cardiovascular disease, dyslipidaemia, obstructive sleep apnoea, non-alcoholic fatty liver disease (NAFLD) and several types of cancer, all of which have negative impact on the quality of life [2, 3]. To date, bariatric surgery is considered the most effective strategy in achieving long-term weight loss, with remission of related comorbidities and decrease of mortality [4]. Whilst bariatric surgery is a safe treatment, with low rate of perioperative morbidity and mortality, in super-obese patients (BMI ≥ 50 kg/m$^2$) it can be challenging because of difficulties in exposure caused by visceral fat, excessive visceral obesity, fatty liver retraction, and strong torque applied to laparoscopic instruments, as well as anaesthesiologic issue [5]. Moreover, these patients suffer from complex health issues, with increased morbidity and mortality [6].

Therefore, the increased risk associated with these patients, led to the creation of several therapeutic strategies with two stage approach including the use of an intragastric balloon (IGB) or medical treatment, as liraglutide, to achieve weight loss, before definitive surgery [7, 8].

Intragastric balloon is an FDA (Food and Drug Administration) approved treatment for obese patients, offering a potentially safe and less invasive method for reducing gastric capacity and inducing weight loss with a lower complication rate than bariatric surgery [9]. The use of IGB alone with lifestyle changes has demonstrated an excess weight loss of 10 % and BMI drop of 3.8 at 60 months in super obese patients [10].

Liraglutide is a long-acting analogue of glucagon-like peptide-1 (GLP-1), binds to GLP-1 receptors found in the peripheral and central nervous system, pancreas, intestine, kidney, stomach, heart. It was initially approved by FDA for medical treatment of type 2 diabetes and then for chronic weight management [11]. Hight dose liraglutide (3.0 mg) is frequently used to promote weight reduction before surgery. It acts by: slowing down gastric emptying time and regulating appetite by inducing a feeling of satiety [12, 13].

The aim of this retrospective study was to compare the efficacy and safety of different two stage approaches in super obese patients: laparoscopic sleeve gastrectomy (LSG) with preoperative liraglutide therapy *vs* LSG with preoperative IGB during a 1-years follow-up.

**Materials and Methods**

A single centre, retrospective observational study was carried out using a prospectively maintained database of obese patients undergoing LSG in a tertiary referral centre for bariatric treatment. The analysis examines patients managed between January 2019 and January 2022. Patients over 18 years of age, with a body mass index (BMI) ≥ 50 kg/m$^2$ with or without obesity-related comorbidity and those who completed a 1-year follow-up were included in the study. Exclusion criteria were the prior use of GLP-1 agonist or IGB therapy, personal or family history of medullary thyroid carcinoma (MTC), personal or family history of multiple endocrine neoplasia (MEN), past history of pancreatitis, hepatic dysfunction (AST/ALT > 3 times normal value), renal dysfunction (eGFR < 45ml/min/1.73 m$^2$), previous bariatric or gastric surgery, acute coronary syndrome in previous 6 months, intolerance or allergy to liraglutide, discontinuation of IGB or liraglutide therapy, pregnancy or breastfeeding, patients with a large hiatal hernia or >5 cm hernia or ≤5 cm with associated severe or intractable gastro-esophageal reflux symptoms and those who had an allergic reaction to materials contained in IGB. All the patients provided informed consent for surgery after thorough explanation and counseling of the benefit-risk ratio.

Patients fulfilling the inclusion criteria were asked to express a preference after discussing potential benefits and complications of both treatments. In the first group obese patients were treated with an End-Ball™ (Medimar S.r.l. Unipersonale. Via Ebro, 8 -20141 Milano) Intragastric Balloon. The deflated elastic spherical balloon, made of polyurethane, preloaded on a catheter, was advanced trans-orally into the stomach. An endoscope was then advanced alongside it, to ensure accurate placement of the balloon in the fundus. Under direct visualization, the balloon was then inflated by injecting 650 ml of saline solution mixed with methylene blue through the external portion of the catheter. The End-Ball™ Intragastric Balloon was implanted for 24 weeks and then retrieved

