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Sleeve gastrectomy versus endoscopic intragastric balloon in decreasing weight and associated comorbidities in Erbil city: A comparative study

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Abstract

Background: Surgical obesity treatment is difficult for both surgeons and patients. The three main categories of bariatric surgery procedures are malabsorptive, restrictive, or both in combination. Intragastric balloon (IB) is an easily applicable restrictive interventional and nonsurgical strategy for obese patients, and the surgical procedure known as laparoscopic sleeve gastrectomy (LSG) is frequently used to help obese patients decrease weight.

Objective: To assess and compare these two restrictive approaches.

Patients and Methods: A prospective study of 138 LSG patients was conducted, (n=82) and IB (n=56) between 1st January 2016 to 31st December 2021 in private hospitals in Erbil, Iraq. The study retrospectively evaluates patients' demographic information, changes in total body weight (TBW), changes in body mass index (BMI), and percentage of excess weight loss (%EWL), morbidities and change of comorbidities during a year of follow-up, at months 1, 3, 6, and 12 after surgery. Comparative analysis was undertaken for the follow-up results after 6 and 12 months.

Results: In the IB group, 12 patients did not tolerate insertion, leaving 56; in the LSG group, 82 patients completed treatment. In terms of age (p=0.121), gender (p=0.242), and BMI (p=0.078), there were no statistical differences between the IB and LSG groups. The LSG group achieved statistically significant superior treatment outcomes in terms of changes in TBW, BMI, and %EWL.

Conclusion: Both LSG and IB are beneficial in the short term for helping obese patients lose weight. IB has the benefit of being performed as an outpatient procedure with less complications, but it is less successful in helping people lose weight than LSG. The best options for various patient groups in terms of clinical outcomes and health system effectiveness must be determined through prospective, randomized control studies.

Keywords: Obesity, Laparoscopic sleeve gastrectomy, Intragastric balloon.

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Introduction

Obesity, a growing global epidemic, is linked to a variety of comorbidities, including diabetes mellitus (DM), hypertension (HT), sleep apnea, coronary artery disease (CAD),

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hyperlipidemia, hepatic steatosis, and stroke, among others. Weight loss improves these conditions and general health while also extending the expected lifespan. [1]. Numerous interventional methods and surgical procedures have been developed for obesity, including malabsorptive, restrictive, and combined bariatric surgical procedures. Malabsorptive surgery comprises a jejunoileal bypass, as Varco's description from 1953[2]. This strategy causes weight reduction of varying degrees but collaterally causes vitamin insufficiency, protein malnutrition, joint pain, as well as liver failure. In 1966, Mason and Ito defined Roux-en-Y gastric bypass with a 30 mL gastric pouch. [3]. Both restrictive and malabsorptive strategies are categorized as this one. The biliopancreatic diversion was initially illustrated by Scopinaro et al. in 1979 [4]. The duodenal switch procedure developed by Hess and Hess includes sleeve gastrectomy and changes to certain anastomosis the duodenojejunal zone. [5]. Restrictive methods include sleeve gastrectomy, gastric plication, intragastric balloon (IB), and advanced adjustable gastric bands introduced in the early 1970s [6, 7]. The two most common restricting operations right now are gastric plication and sleeve gastrectomy.

In a laparoscopic sleeve gastrectomy (LSG) procedure, the greater curvature of the stomach is laparoscopically removed from the angle of His to the distal antrum, creating a small gastric tube over a 34-Fr bougie. About 50 minutes are needed for the operation [8].

An IB is an easily applicable restrictive strategy for obese patients, first utilized in 1985 under US Food and Drug Administration (FDA) approval. Early satiety, delayed stomach emptying, and a reduction in calorie intake are the main contributors to weight loss with gastric balloon therapy. Similar restrictive surgical techniques, such as gastric plication and sleeve gastrectomy, have a similar process. Gastric erosions, ulcers, obstructions of the small intestine, Mallory-Weiss tears, and esophageal tears are some of the drawbacks of balloons. [9]. The silicone elastomer-based bio enteric IB, which has a rounded form, was introduced by Allergan in 1999. The contemporary balloon's primary benefit is that its volume can be changed endoscopically. Although they are less frequent, modern IB method problems are equivalent to those of earlier ones.

