



Comparison of Surgical Outcomes between a 12-Month Adjustable Intra-gastric Balloon Placement versus Laparoscopic Sleeve Gastrectomy in Class I-II Obesity: A Retrospective Study

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Abstract

Objective: To compare weight loss between intra-gastric balloon (IGB) and laparoscopic sleeve gastrectomy (LSG) in patients with class I-II obesity.

Materials and Methods: The authors retrospectively reviewed data of obese patients with a body mass index (BMI) of 30-40 kg/m² who underwent LSG or IGB in Vajira hospital from January 2012 to December 2017. The primary outcome was percent excess weight loss (%EWL), and secondary outcomes were improvement in co-morbidities, rate of complications, and changes in quality of life at 12 months after procedures.

Results: Sixteen patients who underwent either LSG (n = 9) or IGB (n = 7) were enrolled. There were no significant differences in baseline characteristics except co-morbidity status. The median (interquartile range) %EWL following LSG and IGB placement was 67.8 (61.3, 81) and 20.5 (2.5, 34), respectively, at 12 months (p-value = 0.001). Most co-morbidities were improved or resolved after LSG, but none of them was improved after IGB placement. Complications and quality of life were not significantly different following either intervention.

Conclusion: Results suggest that LSG may be more suitable than IGB placement for patients with class I-II obesity in terms of both weight loss.

Keywords: laparoscopic sleeve gastrectomy, adjustable intra-gastric balloon, weight loss



การศึกษาเปรียบเทียบแบบย้อนหลังระหว่างการใส่บอลูน ในกระเพาะอาหารเป็นเวลา 12 เดือนและการผ่าตัดลดขนาด กระเพาะอาหารด้วยการส่องกล้องในผู้ป่วยโรคอ้วนระดับที่ 1 และ 2

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บทคัดย่อ

วัตถุประสงค์: เพื่อศึกษาเปรียบเทียบผลของการลดน้ำหนักระหว่างการใส่บอลูนในกระเพาะอาหารและการผ่าตัดลดขนาดกระเพาะอาหาร

วัสดุและวิธีการ: ทำการศึกษาข้อมูลแบบย้อนหลังในผู้ป่วยที่มีดัชนีมวลกายระหว่าง 30-40 กิโลกรัม/เมตร² ซึ่งได้รับการรักษาโดยการใส่บอลูนในกระเพาะอาหารหรือการผ่าตัดลดขนาดกระเพาะอาหารระหว่าง มกราคม พ.ศ. 2555 ถึง ธันวาคม พ.ศ. 2560 โดยมีวัตถุประสงค์หลักคือศึกษาหลักคือร้อยละของน้ำหนักส่วนเกินที่ลดลง และวัตถุประสงค์รองคือมีอัตราการดีขึ้นของโรคร่วม, อัตราการเกิดภาวะแทรกซ้อน, และคุณภาพชีวิตที่ระยะเวลา 1 ปีหลังการรักษา

ผลการศึกษา: ผู้ป่วยจำนวน 16 คน แบ่งเป็นได้รับการผ่าตัดลดขนาดกระเพาะ 9 คน และได้รับการใส่บอลูน 7 คน ไม่พบความแตกต่างของลักษณะของผู้ป่วยทั้งสองกลุ่มยกเว้นโรคร่วม ค่ามัธยฐานและช่วงระหว่างควอไทล์ของร้อยละของน้ำหนักส่วนเกินที่ลดลงที่ระยะเวลา 12 เดือน เป็น 67.8 (61.3, 81) และ 20.5 (2.5, 34) ในกลุ่มที่ได้รับการผ่าตัดลดขนาดกระเพาะอาหารและกลุ่มที่ใส่บอลูนในกระเพาะอาหารตามลำดับ โรคร่วมส่วนใหญ่ดีขึ้นหรือสงบลงหลังผ่าตัดลดขนาดกระเพาะอาหาร แต่ไม่พบโรคร่วมดีขึ้นในกลุ่มที่ใส่บอลูน ส่วนภาวะแทรกซ้อนและคุณภาพชีวิตไม่ได้มีความแตกต่างอย่างมีนัยสำคัญทางสถิติระหว่างสองกลุ่ม

สรุป: ผลการศึกษาชี้ไปในทางที่ว่าการผ่าตัดลดขนาดกระเพาะอาหารอาจจะเหมาะสมกว่าการใส่บอลูนในผู้ป่วยโรคอ้วนระยะที่ 1 ถึง 2 ทั้งในแง่ของการลดน้ำหนักและการดีขึ้นของโรคร่วม

คำสำคัญ: การผ่าตัดลดขนาดกระเพาะอาหาร, การใส่บอลูนในกระเพาะอาหาร, การลดน้ำหนัก

Introduction

The prevalence of obesity is increasing worldwide. According to the World Health Organization (WHO) 2016 report, the estimated prevalence of obesity is 13% among adults¹. Gaining weight not only affect the quality of life but also increases the risk of other diseases, including coronary artery disease, cerebrovascular disease, metabolic syndrome, obstructive sleep apnea, and cancers²⁻⁴. According to body mass index (BMI), an individual whose BMI ≥ 30 kg/m² will be classified as obese.