endoscopically by puncturing the balloon with a needle, emptying the fluid content, and removing it through the mouth. Placement of the End-Ball™ Balloon was done as an outpatient procedure without general anesthesia, whereas removal was performed in the operating room under general anesthesia. Three weeks after IGB removal, LSG was planned. Possible nausea, vomiting and fluid intolerance were treated with medical therapy.
The second group of patients was treated with liraglutide therapy before undergoing definitive LSG. Medical treatment was administered using a multidose pen injector. The starting dose of liraglutide was 0.6 mg/day administered subcutaneously. This was increased weekly by 0.6 mg up to the maximal dose of 3 mg until 24 weeks. Only patients that reached the maximal dose were included into the study. Patients were trained to self-administer the injection.
Demographic data were collected including age, gender, weight (Kg), BMI (kg/m$^2$) and comorbidities. Patients were revaluated in outpatient setting after 24 weeks of IGB and/or liraglutide therapy, evaluating weight (Kg), BMI (kg/m$^2$), excess weight loss (%EWL) and excess body weight loss (%EBWL). Percent weight loss was calculated by dividing the absolute pounds lost by the patient's initial weight. Percent excess body weight loss (%EBWL) was calculated by dividing the difference between initial BMI and final BMI by the difference between initial BMI and a "normal" target BMI. In this study, %EBWL was calculated using a reference normal BMI of 25 kg/m$^2$ [14].
Postoperative complications of LSG were recorded in accordance with the published Clavien–Dindo classification [15]. At 6- and 12-months follow-up, all patients underwent outpatient setting evaluation and were assessed for weight, BMI, %EWL and %EBWL. Permission for the conduct of this retrospective analysis was provided by the local hospital Ethics Committee. All investigations complied with the principles of the Declaration of Helsinki.

**Statistical analysis**
Continuous parameters were reported as median and interquartile ranges. Categorical variables were recorded as numbers and percentages where appropriate. Comparisons of categorical variables were performed by the $\chi 2$ and Fisher's exact test where appropriate. Comparisons between groups were made using the Mann–Whitney U test. A *p*-value <0.05 was considered statistically significant. Statistical analysis was carried out using RStudio (R version 4.0.3 10/ 10/2020 Copyright© 2020, The R Foundation for Statistical
Computing).

**Results**
A total of 86 patients affected by super-obesity were treated with two-stage management. Forty-four (median age 41.5 years, IQR 37.5 – 49.2, 77% women) of them (51%) underwent IGB prior to LSG, while forty-two (median age 41 years, IQR 35.5 – 48, 93% women) were treated with liraglutide therapy prior to definitive surgery Figure 1. There were no significant differences in terms of gender, age, comorbidities such as cardiovascular disease, diabetes mellitus, chronic respiratory disease, and osteoarthritis. All patients were affected by super-obesity (BMI ≥ 50 kg/m$^2$) without significant difference in terms of weight (151 Kg, IQR 140-163 *vs* 145 Kg, IQR 133.5 – 164.5; *p*=0.302) and BMI (55.9 kg/m$^2$, IQR 53.3 – 59.3 vs 57.5 kg/m$^2$, IQR 51.2- 59.2; *p*= 0.391). The baseline characteristics of the groups are reported in ***Table 1***.
At the end of pre-operative treatment, the group treated with intragastric balloon reported a significant difference in weight (125 Kg, IQR 119-130 *vs* 136.5 Kg, IQR 125.5 – 154.5; *p<0.05*) and BMI (47.24 kg/m$^2$, IQR 46.2-48.9 vs 53.6 kg/m$^2$, IQR 47.7-55.8; *p*<0.391) compared to liraglutide group. The median percentage of weight loss (%EWL 15.5, IQR 13-18.7 *vs* 6.71, IQR 5.8 – 7.4; *p<0.05*) and the median percentage of excess body weight loss (%EBWL 28.5, IQR 24.8 – 33.07 *vs* 11.8, IQR 10.3- 14.3; *p<0.05*) were significantly higher in IGB group when compared to liraglutide group.
In all patients, sleeve gastrectomy was performed laparoscopically without the need for open conversion. There were no differences recorded between the two groups concerning post-operative complications according to Clavien-Dindo grade (***Table 2***). The two leaks recorded in the group 1 and the one in the second group were all successfully managed with laparoscopic peritoneal lavage and insertion of a silicon drain in the subdiaphragmatic space. There was no mortality in the immediate post-operative period.
The relationship between different two-stage management and BMI, %EWL and %EBWL at 6 and 12 months is show in ***Figure 2***. At 6 months the liraglutide group had a significantly higher weight (124 Kg, IQR 109.5 – 141 *vs* 101, IQR 99-107; *p<0.05*) and BMI (47.5 kg/m$^2$, IQR 41.1 – 53 *vs* 38.9 kg/m$^2$, IQR 39.10 – 40.5; *p<0.05*) with lower %EWL (15.8, IQR 11.1 – 21.1 *vs* 29.84, IQR 26.8-34.6; *p<0.05*) and %EWBL (27.8, IQR 19.6 – 38.9 *vs* 55.6, IQR 49.9 - 61.7; *p<0.05*) when compared to intragastric balloon group. Furthermore, at 12 months the intragastric balloon