LSG has grown in popularity recently and is now widely used across the globe. According to five-year follow-up statistics, LSG results in a mean excess weight loss (EWL) of 55.0 +/- 6.8%, showing that it promotes stable, long-term weight loss. However, there are certain issues with the long-staple line during sleeve gastrectomy surgery, including leaks and bleeding [11-12], yet due to their shape and substance, the original balloons utilized at that time posed various issues. Modern IBs have a circular shape and an adjustable volume. Imaz et al. [13] published a meta-analysis in 2008 about the security and efficiency of IBs that includes 3608 patients. They assert that IB is extraordinarily successful at losing weight quickly within the context of multidisciplinary care. The average weight loss among 4,371 patients in 22 non-randomized investigations was 17.8 kg,

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however 20–40% of patients failed to lose weight, presumably as a result of IB expulsion too soon. In the studies under evaluation, reported complication rates varied, and three fatalities were recorded as a result of bronchial aspiration (n=1) and stomach perforation (n=2), respectively. Esophagitis and gastroduodenal ulcers (0.4% each) were other side effects [3].

The percentage of excess weight loss (%EWL), tolerability, and effects on lowering BMI following laparoscopic sleeve gastrectomy are compared in the current study. We speculate that a gastric balloon is as effective as a sleeve gastrectomy for temporary weight reduction.

Patients and Methods

Research design

This is a prospective study of 138 patients who underwent LSG and IB in private hospitals in Erbil, Iraq, between January 1, 2016, and December 31, 2021. Over a year of follow-up, information on patient demographics, changes in total body weight (TBW), body mass index (BMI), %EWL, morbidities, and changes in comorbidities were collected at one, three, six, and twelve months (M1, M3, M6, and M12, respectively). The outcomes were assessed and compared.

Inclusion and exclusion criteria

- Willingness to consent
- BMI of at least 35 kg/m^2
- Age of eighteen or older
- Able to cooperate in endoscopy
- The cause of the obesity is not inherited or hormonal
- No history of cancer during the past five years
- No desire to get pregnant
- No IB discontinuation prior to six months
- Not using psychiatric drugs, anti-obesity drugs, or non-steroidal anti-inflammatory drugs (NSAIDs)

Intervention

Balloon

The IB expands into a rounded form 10.5 cm in diameter when filled with 600 mL of air and is compact and flexible in its collapsed state. Its three concentric layers of soft polyurethane material serve as its shell, protecting it from stomach corrosion. When completely inflated, the balloon weighs about 50 grams (with 600 ml of air).

Balloon insertion

Midazolam (3mg) was injected intravenously, and then an endoscopy was done to look for any abnormalities that would prevent the patient from taking part in the study. The balloon was inserted into the stomach fundus after the gastroscopy was removed. The balloon was filled with the recommended 600 mL of air using a syringe that was connected to the balloon fill tube. A brief draw on the fill tube released the balloon, which was then followed by the evacuation of the fill tube and empty assembly group. The endoscope confirmed the free-floating balloon's position after this initial implantation. Patients were hospitalized following the operation to see their tolerance to the IB. Six hours following the treatment, patients who did not have severe nausea or abdominal pain started a fluid diet. If they tolerated this diet, they were allowed to leave the hospital. They were then limited to a liquid diet for the first week, after which a dietician-planned low-calorie diet was advised. Antiemetic and antispasmodic medications were

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administered to patients who experienced symptoms of nausea, vomiting, and acid reflux, particularly during the first 72 hours. For the first 3-5 days, it is recommended to drink only fluids.

