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Risks and Rewards of Bariatric Surgery Vs Intragastric Balloon Placement: A Comparative Study at HMC Qatar

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Keywords:

Bariatric; Intra-gastric balloon; Fatty Liver; Weight Loss

Abbreviations:

BIB: BioEnterics Intragastric Balloon; BMI: Body Mass Index; EWL: Excess Weight Loss; HDL: High Density Lipoprotein HMC Hamad medical corporation IGB Intra-gastric balloon; LDL: Low Density Lipoprotein; LSG: Laparoscopic sleeve gastrectomy NAFLD Non Alcoholic Fatty Liver Disease TBWL Total Body Weight Loss

1. Abstract

1.1. Introduction: Obesity is one of the greatest public health concerns in many industrialized countries. In Qatar and according to new data released by the Supreme Council of Health, the obesity epidemic has overtaken the US, with approximately 70% of people in Qatar are either overweight or obese Introduction. In Qatar, bariatric surgeries and IGBs have been used over the last few years for the treatment of obesity in both governmental and private health sectors. we do not have the local data showing their effectiveness and safety and whether they meet the international standards.

1.2. Aim: To comparatively evaluate the safety and effectiveness of LSG vs IGBs.

1.3. Study Design: A comparative retrospective cohort study of bariatric who underwent LSG or IGB placements at HMC, Qatar, and followed up for 6 months' post-procedures.

1.4. Results: Overall, 100 patients (50 in each group) were analyzed. The mean of excess weight loss (EWL)% was higher in the LSG group (65.024) as compared to the IGB group (21.48). However, there was no significant difference between the means (p-value = 0.90). LSG resulted in higher total body loss as compared to IGB (calculated means were 26.63 and 9.102, respectively), but there was no significant difference between the means (p-value = 0.574). Our study showed that IGB was safer than LSG, with complications occurred only in 12% of patients in IGB group (acute pancreatitis and severe nausea and vomiting required IGB removal) compared to 18% in LSG group (hypoxia, gastroesophageal reflux disease and gallbladder stones).

1.5. Conclusion: This study suggests that LSG and IGB placements are both effective, if not equally, in the treatment of obesity.

2. Introduction

Obesity is one of the greatest public health concerns in many industrialized countries. In the US, the prevalence rate of obesity has doubled over the last 25 years, with more than 67% of the US population are either overweight or obese [1]. Surprisingly in Qatar and according to new data released by the Supreme Council of Health, the obesity epidemic has overtaken the US, with approximately 70% of people in Qatar are either overweight or obese [2]. Moreover, a survey including 164,963 students from the general population living in Qatar aged 5–19 years between 2015 and 2016 showed that the prevalence rate of overweight and obesity was approximately 45.6% and 40.9% among Qatari and non- Qatari students, respectively [3]. Furthermore, obesity is a well-known associated risk factor for many diseases, such as type 2 diabetes, hypertension, dyslipidaemia, cardiovascular diseases, musculoskeletal disorders and certain types of cancer [4]. The repercussion of obesity and its associated diseases does not only lead to reduced life expectancy but also to the development of severe physical and psychosocial impairment, such as reduction in quality of life, incurring the health care system huge costs. Many studies have shown that weight loss of at least 5%–10% of the body weight has been associated with marked reduction in the risk of obesity-related chronic illness [5]. Recently, many obese patients worldwide have developed an intensified interest in bariatric surgeries and Intra-Gastric Balloon (IGB) placement to achieve their target weight loss. Sleeve Gastrectomy (SG) or Laparoscopic SG (LSG), a new and one of the most common bariatric procedures, involves removal of the gastric fundus and greater curvature portion of the stomach, leaving only the narrow tube between the gastroesophageal junction and pylorus. It has proven to be a safe procedure for morbidly obese patients, especially for the super morbidly obese [6]. Weight loss following SG is believed to reduce food intake secondary to decreased stomach volume and possibly modulation of gastrointestinal hormone [7]. On the contrary, IGB aims to achieve weight loss in non- morbid obesity and/or to reduce bariatric surgical risks and general surgical risks [8]. IGBs induce satiety by decreasing the capacity of the gastric reservoir, thereby reducing food intake and leading to weight loss [9]. In Qatar, bariatric surgeries and IGBs have been used over the last few years for the treatment of obesity in both governmental and private health sectors. The number of LSG and IGB procedures performed has fundamentally increased over the last 3 years, although we do not have the local data showing their effectiveness and safety and whether they meet the international standards. In addition, most of the studies listed in the References section focused on the effectiveness and safety of bariatric surgery and IGB procedures separately. To the best of our knowledge, this is the first study that combined and compared these two procedures in terms of their safety and effectiveness in controlling obesity and its associated diseases.

