

Comparison of Short-Term Results of Laparoscopic Gastric Plication and Intra-gastric Balloon

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Abstract

Introduction: Management of obesity is difficult problem for doctors and patients. There are many methods for dealing with obesity. Intra-gastric Balloon (IB) is interventional and nonsurgical way of promoting weight loss in obese patients. Laparoscopic Gastric Plication (LGP) is most physiologic surgical method of bariatric surgery. This study aimed to evaluate and compare these two restrictive methods.

Methods: Ninety-five obese patients (34 male and 61 female) included in this study. We compared patients treated with IB (n=52) and LGP (n=43). Data on patient demography, change in Body Mass Index (BMI) and %excess weight loss (%EWL) of 1st and 6th months were collected.

Results: The study had started with 69 patients for IB group, but 4 (5.7%) of them did not tolerate the insertion and 13 had removed the balloon early after insertion (n=13 (20%)) were excluded from the study. There were 52 patients left in IB group and 43 patients in plication group. There were no statistically difference between IB and plication groups in terms of age (p=0.132), sex (p=0.262) and BMI (p=0.081). Change in total body weight (TBW), BMI and %excessive weight loss (EWL) parameters were statistically different in favor of the plication group.

Conclusion: Our clinical experience has suggested that LGP and IB are effective in loss of weight in obese patients in short term. IB has an advantage of being done outpatient and has fewer complications, but it is less effective on weight loss compared to LGP. Prospective, randomized control trials are needed to choose best way.

Keywords: Obesity; Intra-gastric balloon; Laparoscopic; Gastric plication

Introduction

Obesity is a growing health problem all over the world. As weight of the patient increases comorbid diseases, like Diabetes Mellitus (DM), Hypertension (HT), sleep apnea disease, Coronary Artery Disease (CAD), hyperlipidemia, hepatic steatosis, stroke and etc. come up. Weight loss improves many of these factors and prolongs the expected life time [1].

As obesity becoming a bigger problem for all over the world many interventional techniques and surgical methods have been developed. There are many surgical procedures used for bariatric surgery. We can summarize these methods under three subtitles: malabsorptive procedures, restrictive procedures and both. First malabsorptive procedure was jejunioileal bypass, which is described by Varco in 1953 [2]. This method caused weight loss too much or too little. They also had vitamin deficiency, protein malnutrition, arthritis and liver failure. Mason and Ito defined roux-en-Y gastric bypass with 30 mL gastric pouch in 1966 [3]. This procedure is classified as both restrictive and malabsorptive. Scopinaro et al. first time described biliopancreatic diversion in 1979 [4]. Hess and Hess added sleeve gastrectomy and also modified some anastomosis to duodenojejunal area, so this procedure is called as duodenal switch [5].

The restrictive procedures are gastric plication, sleeve gastrectomy, intra-gastric balloon adjustable gastric banding which were evolved in early 1970s [6,7]. Currently gastric plication and sleeve gastrectomy are mainstay restrictive procedures. Laparoscopic gastric plication (LGP) is firstly described by Talebpour and Amoli in 2007 [8]. The procedure can be explained briefly as firstly division of greater omentum from greater curvature, than greater curvature of the stomach is folded inside by sewing one or more large folds. This causes up to 70% decrease in stomach volume. LGP is the most conservative and cheapest operation when compared to other restrictive techniques. Just because of the cost efficiency in some countries surgeons prefer to do this method. Complications related to this technique are gastric obstruction, leaks, perforation [9,10]. After the operation main complaint of the patients are nausea and vomiting. This is caused by creation of septum by inverted gastric wall [11]. Nausea and vomiting can be decreased by doing plication with using four-bite stitches in the inner row of plication to avoid formation of a large septum [12].

