ORIGINAL ARTICLE

Intra-Gastric Balloon for Weight Loss: Preliminary Analysis of Efficacy & Tolerability

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ABSTRACT

Aim: To assess the efficacy and tolerability of intragastric Balloon Placement in association with restricted diet that is being used for the short-term treatment of morbid obesity.
Study design: Cross sectional Study
Place and duration of study: Department of Medicine Ghurki Trust Teaching Hospital, between June 2009 and December 2011.
Methods: Intragastric balloons were placed in 30 patients with obesity. The inclusion criteria were obesity (BMI >35 kg/m^2), the presence of obesity-related problems, and failure with conventional treatments for at least 6 months. Balloon placement was done on an inpatient basis, under Propofol anesthesia. Inflation of balloon varied between 600-650ml saline, depending upon stomach's capacity. Intravenous antiemetic, PPI and spasmolytic drugs were given to control post-insertion nausea for 24 hours, and oral medication were administered later on. A standard 1200 Kcal diet was prescribed after dietitian's consultation. Balloon was kept for six months and then removed endoscopically. Any morbidity, complications, BMI and weight loss were evaluated. Data were expressed as mean ±SD.
Results: 30 patients (16 M, 14 F) with mean age of 33±8 years were included after pre-procedure evaluation. 28 patients were eligible for review after 6 months; Mean weight loss was 21.2±9.05 (3-56 kg). Mean initial weight was 125.8±37.5 (102 to 236 Kg) and it dropped to 104±25.9 (82 to 180Kg) ($p<0.05$) six months later. Mean pre-procedure BMI was 43.6±3.6 (37.6 to 50 kg/m^2) while 6 months later it dropped to 37.7±4.2 ($p<0.05$). 100% of the patients complained of severe nausea, vomiting, epigastric discomfort and retrosternal burning, resulting in early removal of the balloon at day 7 in two patients. In 82% patients, esophagitis (grade III to IV) and diffuse gastric erosions were present at the time of withdrawal of balloon.
Conclusion: Intragastric balloon is associated with successful weight loss. Although severe morbidity can occur, but it provides a good means of weight reduction in conjunction with dietary measures and exercise.
Keywords: Intra-gastric Balloon, Body Mass index, Obesity, weight-loss.

INTRODUCTION

Obesity (defined as a BMI ≥30 kg/m^2) is a chronic, multifactorial and genetically determined disease of excess fat storage. The absolute and relative excess of adipose tissue and the visceral distribution of fat, place the obese individual at risk of pre mature death and obesity-associated comorbidities[1]. The aims of treatment for obesity are to reduce body weight and then to maintain reduced body weight, thus reducing risk of cardiovascular disease, preventing obesity-related diseases, and improving quality of life.

The first approach to reducing body weight should consist of a combination of a low Calorie diet, physical activity and behavior modification[2]. This approach remains an integral part of any subsequent treatment with drugs or bariatric surgery. When motivated patients have attempted to lose weight but have failed, pharmacotherapy is recommended. Most guidelines justify drug treatment in individuals with a BMI ≥30 kg/m^2 or a BMI ≥27 kg/m^2 in the presence of relevant co-morbidities, such as type 2 diabetes, hypertension, dyslipidemia, sleep apnea and coronary heart disease[1,2,3]. Surgical approach is restricted to very obese individuals (BMI ≥40 kg/m^2 or BMI ≥35 kg/m^2 with obesity associated co-morbidity). There is a large group of patients with a BMI of 30–40 kg/m^2 who may not respond to medical therapy but are not yet surgical candidates. Endoscopic treatment, such as Intra-Gastric balloon, may have a role as an alternative or adjunct to medical treatment in these patients. This type of therapy might also be an option for very obese patients who are unfit and therefore less suitable surgical candidates.

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Intra-gastric balloon occupies a portion of the gastric volume and this theoretically reduces the stomach's capacity. This device physically impedes the intake of nutrients and, through outlet obstruction, delays gastric emptying. Reduced gastric capacity generates early satiety, a reduced sense of hunger, a sensation of fullness and a diminished desire to eat[4]. In addition to the peripherally mediated sensation of satiety, distension of the gastric walls activates the nucleus of the tractus solitarius and the paraventricular nucleus, resulting in a centrally mediated feeling of satiety. Patients may behave differently according to social and dietary habits to IG balloon. A lot of long and short term studies have been done in different parts of world on the performance of IG balloon but most of them have been sponsored by the manufacturer of balloons due to which results seem biased and they have not been done on Asian people. We performed this study to look at the effects and adverse responses in our population and to have an idea about its efficacy, tolerability, acceptability and safety.

