A view on Patterns of weight loss after Intragastric Balloon insertion in Iraqi Patients.

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Abstract

Obesity is a major metabolic illness that results from increased body fat and leads to negative health consequences. Obesity increases the prevalence of various diseases, including diabetes mellitus, hypertension, coronary heart disease, sleep apnea, CVA, GERD disease, gall bladder disease, certain types of malignancy, and non-alcoholic fatty liver disease[1]. Moreover, it is also a major avoidable health detriment. Current therapeutic approaches to obesity are lifestyle changes, pharmacologic treatment, and bariatric surgery.

Patients and methods

Twenty-seven patients visited our obesity clinic in Al Dewania Teaching Hospital from September 2016 to September 2017 and selected for intra-gastric balloon insertion after discussion with the patients, all current bariatric operative options beside the discussion to choose different balloon types. Air filled balloon was chosen.

Result

female to male ratio 3.1:1, with mean age 34±6.1 and mean body mass index 40.48 ± 5.16 had excess body weight 38.93 ± 8.44 Kg, all patients had been received IGB heliosphere 720 ml as treatment of their obesity. Each patient has been followed up 6 months and weight loss patterns observed. Mean weight loss after six month 9.6 ± 4.8 Kg

Conclusion

In regards of patient selection to the procedure, Patients should be selected according to their commitment to the recommended diet and life style modification, thiswould largely affect the outcome.

Introduction

Obesity is a major metabolic illness that results from increased body fat and leads to negative health consequences. Obesity increases the prevalence of various diseases, including diabetes mellitus, hypertension, coronary heart disease, sleep apnea, CVA, GERD disease, gall bladder disease, certain types of malignancy, and non-alcoholic fatty liver disease[1]. Moreover, it is also a major avoidable health detriment. Current therapeutic approaches to obesity are lifestyle changes, pharmacologic treatment, and bariatric surgery. Although intensive lifestyle modification was reportedly associated with only limited weight reduction[2-4], when it is combined with weight-loss drugs approved for long-term use, an additional weight reduction of 3%-9% can occur within 1 year[5]. Such drugs are said to improve several cardio-metabolic risk factors, but they are also related to harmful adverse effects[5]. Although new obesity medications have recently been approved and introduced[6-8], they are associated with issues of safety and high costs. Weight-loss surgery provides the most

sustained and effective therapeutic choice for obesity. Accessible methods include the adjustable gastric band, Roux-en-Y gastric bypass, or sleeve gastrectomy[9,10]. Regardless of its proven effectiveness, only 1% of obese patients eligible for the surgical procedure choose to undergo it[11]. The major issues with surgery are difficult accessibility, high costs, patient non-preference, and significant morbidity and mortality. Although its associated mortality has decreased considerably, the complication rate in the early and late stages of the bariatric procedure persist at 17% (95%CI: 11%-23%)[10].

Therefore, minimally invasive and effective methods are needed for the treatment of obesity. As such, endoscopic bariatric treatment was recently introduced. It includes intragastric balloons, gastroplasty techniques, aspiration therapy, and gastrointestinal bypass sleeves. Among them, the intra-gastric balloon has been the most frequently used in practice and the most studied for obesity treatment.

In 1985, the Garren-Edwards gastric bubble (GEGB) was the first intra-gastric balloon approved for obesity treatment and was introduced in the United States market.[12]. However, several adverse events were associated with its use, including small bowel obstruction associated with spontaneous deflation and gastric mucosal injury. Although the GEGB is no longer used, considerable advancements to its design have led to the development of a more effective and safer intra-gastric balloon. It is now being used in numerous countries.

The increased prevalence of obesity has motivated experts in bariatric medicine to advance minimally invasive endoscopic treatment for obesity management as well as innovative techniques that address important features of treatments, such as their efficiency and safety. A new meta-analysis showed that endoscopic obesity treatment could be effective and of substantial value if combined with a multidisciplinary and comprehensive treatment plan[13].