According to the 2005 Asia-Pacific Bariatric Surgery Group consensus, bariatric surgery eligibility criteria are as follows: BMI ≥ 37 kg/m² without any co-morbidities, or BMI ≥ 32 kg/m² with obesity-related co-morbidities, and inability to achieve or maintain weight loss through diet modification⁵. Among bariatric procedures, laparoscopic sleeve gastrectomy (LSG) is the most common restrictive procedure, which accounted for 60% of bariatric surgeries from 2011 to 2017, according to a report of the American Society for Metabolic and Bariatric Surgery⁶. The procedure usually produces excellent results, with 60% to 80% excess weight loss (%EWL) typically seen after LSG⁷⁻⁹.

Endoscopy is another approach for weight-reduction. This approach could be performed as a 1-day procedure. Intra-gastric balloon placement (IGB) is the most common endoscopic procedure, which was first performed in 1985 using the Garren-Edwards Gastric Bubble (GEGB)¹⁰⁻¹¹. This intervention aims to reduce intra-gastric volume; thus, satiety could be achieved by a smaller amount of food. Although the GEGB is no longer used due to device-related complications, a new balloon device has been developed to be more durable in acidic environments. However, most IGBs are indicated for only 6-month implantation, except for the Spatz™

balloon system, which can be placed in the stomach for 12 months¹². Another advantage of the Spatz™ balloon is that it is the only IGB system which allows the balloon volume adjustment after implantation. Admirable percent excess weight loss (%EWL) after the Spatz™ balloon placement was observed in the study of Machytka et al¹³. and Brooks et al¹⁴.

Due to the technical aspects of the procedure, IGB might be considered as a restrictive procedure. Comparable %EWL at 6 months and 12 months after interventions were observed between BioEnteric™ balloon (6-month balloon) placement and LSG in the case-control study of Genco et al¹⁵. Cayci and Erdogan¹⁶ compared the results of surgery using the adjustable IGB (Spatz™) with LSG, and found that the IGB resulted in a significantly lower %EWL than LSG. However, this study population was patients with class III obesity (BMI ≥ 40 kg/m²). Given that IGB is considered more suitable in patients with less severe obesity, this study might be biased toward LSG.

To date, no studies have compared the effectiveness of the adjustable IGB (Spatz™) placement with LSG in patients with class I or II obesity (BMI 30-39.9 kg/m²). Therefore, this study aimed to address this gap in the knowledge and compare these two procedures in terms of %EWL, reduction in the severity of co-morbidities, complication rate, the severity of complications, and postoperative quality of life (QoL).

Materials and Methods

Recruitment

The authors retrospectively recruited all patients with a BMI of 30–40 kg/m² who underwent adjustable IGB (Spatz3™; Spatz FGIA, Great Neck, NY, USA) placement or LSG from January 2012 to December 2017 in Vajira hospital. None of gastroesophageal reflux disease (GERD) patients

were offered IGB and LSG in our center. Data were collected from in- and out-patient charts. Telephone interviews were also carried out in cases when recorded data were not available. Body weight was measured before treatment and every 6 months until 24 months postoperatively. This study was approved by the Vajira’s ethics committee before data collection.

Study outcomes

The primary outcome was %EWL, defined as the percentage of weight loss divided by excess body weight. Excess body weight was calculated by subtracting the ideal body weight from the preoperative body weight.

Excess body weight = preoperative body weight – ideal body weight

$$\text{and } \%EWL = \frac{\text{weight loss}}{\text{excess body weight}} \times 100$$

Secondary outcomes were improvement in co-morbidities, complications, and postoperative QoL. Postoperative co-morbidity status was evaluated based on the amount of medication taken to control co-morbidities; co-morbidity status was defined as *resolved* if all medications were ceased, as *improved* if the number of medications was reduced, or *not improved* in all other cases. For obstructive sleep apnea (OSA), we used the hypoxic apnea severity index and improvement of bi-level positive airway pressure (Bi-PAP) ventilator setting to evaluate OSA status. Complications were classified according to the Clavien-Dindo grading system¹⁷. The Europe Quality of life with Five Dimensions and Five Levels (EQ-5D-5L) assessment tool from the EuroQol group was used to assess QoL¹⁸. The severity of GERD was assessed using the Gastroesophageal Reflux

Disease-Health-Related Quality of Life (GERD-HRQL) questionnaire¹⁹. Evaluation of QoL (i.e., EQ-5D-5L and GERD-HRQL) was performed one year after the procedure.