Balloon removal

The balloon was taken out using endoscopy six months after it was inserted. The balloon was deflated as much as possible before being grasped with a catch or forceps. The balloon that had been grabbed and the endoscope were carefully emptied. A gastroscopic examination of the esophagus and stomach was performed following the evacuation of the balloon, and patients were advised with regard to dietary restrictions, exercise, and lifestyle changes, and follow-up continued over the course of 12 months.

Laparoscopic sleeve gastrectomy technique

Two surgical teams performed all LSG operations, which were all carried out in the Lloyd Davies position. An anesthesiologist implanted a 34-Fr gastric calibration tube after inserting 5 trocars with pneumoperitoneum of 14–16 mmHg. Excision of the greater curvature of the stomach from the angle of His to the distal antrum was performed under the guidance of the tube, using special staplers to remove about 80% of the stomach, leaving the remaining stomach capacity of only about 100 ml. None of the cases required progression to open surgery. The procedure took around 50 minutes to complete. Before the procedure, a fluid diet was administered to all patients. Also, all patients were fitted with pneumatic compression stockings the night before surgery and received subcutaneous injections of low molecular weight heparin (Enoxaparin, Sanofi, Paris, France) for the prevention of deep vein thrombosis. After experiencing flatulence throughout the postoperative phase, a fluid diet was started. On the fourth postoperative day, patients who tolerated oral intake and had no morbidities were sent home.

Morbidities

The morbidities or complications of interest to this study are defined as major ones requiring returning the patient to the operative theatre, staying in the hospital for more than 7 days, and readmitting the patient to the hospital; all other morbidities are considered minor.

Statistical Analysis

Utilizing descriptive statistical techniques (mean and standard deviation), an independent t-test for comparing binary groups, a t-test paired for comparing results at the M6 and M12 follow-up, and a Chi-square test for qualitative data, patient data were analyzed using Microsoft Excel and SPSS version 23. The P-value was significant in each test when it was less than 0.05.

Results

A total of 138 patients were included in the study. From the initial 68 patients in the IB group, 12 did not tolerate insertion, and were thus withdrawn. A final total of 56 patients participated in the IB group, comprising 37 females and 19 males. There were 82 patients in the LSG group, including 52 females and 30 males. There was no statistical differences between IB and LSG groups in terms of age (p=0.121), sex (p=0.242) and BMI (p=0.078) Table (1).

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Table (1): Demographic and clinical characteristics of patients

Data		Laparoscopic sleeve gastrectomy		Intragastric Balloon		P-value
Age		36.62±7.2		40.6±4.3		0.121
Gender	Male	30	36.6%	19	33.9%	0.242
	Female	52	64.4%	37	66.1%	
BMI		47.62±8.52		46.44±5.64		0.078
Change in body weight (months)	1	10.52±6.56		6.72±3.64		0.006
	3	15.41±4.52		11.62±4.32		0.004
	6	24.4±5.32		14.6±5.81		0.002
	12	49.8±4.8		9.64±4.32		0.004
Change in BMI (months)	1	4.4±1.65		2.64±1.42		0.001
	3	5.6±2.12		3.42±2.1		0.003
	6	7.82±3.65		4.76±2.18		0.002
	12	25.3±5.72		2.1±1.2		0.001
EWL (months)	1	20.62±9.44		11.32±8.4		0.002
	3	32.4±6.8		15.31±6.7		0.002
	6	45.52±15.8		22.2±16.3		0.003
	12	68.4±16.5		12.42±7.8		0.002
Morbidities		7	8.53%	0	0%	0.221
Pre-procedure comorbidities	HT	18	21.9%	12	21.42%	0.044
	DM	20	24.4%	17	30.4%	
	Dyslipidemia	59	71.9%	27	48.2%	
Post-procedure comorbidities after 12 months	HT	11	13.4%	9	16.07%	0.221
	DM	15	18.3%	14	25%	
	Dyslipidemia	32	39.02%	22	39.3%	

In terms of change in body weight (kg) at the studied time points, patients in the LSG group lost an average of 10.52 (M1), 15.41 (M3), 24.4 (M6), and 49.8 (M12); and those in the IB group lost an average of 6.72 (M1), 11.62 (M3), 14.6 (M6), and 9.64 (M12). The greater weight loss value in the LSG group was statistically significant for all time points, with p=0.006 (M1), 0.004 (M3), 0.002 (M6), and 0.004 (M12). The body weight change at M12 in the IB group is less compared to M1, M3, and M6 because the balloon is removed at M6, which reduces patients' compliance with dietary restrictions and lifestyle factors Table (1) ,Figure(1).