group preserved the lower weight ( 89 Kg, IQR 85 – 91 *vs* 112, IQR 95.2 – 128.75; *p<0.05*) and BMI ( 33.9 kg/m$^2$, IQR 32.2 – 35 *vs* 41.8 kg/m$^2$, IQR 36.8 – 48.9; *p<0.05*) with higher %EWL (39.9, IQR 37.6 – 42.9 *vs* 25, IQR 16.8-31; *p<0.05*) and %EWBL (71.2, IQR 68.8 – 76.5 *vs* 42, IQR 24.5 -64; *p<0.05*) compared to liraglutide group (***Table3***).

**Discussion**

Bariatric surgery in super-obese (BMI ≥ 50 kg/m$^2$) patients is a challenging treatment due to increased size of organs, excessive intraperitoneal fat and increased perioperative risk related to the high rate of associated medical conditions such as hypertension, type II diabetes mellitus, hepatic steatosis, cardiac and respiratory comorbidities [16]. Moreover, it has been widely shown that bariatric surgery is an effective and safe treatment but in super-obese patients the therapeutic success is often less favourable with high rate of morbidity and mortality due to the increased risk of severe complications, such as pulmonary embolism [17].

In literature, the degree of bariatric surgery risk reduction is strictly linked with the decrease in median preoperative weight [18, 19], for this reason different types of bridging therapies have been proposed but, to date, there are no standard international guidelines and/or recommendations regarding the preoperative management of super-obese patients [20].

Liraglutide is one of the currently approved pharmacotherapies for obesity based on gut hormones. This long-acting analogue of GLP-1 in combination with a healthy, low calory diet showed a 6-8% weight loss in adult without diabetes and 6% weight loss in patients with type II diabetes [13]. In our study, the group treated with 6 months of liraglutide 3 mg therapy, prior to definitive bariatric surgery, had a median %EWL of 6.71 and %EBWL of 11.8 with a reduction of the BMI at median value of 53.6 kg/m$^2$. These important results were obtained by including only patients who underwent liraglutide 3 mg therapy continuously for 6 months. Furthermore, liraglutide efficacy was reported as long-term maintenance of weight loss in the SCALE-maintenance study, after 4-12 weeks of diet, liraglutide 3 mg showed a further 6% weight loss at 56 weeks compared with 0.2% of placebo [21]. Our cohort of liraglutide patients after 6 months of bridging medical therapy underwent definitive bariatric surgery with short- and long-term weight reduction. After 6 months, of strict and rigorous outpatient follow-up, the group had an %EWL of 15.8 with a %EBWL of 27.8 and a reduction of BMI to median value of 47.5 kg/m$^2$, this reduction of body weight increased at 12 months at a median %EWL of 25, % EBWL of 42 and a definitive reduction of BMI at 41.86 kg/m$^2$, underling the long-term maintenance of weight loss. Hakim et al. [7], in a recent observational prospective study, demonstrated an incidence of adhesion in 22.2% of patients undergoing LSG after preoperative liraglutide intake. The risk of adhesion was reported in patients with a history of cessation of liraglutide due to abdominal pain, which could be explained by bouts of acute pancreatitis. However, none of the cases with adhesions had any complications. In our cohort of patients, we didn't find intraoperative adhesions, and there were no statistical differences in term of post-operative complication according to Clavien–Dindo classification between two groups. We reported only one post-operative leak in liraglutide group compared to two leaks in IGB group (*p*=1). It is still unclear if the adhesion risk in patients treated with liraglutide could increase intra/post-operative complications.