Procedures

In the IGB group, procedures were performed under intravenous sedation. The balloon was inflated to 450–500 ml in volume. Patients whose %EWL was <15% 6-months postoperatively were advised to undergo treatment to increase IGB volume. However, the final decision of whether to increase volume was made by the patient. After 1-year implantation, the balloon was removed.

All LSG group patients received an anticoagulant injection, and the intermittent pneumatic pump was used for venous thrombosis prophylaxis during the perioperative period. The operation was performed under general anesthesia. Gastric greater curvature was mobilized from the antrum to the angle of His. Then, a 36-Fr bougie was used to determine the size of the gastric tube. Vertical gastric transection was performed using a gastrointestinal anastomosis stapler starting from 6-cm proximal to the pyloric ring to the angle of His. The staple line was imbricated by running suture.

In both groups, diet progression followed the standard regimen, which was gradually progressed from liquid in week 1 to solid food in week 4. Patients were advised to undertake isometric exercise, a high protein diet, and total calories restriction to ≤1500 kcal/day.

Statistical analysis

All eligible patients were analyzed according to the received treatment without exclusion. Continuous variables were expressed with median and interquartile range (IQR), whereas categorical

variables were described with frequency and percentage. Data were compared between two treatment groups using the Mann-Whitney U test for continuous variables and Fisher exact for a categorical variable. P-value < 0.05 was considered as statistical significance. All analyses were performed using STATA version 16.1 (StataCorp, Texas, USA).

Results

Sixteen patients were enrolled in the present study. Nine underwent LSG, and seven underwent IGB placement. There were no statistically significant differences in baseline characteristics (Table 1). Results indicated that LSG was associated with a greater %EWL than IGB placement at all follow-up periods, see Table 2. Weight re-gain was observed after balloon removal (Figure 1). Conversely, patients who underwent LSG continued to lose weight, reaching a maximum effect

18 months after treatment. (Figure 1). Three of the seven patients in the IGB group did not show adequate weight loss 6 months after balloon insertion. Only one patient decided to undergo volume adjustment; however, she did not lose a substantial amount of additional weight (2 kg more were lost).

The LSG group had more co-morbidities than the IGB group preoperatively. Three patients of the LSG group were diagnosed with diabetes; two of these resolved after surgery. Hypertension, dyslipidemia, and OSA were detected in two, four, and three patients, respectively. These co-morbidities were also ameliorated after LSG. Co-morbidities were identified in three patients of the IGB group; however, none improved after intervention. Hypertension and dyslipidemia improvement rates (i.e., improved plus resolved patients) did not significantly differ between LSG and IGB (Table 3).

Table 1:

Baseline characteristics

Baseline Characteristic	LSG (N = 9) Median (IQR)	IGB (N = 7) Median (IQR)	p-value
Age (year)	34 (30, 49)	33 (31, 48)	1.000
BMI (kg/m ²)	36.2 (33, 36.7)	34.7 (33.8, 37.3)	0.832
Body weight (kg)	93 (89, 110.5)	106 (81, 115)	0.525
Ideal body weight (kg)	58.4 (51.5, 61.4)	69.6 (49.7, 75)	0.491
Excess body weight (kg)	40 (32.1, 41.8)	38.2 (33.7, 43.4)	0.874
Sex			
Male, N (%)	2 (22.2)	5 (71.4)	0.126
Comorbidities, N (%)			
Diabetes	3 (33.3)	0 (0)	0.213
Hypertension	2 (22.2)	1 (14.3)	1.000
Dyslipidemia	4 (44.4)	2 (28.6)	0.633
OSA	3 (33.3)	0 (0)	0.213

BMI body mass index, IGB intragastric balloon placement, IQR interquartile range, LSG laparoscopic sleeve gastrectomy, OSA obstructive sleep apnea

Table 2:

Excess weight loss after laparoscopic sleeve gastrectomy and intragastric balloon placement