3. Aim

To comparatively evaluate the safety and effectiveness of LSG vs IGBs.

4. Materials and Methods

4.1. Study Design

A comparative retrospective cohort study of bariatric who underwent LSG or IGB placements at HMC, Qatar, and followed up for 6 months' post-procedures. The sample size calculated was 197 patients for each group, but we could only include 50 patients in each group from the GI unit of the Ambulatory Care Center. These patients underwent LSG or IGB placement and followed up for 6 months' post-procedure.

4.2. Patients

Patients who underwent LSG or IGB placement in HMC, Qatar, and followed up for 6 months' post- procedure.

Time frame

January 2018 to June 2019

4.3. Inclusion Criteria

Obese patients who underwent LSG or IGB placements at HMC, Qatar, patients aged >18 years, and Eastern Cooperative Oncology Group Scale performance status ≤2.

4.4. Exclusion Criteria

Patients who did not underwent LSG or IGB placement in HMC, Qatar. Problems precluding safe endoscopy; esophagitis (Grade 1); hiatal hernia (>5 cm); chronic therapy with steroids, non-steroidal anti-inflammatory drugs, or anticoagulants; active peptic ulcer or its previous complications; previous GI resections; structural abnormalities of the GI tract; lesions considered at risk for bleeding; pregnancy; and patterns of eating disorder.

4.5. Assessment

4.5.1. Patients

Clinical and electronic health records of patients were retrospectively reviewed. The following patient demographic data were recorded: age, sex, nationality, gender, type and date of procedure, date of 6- month follow-up, baseline Body Mass Index (BMI), 6-month post-procedure BMI, baseline hbA1c, 6- month post-procedure A1c, baseline systolic blood pressure (SBP), 6-month post-procedure SBP, baseline diastolic BP (DBP), 6-month post-procedure DBP, baseline NAFLD, 6-month post-procedure NAFLD, baseline fasting cholesterol, 6-month post-procedure cholesterol, baseline fasting low-density lipoprotein (LDL), 6-month post-procedure LDL, baseline Hb , 6-month post-procedure Hb, post- procedure complications, type and date of complication and mortality. The effectiveness of the procedures was determined by the improvement in obesity and its associated chronic condition parameters, and the safety was determined by recording any post procedure complications.

4.6. Diagnosis and Treatment

BMI, a person's weight (in kilograms) divided by the square of his or her height (in meters) was used. A person with a BMI of ≥30 is generally considered obese and a person with a BMI ≥25 is considered overweight. Patients were selected according to the National Institutes of Health (NIH) guidelines and criteria for bariatric surgery. Bariatric surgery should be indicated for patients with clinically severe obesity (commonly referred to as "morbid obesity"), i.e. a BMI ≥40 or ≥35 with comorbid conditions, and when other treatment methods have failed.

https://www.nhlbi.nih.gov/files/docs/guidelines/prctgd_c.pdf

4.7. Treatment

The BioEnterics Intra-gastric Balloon (BIB) was used in patients who were selected according to the NIH guidelines and criteria for bariatric surgery. Written informed consent was obtained from each patient. BIB placement was performed after diagnostic endoscopy under intravenous conscious or unconscious sedation (propofol) with the patient in a lateral decubitus position. The BIB was inflated under direct vision with saline (500–700 ml) and methylene blue solution (10 ml). After 6 months, endoscopy was performed and BIB removal was carried out using a dedicated instrument, following complete deflation of the device.

LSG was performed in patients who were selected according to the NIH guidelines and criteria for bariatric surgery. Patients were positioned in the reverse Trendelenburg French position using a five- trocar approach. The abdominal cavity is insufflated with carbon dioxide to a pressure of 15 mmHg using a 10-mm optic port placed at or within a variable distance above the umbilicus, based on the patient's age. This port serves as the camera trocar. Four additional trocars were placed under laparoscopic view. The greater curvature is freed close to the stomach wall at approximately 2 cm proximal to the pylorus to the angle of His using a Ligasure™ device (Valleylab, USA). The left crus is then dissected and the angle of His is delineated. Posterior adhesions to the pancreas are lysed. A 36-Fr calibrating tube (34-Fr for patients <12 years old) was placed transorally and carefully advanced through the pylorus to the duodenum. At 3–4 cm from the pylorus, the stomach was divided using a linear stapler (Echelon 60 Disposable, Ethicon, Endo-Surgery, Inc., Cincinnati, OH). A green load (4.1 mm), followed by gold (3.8 mm) and blue loads (3.5 mm), was used for all patients, except for those <12 years old with thinner stomach in whom only gold and blue loads were used.