In literature, different authors investigated the role of IGB as bridging therapy in super-obese patients [22, 10, 20] without uniformity of results in term of weight loss. Ashrafian et al. [10] suggested the use of definitive bariatric surgery after IGB removal to continue weight loss and maintain it over a long time. They reported a transient fast short-term weight reduction (%EWL 18%) at 18 months associated with weight regain at 5 years with %EWL of 9%. Meanwhile, IGB with subsequent LSG at 5 years showed a EWL of 52.8%. In line with this study, our results showed a EWL of 39.9% and EBWL of 71.2% with a statistically significant difference compared to the group treated with medical therapy prior to surgery. Conversely, Hering et al. [8] and Banks et al. [23] reported comparable weight loss in patients without IGB prior to LSG, at 12 month and 24 months respectively. However, both these studies included a very small number of patients, precluding a definitive comment on this subject. This variability in reported outcomes could be associated with the baseline heterogeneity of super-obese patients in term of: baseline BMI, comorbidities and different type of balloon received. The decrease of visceral fat tissue and of organ size could improve technical operability, reducing intra and post-operative complications. However, previous authors [24, 23] showed higher complications and length of hospital stay in patients who received IGB prior to surgery. The application of IGB is a safe technique but often leads to a gastric fundal inflammation, hypertrophy and fibrosis of the gastric wall that could increase the risk of leakage from the staple line after LSG [25, 26]. In contrast Busetto et al. [27] and Zerrweck et al. [28] reported decreased intraoperative conversion to open surgery, intra-operative time and length of stay in the cohort of patients treated with IGB prior to definitive surgery. To reduce severe side effects, Hering et al. [8], in line with our methods, suggested a time interval of 21

days between IGB removal and bariatric surgery thus allowing resolution of gastric inflammation and hypertrophy. Moreover, during bridging therapy with IGB, they reported a spike of weight loss at 3 months followed by a plateau and even a slight weight regain at 5 months, suggesting a reduction of preconditioning period to reduce peri-operative complications such as: perforation, nausea, vomiting and dehydration. In our cohort of patients there was no mortality in the immediate post-operative period, without the need for open conversion in any case and with no statistical differences recorded between the two groups concerning post-operative complications. However, we reported more post-operative leaks compared to the liraglutide groups.
To date, there are no other studies comparing the efficacy and safety of laparoscopic sleeve gastrectomy with preoperative liraglutide therapy *vs* LSG with preoperative IGB during a 1-year follow-up in super-obese patients. The main limitations of this study are the single centre experience, limited follow-up, and its retrospective nature, which opens it to possible selection bias. Prospective, multi-centre, and long-term follow-up research studies are needed.

**Conclusion**

A two-stage therapeutic approach with intragastric balloon prior to laparoscopy sleeve gastrectomy in super-obese patients could be considered an attractive alternative to liraglutide for preoperative optimization before bariatric surgery. This invasive pre-operative therapy provides additional benefits for short- and long-term weight loss, without increasing perioperative complications.

**Author Contributions**

Conceptualization: GT and GM; Methodology: GT, AD, CG, VL and GM. Data curation: GT, AD, CG, VL, MTR and GM; Writing - Original draft preparation: GT, AP, AD, GM; Writing - Reviewing and Editing: all authors. All authors contributed to the article and approved the submitted version.

**Funding Sources**

This research did not receive any specific funding from any agencies in the public, commercial, or not-for-profit areas.

**Conflict of Interest/Disclosure**

The authors have no conflicts of interests or disclosures to report.

**Data availability statement**

All data generated or analysed during this study are included in this article. Further enquiries can be directed to the corresponding author.

**Ethics statement**

The studies involving human participants were reviewed and approved by the Ethics Committee of “Azienda Ospedaliera Universitaria Policlinico di Bari”. The patients/participants provided their written informed consent to participate in this study. This study protocol was reviewed and approved the Ethics Committee of “Azienda Ospedaliera Universitaria Policlinico di Bari”, approval number 835512/date:15/06/2022."