Intra-gastric balloon (IB) is one of the practical restrictive methods for obese patients. It is first used in 1985 as U.S Food and Drug Administration (FDA) proved. Main principle of cause of weight loss of gastric balloon is increasing satiety, delaying gastric emptying and so reducing caloric intake. Increasing satiety and reducing caloric intake are caused by restriction of stomach for getting more food. Its mechanism is similar to other restrictive type of surgical techniques that are gastric plication and sleeve gastrectomy. Disadvantage of first balloons are gastric erosions, ulcers, small bowel obstruction, Mallory-

Weiss tears and esophageal lacerations [13]. Allergan had introduced bioenteric IB in 1999. It is spherical in shape and made of silicone elastomer. Main advantage of new balloon is that its volume can be adjusted endoscopically. Complications of using IB are similar to older ones but they are seen less commonly. In the present study, we aimed to compare percentage of Excess Weight Loss (%EWL), tolerability and effects on decrease of body mass index of intra-gastric balloon and laparoscopic gastric plication. Our hypothesis is gastric balloon is as effective as gastric plication on weight loss on short term.

Methods and Patients

Retrospective study of 95 patients undergone LGP and IB between July 2011 and March 2012 at Bagcilar Training and Research Hospital, Istanbul, Turkey. Data on patient demography, Change of total body weight (TBW), change of body mass index (BMI) and percentage of excess weight loss (%EWL) of 1st and 6th months were collected.

The study protocol was approved by the local ethical committee of Bagcilar Training and Research Hospital (2014-295). Written informed consent was obtained from each participating patient.

Inclusion criteria of the study were: (1) willing to give consent, (2) age 18 years or older, (2) a BMI of at least 35 kg/m² and stable, Exclusion criteria were the following: (1) a hormonal or genetic cause for the obese state, (2) malignancy within the previous 5 years, (3) pregnancy or a desire to become pregnant, (3) withdrawal of IB before six months, (4) patients who were unable to cooperate at endoscopy and (5) patients who use psychiatric drugs. The use of anti-obesity drugs and Non-Steroidal Anti-Inflammatory Drugs (NSAID) was prohibited.

Balloon

The intra-gastric balloon is small and flexible in the collapsed state, expands into a spherical shape 10.5 cm in diameter when filled with 600 mL air. Its shell is made of 3 layer of soft polyurethane material that is resistant to gastric acid. The mass of balloon is about 50 grams when inflated with 600 ml of air.

Balloon insertion

After intravenous administration of midazolam (3 mg), endoscopy was performed to rule out abnormalities that would preclude the patient from participation in the study. After removal of gastroscopy, the balloon was placed to corpus-fundus region of stomach. A syringe was attached to the balloon fill tube and the balloon was filled with the recommended 600 mL of air. The balloon was released by a short pull on the fill tube, whereupon the fill tube and empty placement assembly

were removed. After this initial placement, the position of the free-floating balloon was confirmed by endoscope. If the patient feels nausea, vomiting, and acid reflux symptoms, especially for the first 72 hours, antiemetic and antispasmodic drugs were given. Liquid diet is advised for the first 3-5 days.

Balloon removal

After six month of the insertion endoscopy was performed for the removal of the balloon. For balloon removal, as much air as possible was removed before grasping the balloon with a snare or a forceps. The endoscope and the grasped balloon were gently removed. After removal of the balloon, gastroscopic examination of esophagus and stomach was done.

Laparoscopic gastric plication technique

After insertion of 5 trochars with the pneumoperitoneum of 14-16 mmHg, greater omentum is dissected beginning 5 cm from pylorus to gastroesophageal junction. After dissection, a 36-Fr gastric calibration tube is inserted by anesthesiologist. Under the guidance of the tube, plication is done from gastroesophageal junction to distal part of dissected greater curvature of the stomach. We use two layered greater curvature plication technique. The inner layer of plication is done with 0 V-Loc™ sutures and outer layer is with 0 polypropylene sutures. Operation time is approximately 45 minutes.

Statistical analysis

In this study, statistical analysis was performed by software NCSS (Number Cruncher Statistical System 2007) statistical software package program (Utah, USA). For the evaluation of the data, we used descriptive statistical methods (mean, standard deviation) as well as independent t test for comparison of binary groups, t-test mating for the 1st and 6th month results and Chi-square test for qualitative data. In all tests P value was significant when <0.05.