There was no routine staple line reinforcement or routine drain placement. The resected stomach was then extracted through the 12-mm port site.

4.8. Statistical Analysis

Analyses of clinical and demographic data were performed using SPSS statistical software version 19.0. A sample and independent sample t- test were used to compare the means of different numerical variables between the two procedures and between the baseline and 6 months' follow-up in each group, with a significant threshold <0.05. The Chi-square test was used to analyze the differences between categorical data with p-values <0.05, which was statistically significant.

5. Results

Overall, 100 patients (50 in each group) were analyzed. Table 1 represents the baseline demographic characteristics of patients from the two groups.

Table 1: Baseline demographic data of patients who underwent IGB placement and LSG

Means of the variables	IGB	LSG	Significant p-value
Age (years)	34.7	31.8	0.084
Gender			
Male	36.7	32.7	0.67
Female	63.3	67.3	0.83
Nationalities			
Qatari	63.3	89.9	0.004
Non-Qatari	36.7	10.2	0.002
Baseline BMI	37.9	44.5	0.033
Baseline weight (Kg)	103.8	118.9	0.356
Baseline systolic BP	124.5	128.2	0.808
Baseline diastolic BP	76	76.3	0.278
Baseline fasting cholesterol	4.6	4.8	0.42
Baseline LDL	2.86	2.75	0.997
Baseline NAFLD	-2.198	-2.55	0
Baseline HbA1c	5.45	6	0.2
Baseline Hb	12.8	12.32	0.07

The mean age for both groups was approximately 33 years, with more female predominance than male. In both treatment groups, most of the patients were Qatari, especially in the LSG group. The means for BMI were 37.9 and 44.5 for IGB and LSG groups, respectively, with a significant p-value of 0.033 for the difference between the means. The means for baseline SBP and DBP were normal in both treatment groups and the difference between the two-means showed no statistically difference (p>0.05). Furthermore, the same trend observed in baseline fasting cholesterol and LDL, as the means were in normal range and the difference between the means weren't statistically different (p>0.05). However, the mean of baseline NAFLD score was lower in the LSG group as compared to the IGB group and the difference between the two means was statistically different with a P value of 0.000. Furthermore, the mean of baseline HbA1c was slightly higher in the LSG group as compared to the IGB group, but the difference was not statistically significant with a p-value of 0.20. Moreover, the means for baseline Hb were 12.8 and 12.3 for the IGB and

LSG groups, respectively, and the difference between the means showed no statistically significance for both groups (p >0.05). Not surprisingly, the mean of excess weight loss (EWL) % was higher in the LSG group (65.024) as compared to the IGB group (21.48). However, there was no significant difference between the means (p-value = 0.90) (Figure 1). LSG resulted in higher total body loss as compared to IGB (calculated means were 26.63 and 9.102, respectively), but there was no significant difference between the means (p-value = 0.574) (Figure 2).