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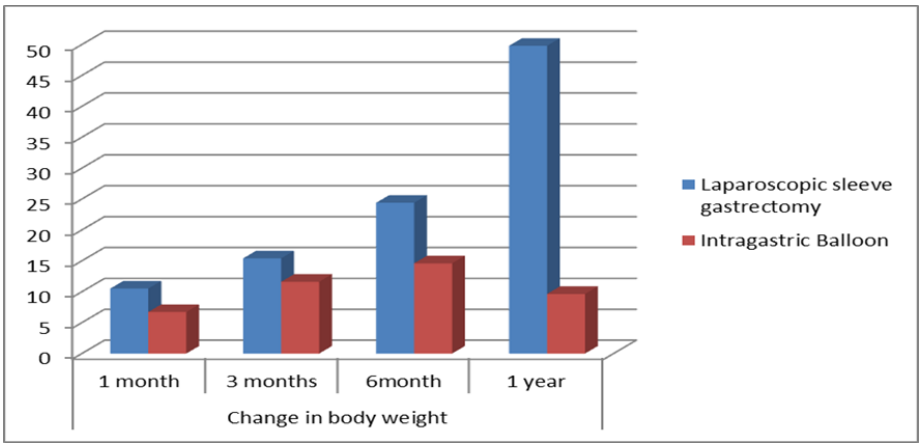

Figure (1): Change in body weight of LSG and IB patients at follow-up points

For changes in BMI at the studied time points, the IB group had an average decrease in BMI (kg/m²) of 2.64 (M1), 3.42 (M3), 4.76 (M6), and 2.1 (M12); the LSG group had average decreases of 4.04 (M1), 5.6 (M3), 7.82 (M6), and 25.3 (M12). These results indicate a statistically significant increased BMI loss in the LSG group at the studied time points, with significance values of p=0.001 (M1), 0.003 (M3), 0.002 (M6), and 0.001 (M12) Table (1) ,Figure (2).

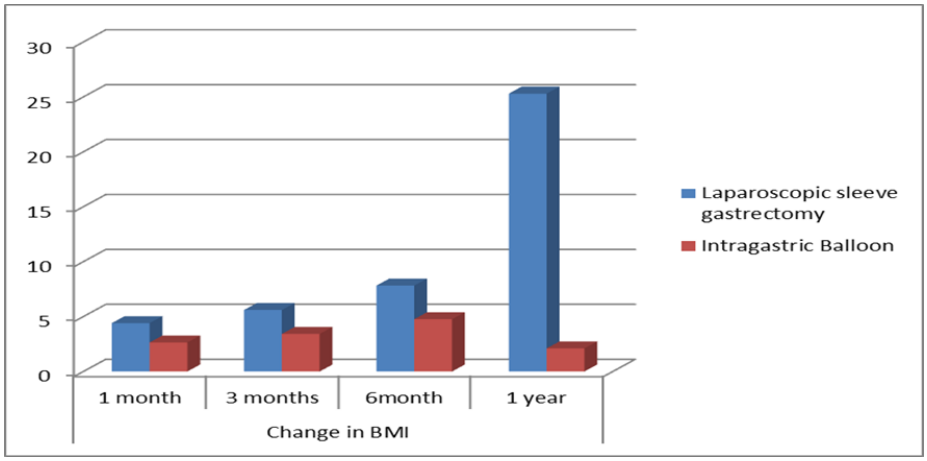

Figure (2): Change in BMI of LSG and IB patients at follow-up points

Excess weight loss (EWL) is expressed description of the loss of excess weight as a percentage. At the studied time points, the EWL percentages of the LSG group were 20.62 (M1), 32.4 (M3), 45.52 (M6), and 68.4 (M12); for the IB group they were 11.32 (M1), 15.31 (M3), 22.2 (M6), and 12.42% (M12). These findings indicate that the gastrectomy group had a statistically significant EWL value, with p=0.002 (M1), 0.002 (M3), 0.003 (M6), and 0.002 (M12) Table (1), Figure (3).