Results

Ninety five patients were included in the study. Patients who did not tolerate the insertion (n=4(7.6%)) and removed the balloon early after insertion (n=13 (20%)) were excluded from the study. 52 patients left in the IB group of which 36 patients (69.23%) were female and 16 patients (30.77%) were male. 43 patients were in LGP group. 25(58.14%) were female and 18(41.86%) were male. There were no statistically difference between IB and LGP groups in terms of age (p=0.132), sex (p=0.262) and BMI (p=0.081) (Table 1).

		Intra-gastric balloon (n:52)		Laparoscopic Gastric Plication (n:43)		p value
Age		38.75 ± 9.05		41.56 ± 8.91		0.132
Gender	Women	36	69.23%	25	58.14%	0.262
	Men	16	30.77%	18	41.86%	
BMI		48.56 ± 10.48		45.45 ± 5.32		0.081

Table 1: Characteristics of the patients included in the study.

After 1 month of operation, patients in the LGP group lost an average of 11.63 kilograms weight (range 5-23) and IB group lost an average of 7.38 kilograms weight (range 4-21). Value of loss of weight of LGP group is statistically significant compared to IB group at the

end of first month (p=0.008). When we look amount of weight lost at the end of six month, plication group lost 25.3 kilograms (range 7-57), IB group lost 14.4 kilograms (range 4-28) (p=0.0001) (Table 2).

		Intra-gastric balloon (n:52)	Laparoscopic Gastric Plication (n:43)	p value
Change in body weight	1st month	7.38 ± 4.06	11.63 ± 5.65	0.008
	6th month	14.4 ± 6.19	25.3 ± 10.8	0.0001
Change in BMI	1st month	2.74 ± 1.76	4.02 ± 1.73	0.001
	6th month	4.65 ± 3.15	8.81 ± 3.33	0.0001
EWL	1st month	12.39 ± 9.27	21.87 ± 10.8	0.002
	6th month	23.75 ± 17.15	46.61 ± 17.75	0.0001

Table 2: Change of body weight, Body Mass Index (BMI) and percentage of Excess Weight Loss (EWL) during the treatment.

The IB group had average decrease in BMI of 2.74 kg/m² at the end of first month, on the other hand LGP group had average decrease in BMI of 4.02 kg/m², so BMI change had emerged statistically different in favor of the LGP group (p=0.001). The similar findings have found at the end of six month of the study which are 4.65 for IB group and 8.81 for LGP group (p=0.0001) (Table 2).

Excessive Weight Loss (EWL) is expressed description of loss of excessive weight as a percentage. EWL of 1st month of LGP was 21.87 (range 5.95-37.23) and 12.39 (range 4-25.6) for IB group which means plication group has statistically significant EWL value. (p=0.002) At 6th month, LGP group had EWL of 46.61 (range 8.99-103.99) IB had 23.75 (range 8-48.3). That also means LGP group has statistically higher value than IB group (p=0.0001) (Table 2 and Figure 1).

Laparoscopic Gastric Plication (LGP) is somewhat similar to LSG (restricting stomach volume), but there is no resection of the stomach, so the risks of the operation is quite lower when compared to LSG. In this technique firstly greater curvature of the stomach is mobilized and dissected from antrum to angle of His like in LSG, and then greater curvature is imbricated by two or three layered sutures [16]. There is no resection of any part of the gastrointestinal system in LGP. It leads to lowering food intake of the patient. It does not affect the plasma level of satiety hormone ghrelin [17].

Intra-gastric balloon was firstly used in 1980s [18]. First balloons used at that time caused many complications due to the shape and material type of them. Recently IB that has spherical shape and adjustable high volume has been used. Imaz et al. [19] published a meta-analysis, which includes 3608 patients in 2008 about the safety and effectiveness of intra-gastric balloon. They claim that within the multidisciplinary management IB is very effective to lose weight in a short term. According to review, published by Dumonceau et al. [20] among 4371 patients of 22 non-randomized studies mean weight loss was 17.8 kg. However 20-40% of patients fail to lose weight, may be due to early removal of IB. Reported complication rate were variable in the studies of this review. Three deaths were reported due to gastric perforation (n=2) and bronchoaspiration. Other complications are gastroduodenal ulcers (0.4%) and esophagitis.