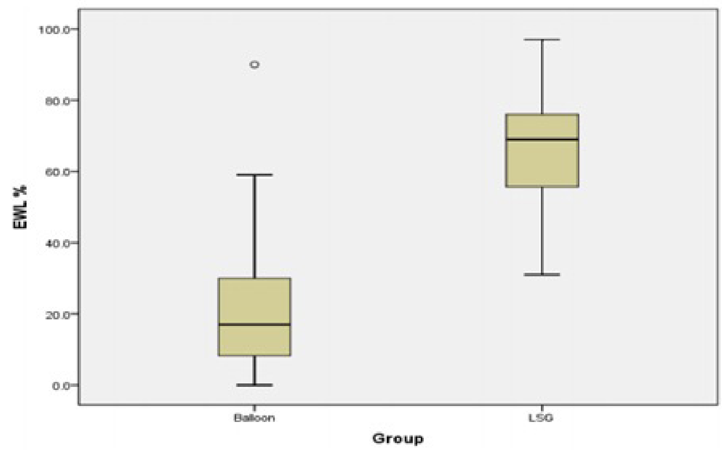

Figure 1: Comparison of the means of %EWL between LSG and IGB placement

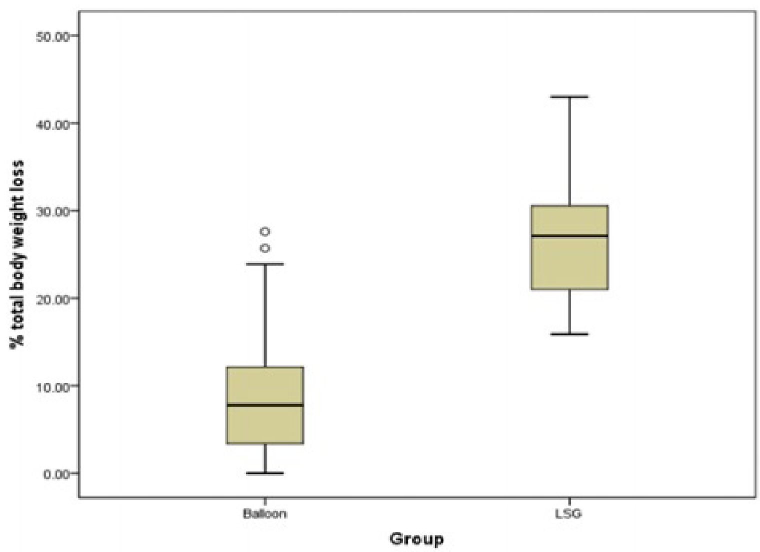

Figure 2: Comparison of the means of %TBL between LSG and IGB placement

5.1. IGB

IGB resulted in reduction in the means of BMI from 37.9 in baseline to 34.7 in 6 months. The follow-up was statistically significant (p-value = 0.00). Similarly, in patients who underwent IGB, the mean SBP reduced significantly with a p-value of 0.032. On the contrary, the baseline fasting cholesterol, LDL, NAFLD score and DBP showed no significant reduction at 6 months' post-procedure with a p-value of 0.522, 0.852, 0.79 and 0.819, respectively.

5.2. LSG

Patients who underwent LSG showed a marked reduction of BMI, with the means of BMI reduced from 44.48 at baseline to 32.7 6 months' post-procedure, with a statistically significant p-value of 0.00. Moreover, the means of SBP, DBP and NAFLD score were markedly reduced at 6 months' post- procedure, with a p-value of 0.00, 0.01 and 0.00, respectively. On the contrary, there was no major reduction in the means of fasting cholesterol and fasting LDL 6 months' post-procedure, with a p-value of 0.616 and 0.941, respectively.

5.3. Safety

Of 50 patients who underwent IGB insertion, 3 (6%) patients developed acute pancreatitis and 3 (6%) patients experienced severe nausea and vomiting, which precluded IGB removal.

Of 50 patients who underwent LSG, 1 (2%) patient had severe hypoxia post-operation, requiring intubation and ICU admission; 6 (12%) patients with gastroesophageal reflux disease required treatment using pump inhibitors; and 2 (4%) patients underwent laparoscopic cholecystectomy for gallbladder stones.

6. Discussion

This study showed that LSG and IGB placements were both effective in treating obesity; however, LSG was more efficient in terms of weight loss. A Turkish study showed similar results with a calculated % of EWL and TBL of 67.68 ± 14.9 and 36.32 ± 11.3, respectively, for the LSG group as compared to 33.42 ± 9.2 and 18.07 ± 10.5, respectively, in the IGB group. There were significant statistical differences of p- value <0.001 [10]. Moreover, a study reported that the mean of % of EWL after 2 years from LSG was 51% as compared to 44% after 6 months post-IGB placement [11].

Although LSG was more efficient than IGB in term of weight loss, it has high risk ratio. In this study, higher and series post-operative complications occurred in the surgical group. Another study reported post-operative hemorrhage in 3.03% of the patients who underwent LSG, while only nausea and vomiting (55%) and abdominal pain (25%) were reported in patients who underwent IGB placement [10]. In addition, a study showed that while most of the patients who underwent IGB placement tolerated the procedure well and only 4.2% of them experienced nausea and vomiting post IGB placement, post- operative complications (staple-line leakage, stricture, wound infection and urinary retention) occurred in 8.5% patients who underwent LSG [11].

This study failed to show significant improvement in NAFLD score in patients who underwent IGB placement, contrary to a study conducted on 21 patients that showed an improvement in nonalcoholic steatohepatitis activity score on liver biopsy in 87% of patients following IGB placement [12]. Furthermore, a study showed that 6 months post-IGB placement there was a significant reduction in BMI and HbA1c ($p < 0.001$) with no statistically significant improvement in LDL, HDL, cholesterol and triglycerides (TG) ($p > 0.05$) [13]. A meta-analysis of 40 studies showed a marked improvement in metabolic parameters (FBG, TG and DBP) in patients treated with IGB placements [14]. Furthermore, this study showed considerable improvement in metabolic parameters (BMI, BP and NAFLD score) after LSG. Similarly, a study reported complete resolution of NAFLD in 56% of the patients who underwent LSG [15]. Furthermore, another study demonstrated a decreased prevalence of DM, dyslipidemia and hypertension and an improvement of liver histology in all patients 1 year post-LSG [16].