**Figure Legend**

**Figure 1:** Included patients flowchart (GLP-1: glucagon-like peptide-1,IGB: intragastric balloon, LSG: laparoscopy sleeve gastrectomy)

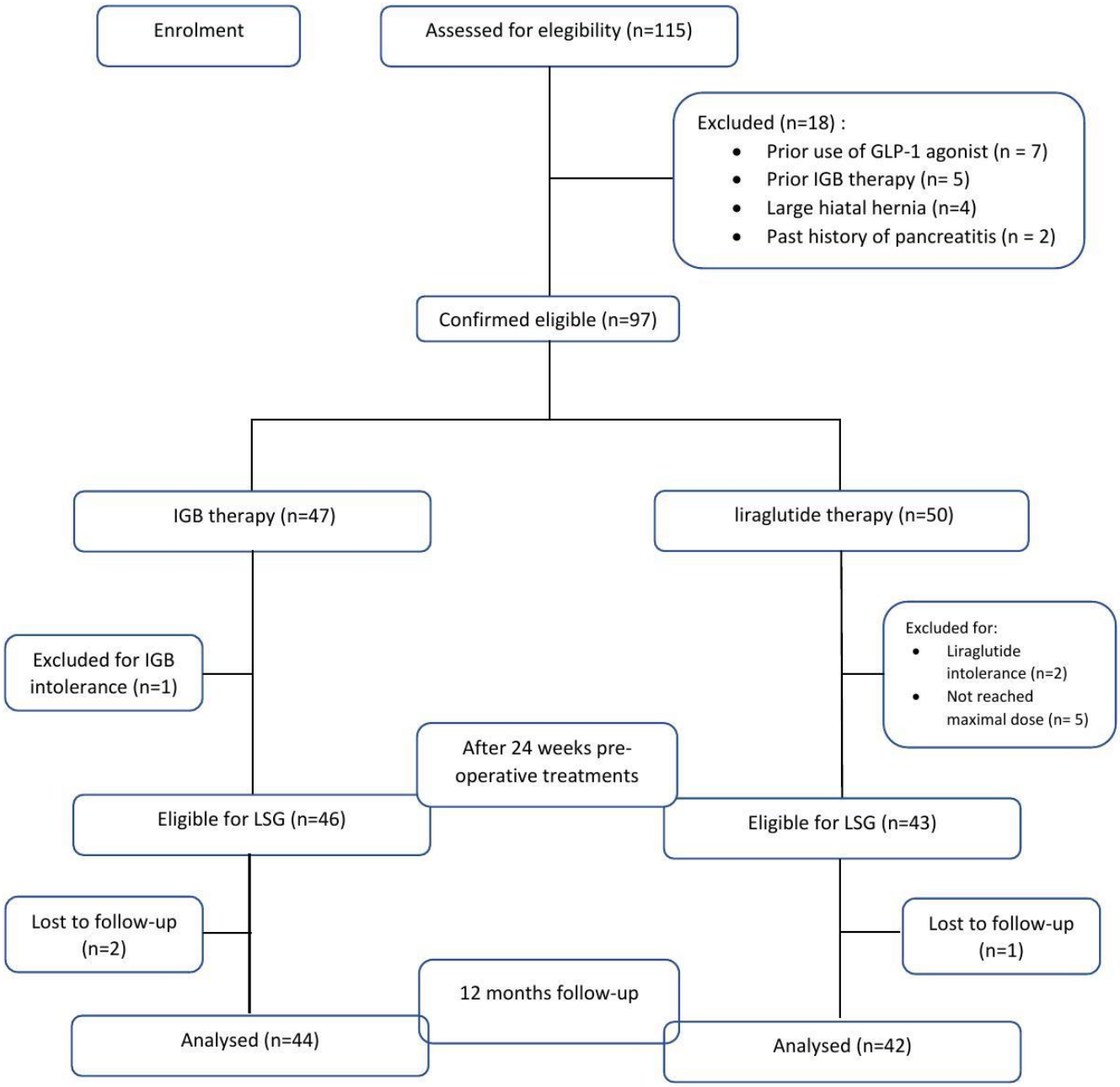
**Figure 2:** The relationship between intragastric balloon (IGB) (with blue) and liraglutide (Lira) (with red) management and body mass index (BMI), excess weight loss (%EWL) and excess body weight loss (%EBWL) at 6 and 12 months