PATIENTS AND METHODS

This study included 30 patients (16 male and 14 Female), with mean age of 33± 8years. Patients were either preobese or obese who failed to respond to previous treatment for weight loss or those who did not meet the standards for bariatric Surgery or those who were not willing to undergo bariatric surgery. Their pretreatment mean weight was 128±37.5 (102 to 236 Kg), mean BMI was 43.9±3.6 (37.8 to 50 kg/m^2), and mean EW was 37.6± 16.6 kg (25.5 to 98.7 kg).

The preliminary evaluation was conducted by a multidisciplinary team that comprised Nutritionist, Bariatric surgeon, Anesthetist and Gastroenterologist/Endoscopist. At this time, information regarding the patient's eating habits and their previous obesity treatments were considered. Free and informed consent from the patients was obtained only after explaining to them the need of the behavioral changes after the IG Balloon placement, the importance of the follow-up visits, and the risks related to this procedure.

For the IGB procedure, we considered the following as absolute contraindications: the presence of hiatus hernia >5 cm, active peptic ulcer, severe esophagitis or gastritis, serious cardiopulmonary, renal or hepatic disease, previous gastric surgery, Alcoholism, psychological disturbances, and lack of motivation or reluctance to follow the treatment protocol, behavior modifications and life-style changes. A standard 1200 Kcal diet was prescribed after dietitian's consultation.

The IG Balloon is supplied empty, and is delicately rolled up inside a thin silicon sheath. This makes its placement and positioning in the gastric fundus possible by endoscopic route. The device consists of a smooth and transparent silicon shell that acquires a round format when filled with saline solution. (Figure 1) The filling is done by a tube with a needle at its extremity, which is connected to a self-sealing valve attached to the device shell[5].

Procedure was performed under sedation using Propofol Anesthesia. During the placement procedure sheath of the deflated balloon is anchored with the help of a snare and smoothly inserted into the stomach under direct visualization with the help of Gastro scope. In the gastric fundus, the balloon is filled with saline solution (mean volume used 600ml) along with methylene blue indicator and urograffin contrast. After filling, balloon is inspected for proper inflation, possibility of any leakage and correct positioning of balloon. Antiemetic, PPI and anti-spasmolytic were routinely prescribed to all the patients. During removal procedure balloon was punctured with the help of sharp needle and all the saline drained with the help its catheter. Deflated balloon is then got hold of with the help of rat tooth forceps and brought out under direct visualization.

To evaluate the efficiency of variables of patients and adverse effects, which completed the 6-month treatment, the Shapiro-Wilk's test for normality was used. The t test for paired observations under significance of 0.05 was used to evaluate the preliminary effectiveness of the proposed treatment. The descriptive statistics values are presented as mean ± standard deviation. Data was processed in SPSS software version14.

RESULTS

In all patients balloon was successfully placed and removed under the cover of propofol anesthesia. In two patients balloon was removed prematurely due to non-acceptability within seven days of placement. There was no case of Balloon rupture, deflation or loss within GI tract. Mean weight loss was 21.2±9.05 (3-56 kg). Mean initial weight was 125.8±37.5 (102 to 236 Kg) and it dropped to 104±25.9 (82 to 180Kg) ($p<0.05$) six months later. Mean pre-procedure BMI was43.6±3.6 (37.8 to 50 kg/m^2) while 6 months later it dropped to 37.7±4.2 ($p<0.05$). Individual detail of patients is shown in Table 1, as categories.

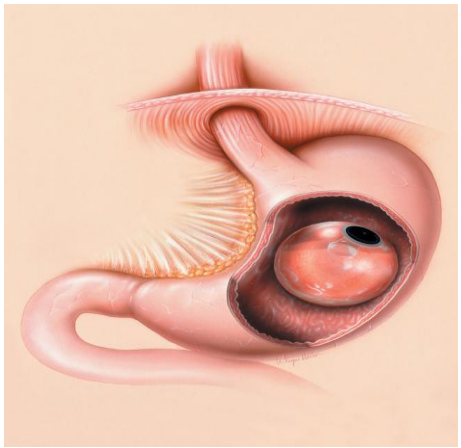
We asked the patients about their experience of tolerability of balloon for six months time period. Majority of patients were of the view that procedure of placement and withdrawal of balloon is simple and pain less but the magnitude of side effects especially in the initial two weeks makes the experience very

unpleasant and difficult to tolerate. Major adverse effects for the patients were nausea, vomiting, pain epigastrium, retrosternal burning, abdominal pain and diarrhea. ($p<0.05$) While those which were found on endoscopy were severe esophagitis and gastric erosions.($p<0.05$).(Table2).

Although none of our patients underwent Hemetemesis or Gastric rupture, but continuous feeling of nausea, vomiting and may be mechanical impedance of balloon to smooth functioning of stomach led to severe Esophagitis and Gastritis as seen in two patients in whom balloon has to be removed prematurely and in 90% of patients at six months time.($p<0.05$).While for diarrhea and abdominal pain p value was more than 0.05.