This study has two limitations. First, this was a single-centered retrospective study and second, it has a relatively small sample size.

7. Conclusion

This study suggests that LSG and IGB placements are both effective, if not equally, in the treatment of obesity. Although LSG is comparatively more effective as compared to IGB in treating obesity and its associated metabolic comorbidities, especially fatty liver and hypertension, IGB could be a reasonable option for obese patients with BMIs that do not qualify them for bariatric surgery or as a bridge for bariatric surgery.

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References

1. Lobstein T & Leach RJ. Tackling obesities: future Choices-International comparisons of obesity trends, determinants and responses-evidence review-2. summary. Foresight, Government Office of the Chief Scientit. 2007.
2. Yahia M. Qatar surpases US in obesity. Nature Middle East. 2013.
3. Al-Thani M, Al-Thani A, Alyafei S, Al-Chetachi W, Khalifa SE, Ahmed A, et al. The prevalence and characteristics of overweight and obesity among students in Qatar. Public Health. 2018; 160: 143-9.
4. Picot J, Jones J, Colquitt JL, Gospodarevskaya E, Loveman E, Baxter L, et al. The clinical effectiveness and cost-effectiveness of bariatric (weight loss) surgery for obesity: a systematic review and economic evaluation. Health Technology Assessment. 2009; 13(41): 1-190.
5. Pi-Sunyer FX. A review of long term studies evaluating the efficacy of weight loss in ameliorating disorders associated with obesity. Clinical Therapeutics. 1996; 18(6): 1006-35.
6. Yehoshua RT, Eidelman LA, Stein M, Fichman S, Mazor A, Chen J, et al. Laparoscopic sleeve gastrectomy--volume and pressure assessment. Obesity Surgery. 2008; 18(9): 1083-8.
7. Wang Y & Liu J. Plasma ghrelin modulation in gastric band operation and sleeve gastrectomy. Obesity Surgery. 2009; 19: 357-62.
8. Mion F, Napoléon B, Roman S, Malvoisin E, Trepo F, Pujol B, et al. Effects of intragastric balloon on gastric emptying and plasma ghrelin levels in nonmorbid obese patients. Obesity Surgery. 2005; 15(4): 510-6.
9. Genco A, Bruni T, Doldi SB, Forestieri P, Marino M, Busetto L, et al. BioEnterics intragastric balloon: the Italian experience with 2,515 patients. Obesity Surgery. 2005; 15(8): 1161-4.
10. Çaycı HM & Erdogdu UE. Laparoscopic sleeve gastrectomy versus endoscopical intragastric balloon placement: early results of morbidly obese patients. Archives of Clinical and Experimental Medicine. 2017; 2(2): 35-38.
11. Wong SK, Mui WL & Ng EK. Development of bariatric surgery: the effectiveness of a multi-disciplinary weight management programme in Hong Kong. Annals of the Academy of Medicine, Singapore. 2009; 38(1): 9-6.
12. Bazerbachi F, Vargas EJ, Mounajjed T, Venkatesh SK, Watt KD, Port JD, et al. 795 impact of single fluid-filled intragastric balloon on metabolic parameters and nonalcoholic steatohepatitis: a prospective paired endoscopic ultrasound guided core liver biopsy at the time of balloon placement and removal. Gastrointestinal Endoscopy. 2018; 87(6): ab118-ab119.

13. Erdem H, Aziret M, Çetinkünar S, Aktimur R, Özdaş S, Yurekli B, et al. Effects of intragastric balloon on body mass index, lipid profile and blood glucose regulation: a prospective study. Dicle Medical Journal / Dicle Tip Dergisi. 2016; 43(1): 22-26.

14. Popov VB, Ou A, Schulman AR & Thompson CC. The impact of intragastric balloons on obesity-related co-morbidities: a systematic review and meta-analysis. American Journal of Gastroenterology. 2017; 112(3): 429-39.

15. Algooneh A, Almazeedi S, Al-Sabah S, Ahmed M & Othman F. Non-alcoholic fatty liver disease resolution following sleeve gastrectomy. Surgical endoscopy. 2016; 30(5): 1983-7.

16. N. Cabré, Luciano-Mateo F, Arroyo SF, Baiges G, Hernández-Aguilera A, et al. Laparoscopic sleeve gastrectomy reverses non-alcoholic fatty liver disease modulating oxidative stress and inflammation. Metabolism Clinical and Experimental. 2019; 99: 81-89.