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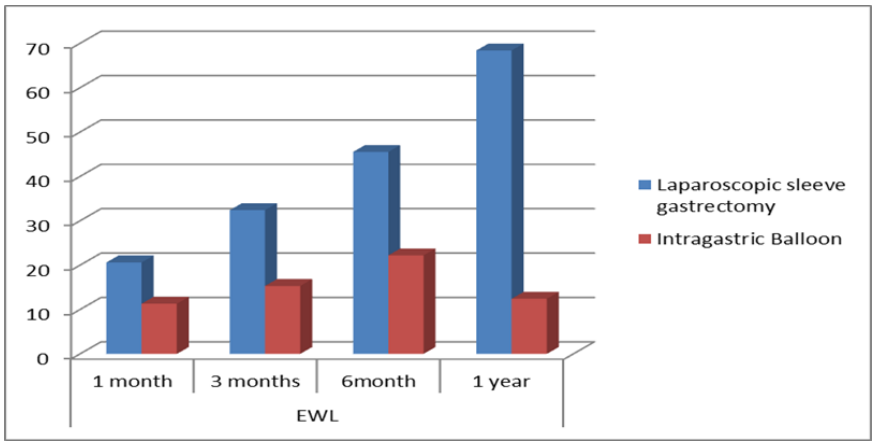

Figure (3): Change in EWL of LSG and IB patients at follow-up points

No morbidities were reported among the IB group, while in the LSG group 7 patients developed morbidities and 5 developed postoperative bleeding; of the latter, 3 were hemodynamically stable and were managed conservatively, while the other 2 patients were not hemodynamically stable, so they were reoperated (laparoscopy) to control the bleeding. A further two patients developed leaks requiring reoperation (laparoscopy). There were no mortalities in either group.

The number of patients with the following comorbidities declined following IB placement: HT (from 12 to 9), DM (from 17 to 14), and dyslipidemia (from 27 to 22). The number of patients with these comorbidities among the LSG group also declined following the procedure: HT (11 to 8), DM (from 20 to 15), and dyslipidemia (from 59 to 32) Figure (4).

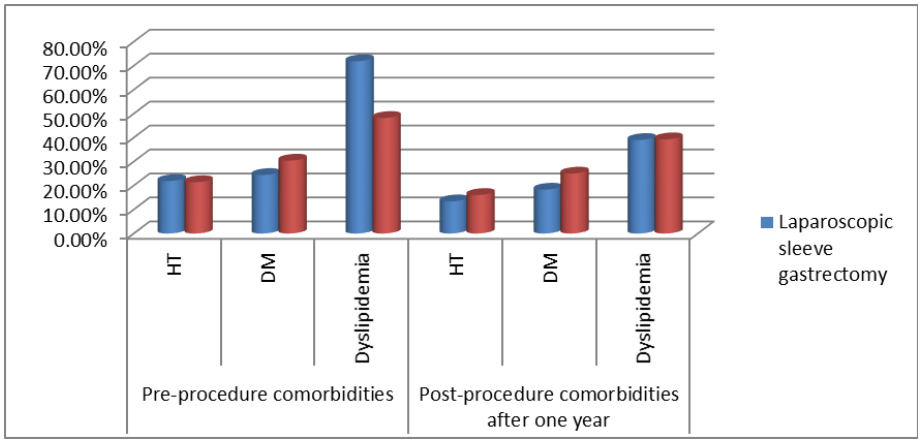

Figure (4): Change in comorbidity before and after LSG and IB

Discussion

According to this study, LSG outperforms IB in terms of diminishing body weight, reducing BMI and EWL, and reducing the co-morbidity status of patients enduring obesity. Mild to moderate weight gain was observed within the IB group beyond 12 months after the procedure. The IB patients lost 14.6 kg at M6, which subsequently declined to 9.64 at M12, comparable to