Outcome/time	LSG Median (IQR)	IGB Median (IQR)	p-value
Excess Weight Loss			
6 months	22 (17.5, 27)	6 (5, 16)	0.002
12 months	27 (25, 31)	7 (1, 13)	0.001
18 months	28.5 (27, 35.5)	5 (3, 9)	0.001
24 months	28 (25, 34)	1.5 (0, 2)	0.001
% Excess Weight Loss			
6 months	55 (54, 63.1)	17.8 (11.5, 39.6)	0.004
12 months	67.8 (61.3, 81)	20.5 (2.5, 34)	0.001
18 months	72.8 (70.2, 81.8)	16.5 (5.9, 26.7)	0.001
24 months	70 (67.2, 77.9)	3.5 (0, 6.6)	0.001

IGB intragastric balloon placement, IQR interquartile range, LSG laparoscopic sleeve gastrectomy

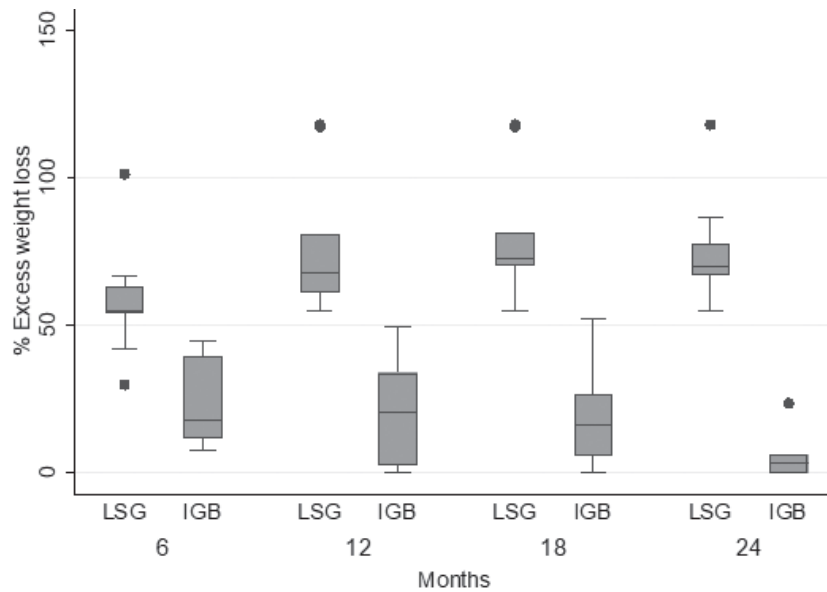


Figure 1: Excess weight loss after laparoscopic sleeve gastrectomy and intragastric balloon placement (IGB intragastric balloon, LSG laparoscopic sleeve gastrectomy)

Table 3:

Co-morbidity status after laparoscopic sleeve gastrectomy and intragastric balloon placement

Co-morbidity status	Diabetes		Hypertension		Dyslipidemia		OSA
	LSG (N = 3)	LSG (N = 2)	IGB (N = 1)	p-value	LSG (N = 4)	IGB (N = 2)	LSG (N = 3)
Resolved N (%)	2 (66.7)	1 (50)	-		1 (25)	-	1 (33.3)
Improved N (%)	-	-	-	1.000	2 (50)	-	2 (66.7)
Not improved N (%)	1 (33.3)	1 (50)	1 (100)		1 (25)	2 (100)	-

IGB intragastric balloon placement, LSG laparoscopic sleeve gastrectomy, OSA obstructive sleep apnea

The complications are presented in Table 4. In the LSG group, one patient was classified as having a grade 3 a complication, a gastric tube angulation, causing severe nausea and vomiting. Fortunately, the condition was successfully managed by endoscopic balloon dilatation, and no recurrence was observed. Grade 1 complications were observed in five patients in the LSG group and four from the IGB group (p-value = 1.000).

All of these were GERD. Proton-pump inhibitors (PPIs) was routinely prescribed in the IGB group, and the dosage was titrated to control GERD symptoms; however, these medications were prescribed in the LSG group only when GERD symptoms were detected. The GERD severity scores were not significantly different between the two groups. However, GERD symptoms improved after balloon removal in all patients who underwent IGB

Table 4:

Complications and quality of life after laparoscopic sleeve gastrectomy and intragastric balloon placement

Outcome	LSG (N = 9)	IGB (N = 7)	p-value
Surgical Complication Grading, N (%)			
No complication	3 (33.3)	3 (42.9)	1.000
Grade 1	5 (55.6)	4 (57.1)	
Grade 3a	1 (11.1)	0 (0.0)	
GERD, N (%)	5 (55.6)	4 (57.1)	1.000
GERD-HRQL score, Median (IQR)	12 (12, 13)	12.5 (10.5, 14.5)	0.711
Heartburn score	10 (10, 11)	8 (7.5, 9.5)	0.167
Regurgitation score	1 (0, 3)	4 (3, 5)	0.080
EQ-5D-5L score, Median (IQR)	1 (1, 1)	1 (1, 1)	0.378
Health performance score	90 (80, 100)	80 (70, 90)	0.082