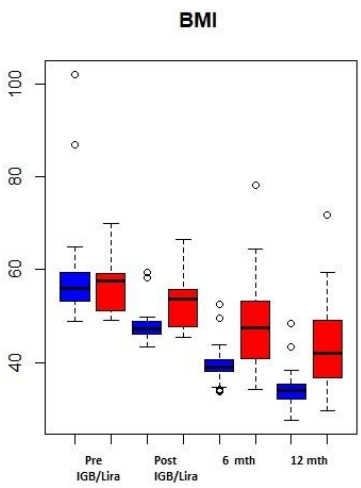
Bibliography

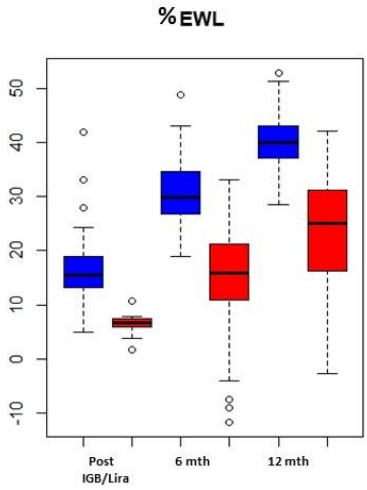
1. Chooi YC, Ding C, Magkos F. The epidemiology of obesity. Metabolism. 2019 Mar;92:6-10.
2. Misra A, Khurana L. Obesity-related non-communicable diseases: South Asians vs White Caucasians. Int J Obes (Lond). 2011 Feb;35(2):167-87.

3. Avgerinos KI, Spyrou N, Mantzoros CS, Dalamaga M. Obesity and cancer risk: Emerging biological mechanisms and perspectives. Metabolism. 2019 Mar;92:121-35.
4. Kuno T, Tanimoto E, Morita S, Shimada YJ. Effects of Bariatric Surgery on Cardiovascular Disease: A Concise Update of Recent Advances. Front Cardiovasc Med. 2019;6:94.
5. Dupree A, El Gammal AT, Wolter S, Urbanek S, Sauer N, Mann O, et al. Perioperative Short-Term Outcome in Super-Super-Obese Patients Undergoing Bariatric Surgery. Obes Surg. 2018 Jul;28(7):1895-901.
6. Peterson K, Anderson J, Boundy E, Ferguson L, Erickson K. Rapid Evidence Review of Bariatric Surgery in Super Obesity (BMI >/= 50 kg/m(2)). J Gen Intern Med. 2017 Apr;32(Suppl 1):56-64.
7. Hakim M, Fathi M, Abdulraziq M, Al Shehri M. Incidence of adhesions in patients using liraglutide before laparoscopic sleeve gastrectomy. Surg Endosc. 2022 Nov;36(11):8503-08.
8. Hering I, Dorries L, Flemming S, Krietenstein L, Koschker AK, Fassnacht M, et al. Impact of preoperative weight loss achieved by gastric balloon on peri- and postoperative outcomes of bariatric surgery in super-obese patients: a retrospective matched-pair analysis. Langenbecks Arch Surg. 2022 Aug;407(5):1873-79.
9. Tate CM, Geliebter A. Intragastric Balloon Treatment for Obesity: Review of Recent Studies. Adv Ther. 2017 Aug;34(8):1859-75.
10. Ashrafian H, Monnich M, Braby TS, Smellie J, Bonanomi G, Efthimiou E. Intragastric balloon outcomes in super-obesity: a 16-year city center hospital series. Surg Obes Relat Dis. 2018 Nov;14(11):1691-99.
11. Monami M, Dicembrini I, Marchionni N, Rotella CM, Mannucci E. Effects of glucagon-like peptide-1 receptor agonists on body weight: a meta-analysis. Exp Diabetes Res. 2012;2012:672658.
12. le Roux C, Aroda V, Hemmingsson J, Cancino AP, Christensen R, Pi-Sunyer X. Comparison of Efficacy and Safety of Liraglutide 3.0 mg in Individuals with BMI above and below 35 kg/m(2): A Post-hoc Analysis. Obes Facts. 2017;10(6):531-44.
13. Papamargaritis D, le Roux CW, Holst JJ, Davies MJ. New therapies for obesity. Cardiovasc Res. 2022 Nov 30.
14. Hatoum IJ, Kaplan LM. Advantages of percent weight loss as a method of reporting weight loss after Roux-en-Y gastric bypass. Obesity (Silver Spring). 2013 Aug;21(8):1519-25.
15. Clavien PA, Barkun J, de Oliveira ML, Vauthey JN, Dindo D, Schulick RD, et al. The Clavien-Dindo classification of surgical complications: five-year experience. Ann Surg. 2009 Aug;250(2):187-96.
16. Nguyen NT, Magno CP, Lane KT, Hinojosa MW, Lane JS. Association of hypertension, diabetes, dyslipidemia, and metabolic syndrome with obesity: findings from the National Health and Nutrition Examination Survey, 1999 to 2004. J Am Coll Surg. 2008 Dec;207(6):928-34.
17. Sapala JA, Wood MH, Schuhknecht MP, Sapala MA. Fatal pulmonary embolism after bariatric operations for morbid obesity: a 24-year retrospective analysis. Obes Surg. 2003 Dec;13(6):819-25.
18. Van Nieuwenhove Y, Dambrauskas Z, Campillo-Soto A, van Dielen F, Wiezer R, Janssen I, et al. Preoperative very low-calorie diet and operative outcome after laparoscopic gastric bypass: a randomized multicenter study. Arch Surg. 2011 Nov;146(11):1300-5.
19. Anderin C, Gustafsson UO, Heijbel N, Thorell A. Weight loss before bariatric surgery and postoperative complications: data from the Scandinavian Obesity Registry (SOReg). Ann Surg. 2015 May;261(5):909-13.
20. Loo JH, Lim YH, Seah HL, Chong AZQ, Tay KV. Intragastric Balloon as Bridging Therapy Prior to Bariatric Surgery for Patients with Severe Obesity (BMI >/= 50 kg/m(2)): a Systematic Review and Meta-analysis. Obes Surg. 2022 Feb;32(2):489-502.
21. Wadden TA, Hollander P, Klein S, Niswender K, Woo V, Hale PM, et al. Weight maintenance and additional weight loss with liraglutide after low-calorie-diet-induced weight loss: The SCALE Maintenance randomized study. Int J Obes (Lond). 2015 Jan;39(1):187.
22. Yorke E, Switzer NJ, Reso A, Shi X, de Gara C, Birch D, et al. Intragastric Balloon for Management of Severe Obesity: a Systematic Review. Obes Surg. 2016 Sep;26(9):2248-54.
23. Banks J, Abouelazayem M, Kaur V, McGlone E, Fiorani C, Reddy M, et al. Routine Intra-gastric Balloon Insertion in the Management of 'Super-Super-Obese' Patients: an Obituary? Obes Surg. 2021 May;31(5):2319-23.
24. Coffin B, Maunoury V, Pattou F, Hebuterne X, Schneider S, Coupaye M, et al. Impact of Intragastric Balloon Before Laparoscopic Gastric Bypass on Patients with Super Obesity: a Randomized Multicenter Study. Obes Surg. 2017 Apr;27(4):902-09.
25. Kim SH, Chun HJ, Choi HS, Kim ES, Keum B, Jeen YT. Current status of intragastric balloon for obesity treatment. World J Gastroenterol. 2016 Jun 28;22(24):5495-504.
26. Perisse LG, Ecbc-Rj PC, Ribeiro KF. Gastric wall changes after intragastric balloon placement: a preliminary experience. Rev Col Bras Cir. 2016 Jul-Aug;43(4):286-8.