There is not much information about first month results of IB in the literature. In our study IB group patients lost mean 7.38 kg at the end of the first month and 14.4 kg at the end of the 6 month. We cannot compare our first month results with the others but 6 month results were similar to the literature [21,22]. On the other hand plication group patients lost mean 11.63 kg and 25.3 kg weight at the end of six month which are similar to the results of 120 cases series of Andraos et al. [23] 11.2 kg and 23 kg.

Our results concerning the basal BMI were similar to the previous studies. We reported BMI of 48.56(±10.48) kg/m² for IB group and 45.45(±5.32) kg/m² for plication group. IB group have decrease of 2.74(±1.76) kg/m² and 4.65(±3.15) kg/m² in BMI values at the end of first and 6 month of the study. These results were lower than series of Ghoneim et al. [24] who found BMI loss of 6.2 kg/m² and series of Saruc et al. [25] that is 7.8. BMI drop values of plication group that are 4.02(±1.73) kg/m² and 8.81(±3.33) kg/m² were higher compared to IB

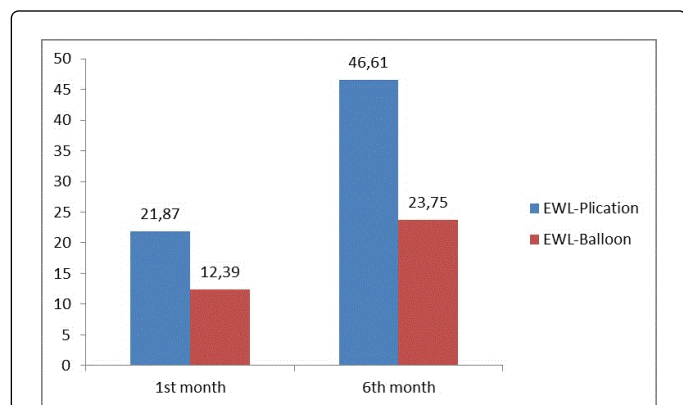


Figure 1: Mean percentage of Excess Weight Loss (EWL) change in the study.

Discussion

Laparoscopic Sleeve Gastrectomy (LSG) has gained popularity in last decade, and it is used worldwide nowadays. 5-year follow-up results showed that a mean EWL of 55.0 +/- 6.8% was achieved, indicating that LSG leads to stable weight loss [14]. On the other hand, the long staple line in sleeve gastrectomy operation has some complications, such as leaks and bleeding [15].

group in our study. Our BMI drop values were also similar to the literature.

The EWL results of our IB and plication groups were statistically different in favor of the plication group. Our EWL results of IB group were 12.39% (± 9.27) for the first month and 23.75% (± 17.15) for the 6 month. Results of 6 month are quite lower compared to the literature. Saruc et al. [25] found 46.9% (± 11.3) and Ghoneim et al. [24] found 64.12% (± 23.48). On the other hand EWL results of plication group were 21.87% (± 10.8) for the first month and 46.61% (± 17.75) for the 6 month that are similar to previous studies. Andraos et al. [23] published a series of 120 patients with the EWL results of 30.2% for the first month and 48.58% for the 6 month. Ramos-Corvala et al. [17] reported a series of 42 cases of plication in which EWL of first month was 20% and 6 month was 48%.

Our present study is the first one comparing two restrictive methods (one is surgical, other one is interventional) dealing with obesity. LGP is defined as having a least morbidity and mortality rates compared to other surgical methods. However IB is less invasive and have less complication compared to LGP. The limitations of current study are small number of patients, short follow-up period and retrospective design.

Our hypothesis at the beginning of our study was 'IB is as effective as LGP in lowering weight of obese patients. However we found that LGP is better than IB in losing weight for obese patients. We believe that this outcome is caused by inadequate weight loss of IB patients. There are some studies of IB showing better results about that. We need some prospective studies with longer follow-up to decide which method is better.

Conclusion

Finally, this study is the first one comparing surgical and interventional anti-obesity methods used widely. An early weight loss result of IB is encouraging and it may compete with the surgical methods by the development of new technologies in the future.

Conflict of Interests

The authors declare that there is no conflict of interests.

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