Intra-gastric balloon is placed in the stomach using endoscopic procedures under mild sedation in an outpatient setting. Intra-gastric balloons allow patients to sense fullness and ultimately reduce their food intake. It is hypothesized that the intra-gastric balloon facilitates satiety peripherally by being an obstacle to food consumption, decreasing intragastric volume, and delaying gastric emptying[14]. Additionally, signals transmitted centrally through the vagal nerves by activated gastric stretching receptors could affect satiety[14]. The intragastric balloon permits an early feeling of satiety, which is thought to be a consequence of gastric distention. The mechanical intragastric distention to a meaningful volume during mealtime significantly decreases the amount of food eaten[15,16].

Aim of study

For evaluation role of Intragastric Balloon insertion to decrease body weight in obese patients

Patients and methods

Twenty-sevenpatients visited our obesity clinic in Al Dewania Teaching Hospital from sept 2016 to sept 2017 and selectedfor intra-gastric balloon insertion after discussion with the patients, all current bariatric operative options beside the discussion to choose different balloon types. Air filled balloon was chosen.

Heliosphere IGB 720 cc positioning was performed, the manufacturer's instructions were followed in positioning the device, after diagnostic endoscopy, under unconscious sedation. After placement, the balloon was slowly inflated with room air to the final volume of 720 ml.All patients were discharged on the same day of insertion with omeprazole (po 20 mg/d), ondansetron (po 8 mg/d) and butylscopolamine bromide (po 20 mg t.i.d.).

All patients from day 3 after placement began liquid diet and were on a 1000 kcal diet (carbohydrate 146 g, lipid 68 g, protein 1 g/kg ideal weight). The patients were followed monthly, and complications and their treatment, post-placement symptoms, BMI and %EWL were recorded. After 6 months, the Heliosphere Bag was removed. Data were analyzedby SPSS 18.

Result

Twenty-seven patients enrolled in these study, female to male ratio 3.1:1, with mean age 34±6.1 and mean body mass index 40.48 ± 5.16 had excess body weight 38.93 ± 8.44 as in table1, all patients had been received IGB heliosphere 720 ml as treatment of their obesity. Each patient has been followed up 6 months and weight loss patterns observed.

Table 1: characteristic of patients

Variables	Mean ±SD
Age	34±6
Body weight (kg)	124.25 ± 35.73
Body mass index (at insertion)	40.48 ± 5.16
Excess body weight (kg)	38.93 ± 8.44

In table two show the difference in excess body weight and body mass index with gender. In male the excess body weight were 44.45±10.58 while in female 36.38±15.2 the difference not statistically significant. The BMI in male were 43.52±4.89 and in female were 39.2±5.914 which is not significantly difference between them.

Table 2: distribution of weight according to gender.

	Sex	Mean± Std. Deviation	p-value
Excess WT(kg)	Male	44.45±10.58	0.83
	Female	36.38±15.02	
BMI	Male	43.52±4.89	0.25
	Female	39.2±5.914	

After six months mean BMI of all sample were 33.28±6.21, mean loss of BMI 4.75 ± 1.87, mean of body weight loss 9.6 ± 4.8. more weight loss occurred in two months after insertion of balloon in mean loss 9.4±5.35, as shown in table 3.

Table 3: show body weight variation during and after six months of insertion balloon.

Variables	Mean± Std. Deviation
BMI after 6 month	33.28±6.21
Weight loss in six month(kg)	9.6 ± 4.8
BMI loss (kg/m2)	4.75 ± 1.87
EBMIL%	26.67 ± 12.88
Two month weight loss(kg)	9.4±5.35
Four month WT loss(kg)	3.82 ±3.4
Six month WT loss(kg)	1.51± 2.86

Other result reveal male had more weight loss than female, in male mean 13.45±5.41and in female 8.47±3.52, on other hand percent of weight loss according to body weight in female 27.12±11.01and in male 26.05±10.71 as in table 4.