27. Busetto L, Segato G, De Luca M, Bortolozzi E, MacCari T, Magon A, et al. Preoperative weight loss by intragastric balloon in super-obese patients treated with laparoscopic gastric banding: a case-control study. Obes Surg. 2004 May;14(5):671-6.
28. Zerrweck C, Maunoury V, Caiazzo R, Branche J, Dezfoulian G, Bulois P, et al. Preoperative weight loss with intragastric balloon decreases the risk of significant adverse outcomes of laparoscopic gastric bypass in super-super obese patients. Obes Surg. 2012 May;22(5):777-82.


Enrolment
Assessed for elegibility (n=115)
Excluded (n=18) :
Prior use of GLP-1 agonist (n = 7)
Prior IGB therapy (n= 5)
Large hiatal hernia (n=4)
Past history of pancreatitis (n = 2)
Confirmed eligible (n=97)
IGB therapy (n=47)
liraglutide therapy (n=50)
Excluded for IGB intolerance (n=1)
Excluded for:
Liraglutide intolerance (n=2)
Not reached maximal dose (n= 5)
After 24 weeks pre-operative treatments
Eligible for LSG (n=46)
Eligible for LSG (n=43)
Lost to follow-up (n=2)
Lost to follow-up (n=1)
12 months follow-up
Analysed (n=44)
Analysed (n=42)