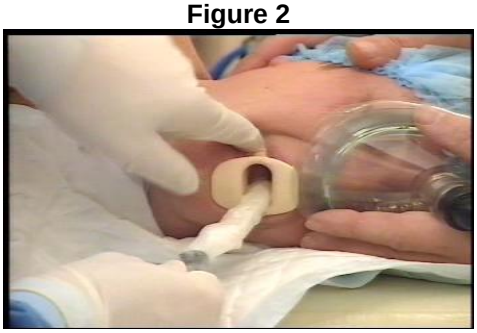
Figure 1

Intragastric Balloon



IG balloon in stomach

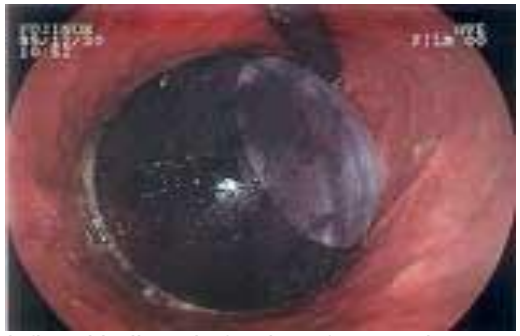
Figure 2



Introduction of balloon

Balloon Inside the stomach

Inflation with saline



Fully inflated balloon in fundus of stomach

Table 1: Results of IGB placement in patients who completed treatment

Pt No	Initial Weight	Final Weight	Weight loss	Initial BMI	Final BMI	Tolerability Acceptability
1	108	82	26	37.8	31.0	Poor
2	104	84	20	40.2	32.6	Poor
3	130	100	30	42.3	36.4	Fair
4	128	119	9	46.2	39.0	Fair
5	236	180	56	50.0	39.4	Good
6	144	120	24	48.2	41.6	Fair
7	162	110	52	47.3	40.4	Poor
8	102	86	16	45.4	41.0	Poor
9	130	96	34	47.4	38.6	Poor
10	110	91	19	41.2	33.5	Poor
11	103	100	3	42.6	41.6	Poor
12	102	96	6	42.0	40.5	Fair
13	105	88	17	41.0	36.0	Poor
14	110	82	28	37.6	31.0	Poor
15	106	86	20	40.0	32.8	Poor
16	130	102	28	41.6	36.2	Fair
17	132	118	14	46.2	39.0	Fair
18	198	170	28	51.2	39.6	Good
19	140	116	24	49.6	41.0	Fair
20	110	82	28	43.3	36.7	Poor
21	112	86	26	42.4	37.0	Poor
22	130	106	24	42.4	36.6	Poor
23	112	91	21	41.0	34.5	Poor
24	129	123	6	46.6	45.6	Poor
25	104	88	16	41.0	36.0	Poor
26	112	98	14	41.0	37.0	Poor
27	112	108	4	41.0	40.6	Fair
28	122	108	14	46.0	41.6	Fair

Table 2: Adverse effects experienced

Adverse effects	1 month	3 months	Six months	p-value
Nausea	30/30	28/28	12/28	P< 0.05
Vomiting	30/30	25/28	11/28	P< 0.05
Pain epigastrium	30/30	20/28	13/28	P< 0.05
Retrosternal Burning	30/30	28/28	22/28	P< 0.05
Abdominal Pain	15/30	0/28	2/28	P= 0.16
Diarrhea	6/30	1/28	0/28	P= 0.12
Esophagitis	2/2	-	23/28	P< 0.05
Gastric erosions	2/2	-	20/28	P< 0.05
Peptic ulcerations	0/2	-	0/28	P< 0.05
Gastric perforation	0/30	0/28	0/28	P< 0.05

*Esophagitis, Gastric Erosions and Peptic Ulcerations were found as Endoscopy findings at the time of balloon removal

DISCUSSION

Intra-gastric balloons have been used since the 1980s, but were abandoned in 1987 because of complications and premature balloon deflation[12]. Requirements for an optimal balloon design were formulated and have resulted in the development of an IG balloon that is devoid of most of the shortcomings of older variants. In an attempt to lose weight the first approach remains a combination of energy restricted diet, physical activity and behavior modification[13]. These first steps remain an integral part of any subsequent treatment with drugs or bariatric surgery. When motivated patients fail to lose weight pharmacotherapy is indicated as it has been advised by many guidelines especially for those who are having co-morbidities like Diabetes, Hypertension and Hyperlipidemia. Endoscopic treatment, such as an intragastric balloon, may have a role as an alternative or adjunct to medical treatment in these patients and also for those who are poor surgical or anesthesia candidates[14].