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previous findings Ghoneim H et al [14]. On the other hand, the LSG patients lost 24.4 kg weight at M6, and 49.8 kg at M12, comparable to previous studies Saruç M et al ,which reported a six-month weight loss of 25.3kg [15] and a twelve-month weight loss of 45.3kg ÇAYCI H et al [16]. The reduction in body weight was significantly greater in the LSG group.

Our results concerning the BMI were comparable with those of previous studies, including a BMI of 4.76± (2.18) kg/m² for the IB group at M6 Solmaz A et al [17], and 2.1±1.2 kg/m² at M12 [17]. These results were lower than those reported by other studies, e.g., 6.2 kg/m² Ghoneim H et al [14] and 7.8 kg/m² Saruç M et al [15], which may be attributable to the shorter follow-up periods by those researchers. BMI reductions among the LSG group of 7.82±3.65 kg/m² at M6 and 25.3±5.72 kg/m² at M12 were higher compared to the IB group in our study, and our BMI values in LSG were also similar to previous research ÇAYCI H et al and Solmaz A *et al* [16, 17].

Our IB and LSG groups' EWL findings were statistically different, favoring the LSG group. Our EWL results for the IB group were 12.42 percent at M12 and 22.2% (down from 16.3) at M6.

The M6 results are notably lower than values reported in the literature, such as 64.12% (±23.48) [14], 46.9% (±11.3) [15], and 23.75% (±17.15) Solmaz A et al [17]. At M12 the results were lower than those reported by Laopeamthong et al. (20.5%) [18], which may be due to the remaining IB patients at this time point having removed the IB. The EWL results of the LSG group were 45.52% (±15.8) for M6 and 68.4% (±16.5) for M12, comparable with the 48.58% reported by Andraos et al. [19] at a six-month follow-up for a series of 120 patients. In a group of 42 patients of LSG described by Ramos-Corvala et al. [20], the EWL at six months was 48%. Laopeamthong et al. reported a higher value of 67.8% at this time point [18].

The current study is the first research which done in Iraq to compare two restricted approaches to treating obesity (one is surgical, the other is interventional). Compared to other surgical approaches, LSG is known to have lower rates of morbidity and mortality, although IB is less invasive and has less complications.

None of the trial participants showed any elevated morbidity at M12 after IGB application. Although LSG effectively reduces weight in patients who are morbidly obese, early and late period morbidity rates have been found to range between 9% and 23%, and leakage is documented in 1-6% of cases while hemorrhage is recorded in 2-7.3% of cases [16]. These results are comparable to our study regarding morbidity after LSG, which was 8.53%. The development of leaks following LSG is a significant factor in both morbidity and mortality. In our study, the rate of leakage was 1.5%, requiring reoperation, and haemorrhages developed at a rate of 3.62% in the postoperative term. These cases were treated conservatively in three patients, while reoperation was necessary in two cases. These outcomes are similar to those reported by a previous study [16].

Despite the imbalance of co-morbidities between the two groups, we found the change in co-morbidities to be more prominent after

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LSG than IGB placement. This can be due to modifications in intestine hormone levels (e.g., glucagon-like peptide-1 and peptide YY) taken after LSG [21], leading to the improvement of co-morbidities autonomous of weight loss. At M12 there were no statistically critical differences in comorbidities between the two groups. Considerable changes in co-morbidities contributed to the progressed well-being performance of the LSG group, who reported more prominent satisfaction with their treatment than the IB group, affirming the conclusions of Laopeamthong *et al*. [18].

Conclusions

This is the first study have been done in Iraq to compare widely used interventional and surgical anti-obesity methods. IB has produced encouraging early weight loss results, and as new technologies are developed, it may one day compete with surgical techniques for weight loss.