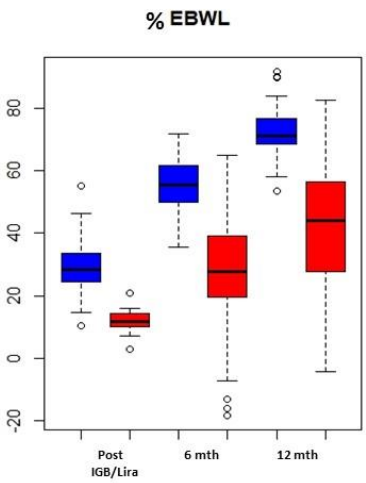



*Table 1* Patient pre-operative characteristics

| | **IGB + LSG** (n=44) | **Liraglutide + LSG** (n=42) | **p- value** |
|---|---|---|---|
| ***Gender (M/F)*** | 10/34<br>23% vs 77% | 3/39<br>7% vs 93% | 0.06 |
| ***Age (years)*** | 41.50 (37.5 – 49.25) | 41 (35.50-48) | 0.58 |
| ***Weight (kg)*** | 151 (140-163) | 145 (133.5 – 164.5) | 0.302 |
| ***BMI (kg/m²)*** | 55.9 (53.3-59.3) | 57.5 (51.2 – 59.2) | 0.391 |
| ***Comorbidity*** | | | |
| - None | 1 (2.3%) | 1 (2.3%) | 1 |
| - Cardiac | 31 (70.5%) | 22 (52.4%) | 0.13 |
| - Respiratory | 22 (50%) | 18 (42.8%) | 0.65 |
| - Diabetes | 38 (86%) | 35 (83.3%) | 0.76 |
| - Osteoarthritis | 12 (27%) | 9 (21.4%) | 0.61 |

Continuous parameters were reported as median and interquartile ranges. Categorical variables were recorded as numbers and percentages. Abbreviations: IGB: intragastric balloon, LSG: laparoscopic sleeve gastrectomy

*Table 2.* Post-operative complications according to Clavien-Dindo grade

| | **IGB + LSG** (n=44) | **Liraglutide + LSG** (n=42) | **p- value** |
|---|---|---|---|
| ***None*** | 37 (84%) | 39 (92.5%) | 0.31 |
| ***Grade 1*** | 3 (7%) | 1 (2.5%) | 0.61 |
| ***Grade 2*** | 2 (4.5%) | 1 (2.5%) | 1 |
| ***Grade 3*** | | | |
| - *3a* | 0 | 0 | 1 |
| - *3b* | 2 (4.5%) | 1 (2.5%) | 1 |

Variables were recorded as numbers and percentages. Abbreviations: IGB: intragastric balloon, LSG: laparoscopic sleeve gastrectomy

*Table 3.* Relationship between different two-stage management and BMI, %EWL and %EBWL at 6 and 12 months

| | **IGB + LSG** (n=44) | **Liraglutide + LSG** (n=42) | **p- value** |
|---|---|---|---|
| ***Weight (kg)*** *6 mth* | 101 (99-107) | 124 (109.5 -141) | < 0.05 |
| ***BMI (kg/m²)*** *6 mth* | 38.9 (39.10 – 40.5) | 47.5 (41.1 – 53) | < 0.05 |
| ***%EWL*** *6 mth* | 29.84 (26.8-34.6) | 15.8 (11.1 – 21.1) | < 0.05 |
| ***%EBWL*** *6 mth* | 55.6 (49.9 -61.7) | 27.8 (19.6 – 38.9) | <0.005 |
| ***Weight (kg)*** *12 mth* | 89 (85 - 91) | 112 (95.2 – 128.75) | < 0.05 |
| ***BMI (kg/m²)*** *12 mth* | 33.9 (32.2 – 35) | 41.86 (36.8-48.9) | < 0.05 |
| ***%EWL*** *12 mth* | 39.9 (37.6 – 42.9) | 25 (16.8 – 31) | < 0.05 |
| ***%EBWL*** *12 mth* | 71.2 (68.8 – 76.5) | 42(24.25 – 64) | <0.05 |

Continuous parameters were reported as median and interquartile ranges.

Abbreviations: IGB: intragastric balloon, LSG: laparoscopic sleeve gastrectomy, BMI: body mass index, %EWL: excess weight loss %EBWL: excess body weight loss.