Table 4: show difference in weight loss between gender.

	Sex	Mean± Std. Deviation	p-value
WT loss within six month(kg)	Male	13.45±5.41	0.02
	Female	8.47±3.52	
Percent weight loss	Male	26.05±10.71	0.63
	Female	27.12±11.01	

During the follow up period many patients had developed complication after insertion of intragastric balloon, 49% had vomiting, 42% had only nausea, 56% feel epigastric discomfort and 11% patient need admission, 3.75 develop gastric perforation, as shown in table 5.

Table 5: show distribution of complication.

Complication	percentage
Vomiting	49%
Nausea	42%
Epigastric discomfort	56%
Re admission	11%
Gastric perforation	3.7%

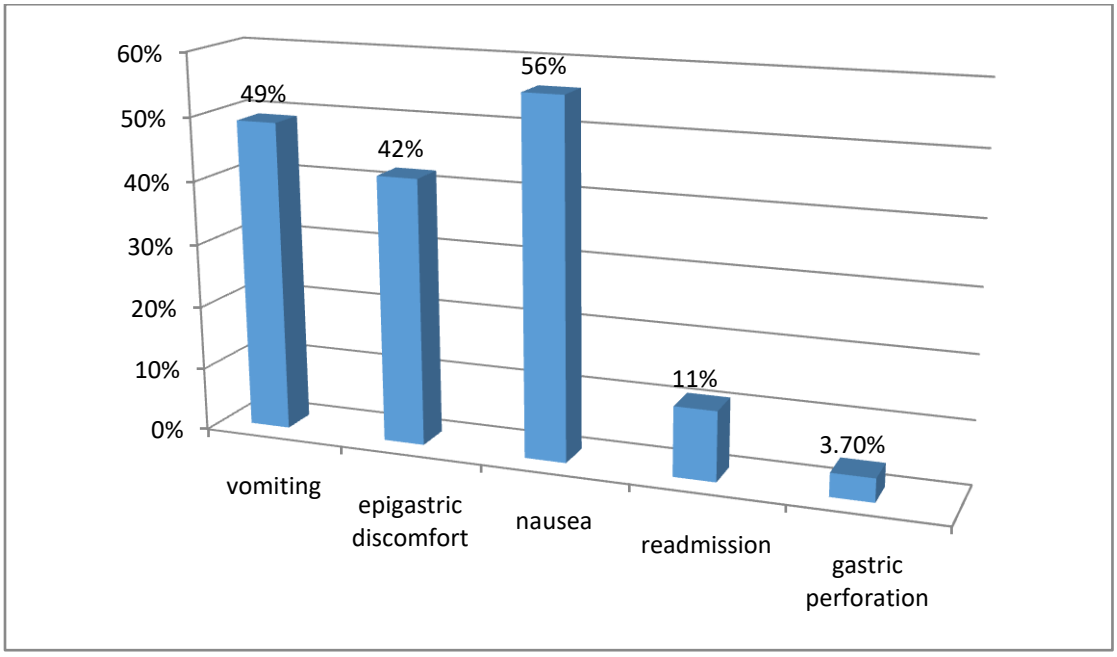

Figure 1: show percent of each complication

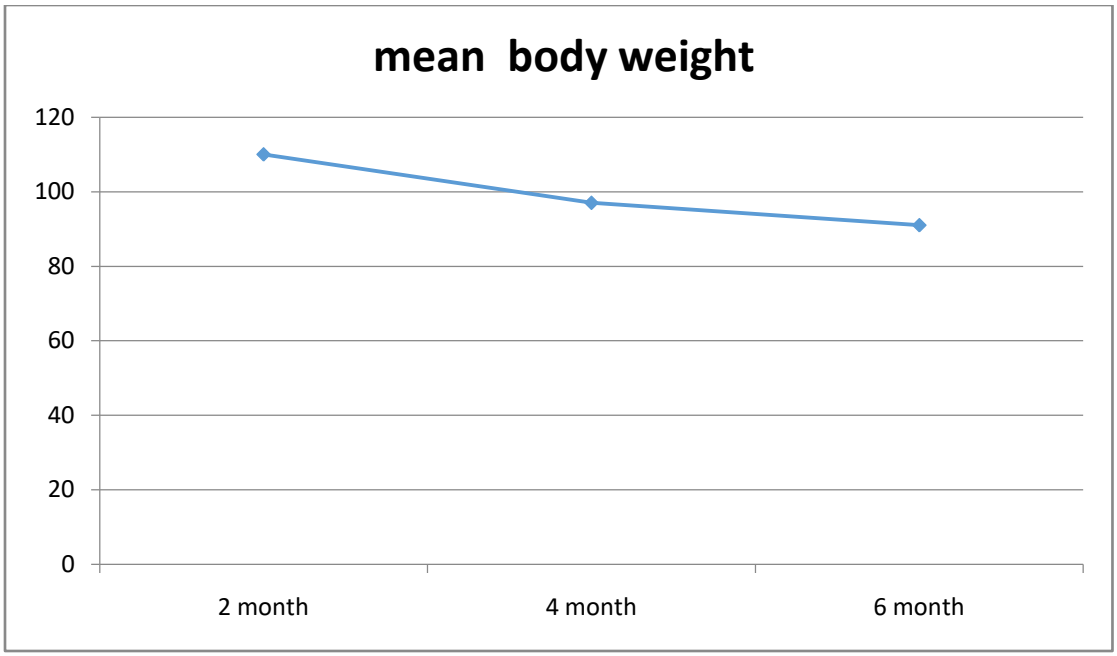

Figure 2: show trend in decrease of mean of body weight after six month.

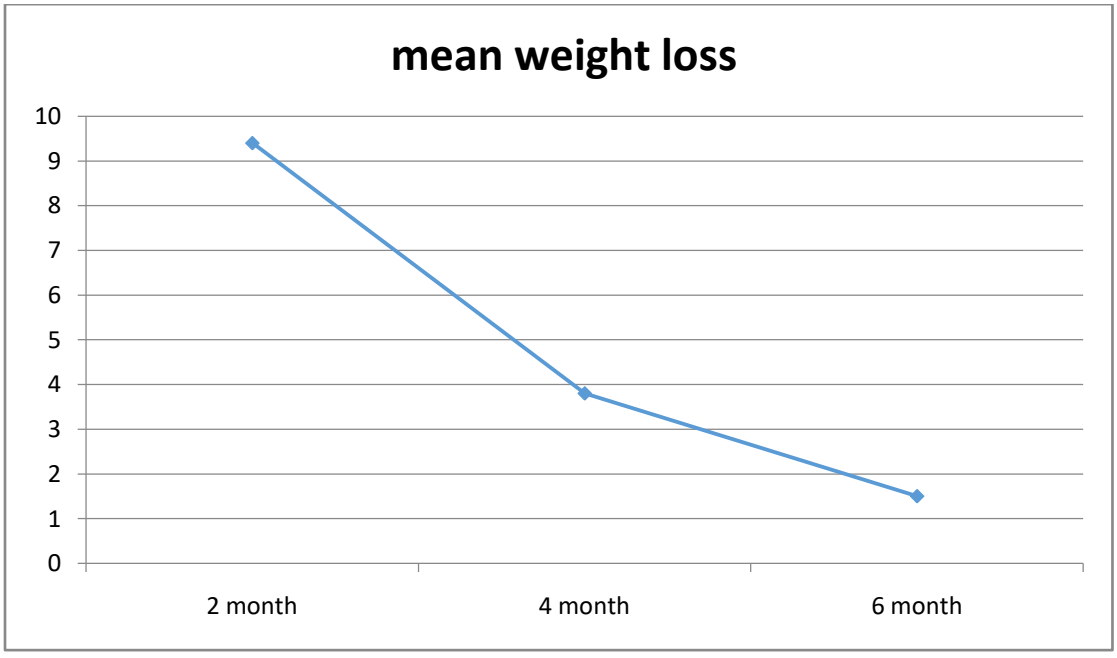

Figure 3:show trend in decrease in amount of weight loss in six month.