Recommendations

Our study has some limitations, most notably the single-centered, retrospective design and the study's low overall case count. We hypothesized at the beginning of our trial that IB is equally beneficial as LSG in reducing the weight of obese people. However, we discovered that LSG is more effective than IB at helping obese patients lose weight. We think that the insufficient weight loss experienced by IB patients is what led to this outcome. There are certain research on IB that show superior results in that regard. To evaluate the clinical and health system effectiveness and efficiency of each approach for distinct patient groups, prospective studies with longer follow-up times are required.

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Ethical clearance: The local College of Medicine Ethics Committee gave its approval to the study protocol at Hawler Medical University (HMU). Informed consent in writing was obtained from each participating patient.

Conflict of interest: Nil

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تكميم المعدة مقابل بالون المعدة بالمنظار لإنقاص الوزن والأمراض المصاحبة لها في مدينة أربيل: دراسة مقارنة

بدرخان سعيد احمد[1]

الملخص

خلفية الدراسة: العلاج الجراحي للسمنة صعب لكل من الجراحين والمرضى. الفئات الثلاث الرئيسية لإجراء جراحة السمنة هي سوء الامتصاص أو التقييد أو كلتيهما معًا. بالون المعدة هي استراتيجية تدخلية وغير جراحية مقيدة قابلة للتطبيق بسهولة للمرضى الذين يعانون من السمنة المفرطة. وكثيرا ما يستخدم الإجراء الجراحي المعروف باسم تكميم المعدة بالمنظار لمساعدة المرضى الذين يعانون من السمنة المفرطة على إنقاص الوزن.

اهداف الدراسة: اتقييم ومقارنة هذين النهجين التقييديين..

المرضى والطرائق: أجريت دراسة استباقية لـ 138 مريضا- تكميم المعدة ن = 82 وللبالون ن = 56 بين 1 يناير 2016 إلى 31 ديسمبر 2021 في المستشفيات الخاصة في أربيل ، العراق. تقوم الدراسة بأثر رجعي بتقييم المعلومات الديموغرافية للمرضى ، والتغيرات في إجمالي تغيرات وزن الجسم في مؤشر كتلة الجسم والنسبة المئوية لفقدان الوزن الزائد ، والمراضات وتغير الأمراض المصاحبة خلال عام من المتابعة ، في الأشهر 1 و 3 و 6 و 12 بعد الجراحة . تم إجراء تحليل مقارن لنتائج المتابعة بعد 6 و 12 شهرًا.

النتائج: في مجموعة حالات البالون ، لم يتحمل 12 مريضًا إدخال البالون متبقي 56 مريض ؛ في مجموعة حالات تكميم المعدة ، أكمل 82 مريضاً العلاج. من حيث العمر والجنس ومؤشر كتلة الجسم لم تكن هناك فروق ذات دلالة إحصائية بين البالون و مجموعة تكميم المعدة. حققت مجموعة حالات تكميم المعدة بالمنظار نتائج علاجية ذات دلالة إحصائية أعلى من حيث التغيرات في وزن الجسم الكلي ، ومؤشر كتلة الجسم والنسبة المئوية لفقدان الوزن على نطاق واسع.

الاستنتاجات: كل من تكميم المعدة بالمنظار والبالون داخل المعدة مفيدان على المدى القصير لمساعدة مرضى السمنة على إنقاص الوزن. يتمتع بالون بميزة أنه يتم إجراؤه كمريض خارجي مع مضاعفات أقل ، ولكنه أقل نجاحًا في مساعدة الأشخاص على إنقاص الوزن من عملية تكميم المعدة بالمنظار. يجب تحديد أفضل الخيارات لمجموعات المرضى المختلفة من حيث النتائج السريرية وفعالية النظام الصحي من خلال دراسات التحكم العشوائية المرتقبة.

الكلمات المفتاحية: السمنة ، تكميم المعدة بالمنظار ، بالون المعدة

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