EQ-5D-5L the Europe quality of life with 5 dimensions and 5 levels, GERD gastroesophageal reflux disease, GERD-HRQL GERD-health-related quality of life, IGB intragastric balloon placement, IQR interquartile range, LSG laparoscopic sleeve gastrectomy

placement, whereas most who underwent LSG required long-term acid-reducing medication to control reflux. Staple-line leakage and death did not occur in the LSG group.

The QoL was satisfactory in both groups; however, the self-assessed health performance status of the LSG group appeared to be better than the IGB group [median (IQR) of 90 (80,100) and 80 (70, 90) for LSG and IGB, respectively; p -value = 0.082], see Table 4. Almost all patients reported that losing weight and health improvements were the most satisfying results.

Discussion

This study demonstrated that LSG is superior to IGB in terms of %EWL and improvement of co-morbidity status for patients with class I-II obesity. Rebound weight gain was observed in the IGB group beyond 12 months after procedure. As a result, the median %EWL at 2 years after intervention was only 3.5. In the LSG group, the maximum effect was observed 18 months after the procedure. The %EWL of approximately 70 after LSG in the present study corresponded well with other reports⁷⁻⁹. This could reflect the quality of our surgical technique and patient care process.

The Spatz™ pilot study reported that mean %EWL was 48.8 after 12-month Spatz™ balloon placement¹³. Mean %EWL of 45.7 was achieved after 12 months of balloon implantation in the other study¹⁴. However, in our study, three of the seven patients who underwent IGB insertion were classified as experiencing treatment failure at 6 months after the intervention. Even though the authors had discussed with these patients to increase their balloon volume, there was only one patient who agreed to undergo this procedure. This could explain why dramatic weight loss was not observed in the present study compared

with the previous studies. Nevertheless, the present study could represent the real-life situation in which treatment should be assigned according to a shared decision-making.

One comparative study of IGB placement versus LSG reported the results of balloon placement (BioEnteric balloon) and LSG to be comparable¹⁵. Considering that the BioEnteric balloon is non-adjustable and must be removed after 6 months, the outcomes were surprisingly satisfactory and contradicted our adjustable IGB placement results, with no apparent explanation. The present study found the median %EWL at 12 months after IGB placement and LSG to be 20.5 and 67.8, respectively, which is congruent with the results of Cayci and Erdogdu's study, which reported mean %EWLs of 33.4 ± 9.2 and 67.7 ± 14.9 for Spatz™ balloon placement and LSG, respectively¹⁶.

Despite the imbalance of co-morbidities between the two groups, the authors found the improvement in co-morbidities to be greater after LSG than IGB placement. This could be due to alterations in gut hormone levels (e.g., glucagon-like peptide-1 and peptide YY) following LSG²⁰, leading to the amelioration of co-morbidities independent of weight loss.

At 12 months after the procedures, there was no statistically significant difference in EQ-5D-5L scores between the two groups. Substantial improvements in co-morbidities contributed to the improved health performance scores of the LSG group. Thus, the LSG group reported greater satisfaction with their treatment than the IGB group. Although GERD's rate and severity were not significantly different between the two groups, IGB placement might be a better choice when GERD is the primary concern because GERD can resolve rapidly if the balloon is removed.

This study had obvious limitations that should be acknowledged. It was not a randomized clinical trial, and the number of subjects was small; thus, an imbalance of unknown co-variables might exist, leading to bias in conclusion. Because data were collected retrospectively, many important co-variables were not available. Both unavailability of co-variables and a small number of subjects made multivariate adjustment impossible. Even so, this is—to the best of the author's knowledge—the only study to compare Spatz™ balloon placement with LSG for the treatment of class I-II obesity.

In conclusion, LSG resulted in a greater %EWL; thus, LSG might be superior to IGB placement for the treatment of class I-II obesity. Given that LSG is indicated only in patients with morbid obesity, there is still a place for IGB in overweight patients who have yet met the indication for bariatric surgery. Another possible role of IGB is being a bridging procedure before undergoing definite surgery in bariatric candidates.

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Conflicts of interest

All authors have no conflict of interest or financial ties to disclose.

Ethics approval

The present study was approved by the ethics committee of Faculty of Medicine Vajira Hospital before data retrieval. (COA149/2560)

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