Discussions

New emerging technology trends in endoscopic treatment for obesity require an extensive and meticulous research plan to promote finding and recognize their optimal role in managing obese patients and their applications for clinical practice[17]. Intra-gastric balloon placement can be performed through a simple endoscopic method and is easily reversible. This simplicity offers an expansive role in obesity treatment based on the degree of obesity.

Intra-gastric balloon treatment might produce only short-lasting effects in obesity treatment. Thus, it is important to maintain weight loss following intra-gastric balloon removal. Long-term management for weight reduction after intra-gastric balloon removal can also comprise intensive lifestyle modification, alone or with pharmacotherapy, and could be suggested to protect against weight regain

According to our results, maximumweight loss achieved, was in the first two weeks of IGB insertion. In this period, nausea and epigastric discomfort were maximum, soon later when patients started to tolerate these symptoms, the weight loss achievement decreases and oral feeding becomes more tolerable.

The corner stone of obesity management is patient compliance. It is crucial and vital. One of our patient who lost only 4 kgs after 6 months, said he was dividing sweet food into pieces so can ingest them without difficulty and without inducing nausea and epigastric cramps.

Three patients developed severe abdominal cramps and they asked to retrieve the IGB, we responded by readmission and prescribing more analgesia and IV fluid without improvement in their symptoms and final decision of retrieval of the IGB was taken, basedon patients request.

All our patients received IGB insertion as their definitive obesity treatment but with possible second line bariatric surgery based on patients' weight loss achieved, all our patients have been informed that IGB could be their definitive therapy if the commit to the diet and life style modification. This was our goal to achieve maximal patient compliance.To encourage the patients to commit to the diet and life style modifications, we informed the patient that the IGB could be their final bariatric intervention.

This point is against most of studies that suggest IGB as bridge to bariatric surgery[18]

One patient developed acute abdominal pain and tenderness 12 hours after insertion with air under diaphragm. At Laparotomy, we found tiny pin point fundal gastric perforation and was repaired with primary closure and drainage of sub phrenic space with nasogastric suction tube patient recovered well and discharged home on the sixth postop day without complication. Such complication was not reported till the date of writing this paper as we did extensive online researches. This was life threatening complication and need urgent intervention. Thus, close clinical follow up is indicated in the first 24 hours after insertion. We recommended adding such complication to the informed consent.

The results of our studysupport most of the studies that recommend intra-gastric endoscopic bariatric interventions and concluded that it is promising procedure. the average of our patient BMI decreases to below 35 % where surgery is not indicated at such level, a part from the higher BMI in those studies, all other variables included, were the same. However no one of these studies BMI decreases below 35 %, due to the higher Baseline BMI .[19] [20] [21]

We concluded the following:

1. In regards of patient selection to the procedure, Patients should be selected according to their commitment to the recommended diet and life style modification, thiswould largely affect the outcome.Larger scales and volume studies are needed particularly those studies that divide patients into groups according to the compliance and commitment to the diet and behavioral and life style changes they need to achieve the ideal body weight beside IGB insertion, those patients who understand that any bariatric procedure is not the only needed to lose weight.
2. Incidence of life threatening complication was 3.7 %, Close follow up is indicated in the first 24 hours to detect gastric perforation.Material and safety issues regarding the intra-gastric balloon should be further investigated.
3. More research should be performed to investigate a pathophysiologic pattern of obesity, the uncertain role of gut hormones, potential predictive factors for the efficacy of the intra-gastric balloon in obesity treatment, and individualized treatment-induced changes.[22][23][24]

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