Dastis NS et al[6] was the first to describe long-term outcomes after a 6-month IG balloon treatment. 100 overweight or obese individuals were enrolled in the study. The results of the study showed that 63% of patients achieved successful weight loss in the first 6 months of IG balloon treatment. This weight loss was maintained by 24% of patients after 2.5 years and by 28% of patients after a mean of 4.8 years. Complications were reported, such as balloon deflation in 4% of patients, balloon intolerance in 7% of patients and esophagitis discovered upon balloon removal in 16% of patients. Similarly Study done by Genco A et al[7] which was a prospective, double-blind, randomized, sham-controlled, and crossover study

demonstrated that the procedure with IG balloon was more effective in treating obese patients than the sham procedure with restricted diet.

Looking at all the major other studies regarding weight loss by IG Balloon the mean weight loss has been around 11-15 kg. Gustavo et al [5] showed a weight loss of 11.3± 6.2 kg, Herve et al [8] and Evans et al[9] obtained a mean weight loss of 12 kg in 100 patients and 15 kg in 58 patients respectively. In contrast, the mean weight loss in the present study was 24 Kg which is higher than the previous studies. Difference in dietry habits may be the reason of this difference in our population. Also the magnitude of side effects has been low in the above mentioned studies especially the one done by Gustavo et al where epigastric pain occurred in only 21% of patients and nausea and vomiting in limited number of cases. But in our study nausea, vomiting, pain epigastrium and retrosternal burning was a constant feature and even the early removal of balloon was done in 2 patients (6.6%) due to similar problem. These adverse effects made balloon a less tolerable device to almost all of the patients. Similarly endoscopic findings at 6 months time which showed esophagitis and gastric erosions were in a very high proportion in present study in contrast to the other studies (Fig. 2).

Unfortunately there is no clear answer to differences of weight loss and tolerability in the present study in contrast to the previous ones[15]. Designs of the study does not show that balloons have a physiological effect on appetite suppression, a behavioral effect on eating, or whether they work primarily through combination with exercise program.[16] As patients in the present study adhered to a low calorie diet and exercise programme so it may be a reason for good weight loss or alternatively weight gain in our population was due to increase dietry intake which when reduced by balloon worked as an additive source.

Only in the study by Dastin et al[6] significant predictive factors for weight loss at 6 months were analyzed and found out to be the amount of weight lost at 3 months, maintenance of a fiber enriched, fat-restricted diet, a full course of balloon treatment, the implementation of an exercise program, and balloon fill volume. For weight maintenance, only weight loss at 3 and 6 months and a fiber-enriched, fat-restricted diet were significant predictive factors.

One other factor is the concomitant use of medications which is usually in the form of PPI is done in all the studies. The continuous use of the PPI during treatment is mandatory to ensure this safety by protecting the gastric mucosa and the balloon shell from the deleterious effect of the hydrochloric acid.[17,18] As a result of this continuous use and consequent reduction in gastric acidity, the patient's digestive tract becomes a more favorable environment to the Candida sp, and other microorganisms, which may then be harmful to the gastric mucosa. Further work up will be needed in this regard. Similarly filling of saline inside the balloon also varies according to the capacity of stomach and balloon manufacturer recommendation. On the average we used 600-650 ml of saline in the IG balloon but it is variable in different studies. Recently air filled balloon is also introduced which has shown promise in the form of low side effect profile.[11]Further studies will be needed to evaluate the role of these variables and their management[19,20].

CONCLUSION

Intragastric balloons may be helpful in combating the obesity epidemic and its associated health implications by achieving weight loss in patients but more data regarding the mode of action of intragastric balloons, the identification of suitable patients for this procedure and management of adverse effects will be needed before its recommendation in usual weight loss programme and obesity management guidelines. Although efficient, but high incidence of adverse-effects make IG balloon a poorly acceptable choice.

REFERENCES

1. World Health Organization. Obesity: preventing and managing the global epidemic. Report of a WHO Consultation on Obesity, Geneva, 3–5 June 1997. Report no.: WHO/NUT/NCD/98.1 (1997).
2. Mathus-Vliegen EM, Tytgat GN, et al. Intragastric balloon for treatment-resistant obesity: safety, tolerance, and efficacy of 1-year balloon treatment followed by 1-year balloon free follow-up. Gastrointest Endosc.2005: 61; 19–27.
3. National institute of Clinical excellence. Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children. National Institute of Clinical Excellence, www.nice.org.uk/CG43 (2006).
4. Pasquali, R. *et al.* Mechanisms of action of the intragastric balloon in obesity: effects on hunger and satiety. Appetite 1990: 15; 3–11.
5. Busetto L, Mirabelli D, Petroni ML et al. Comparative long-term mortality after laparoscopic adjustable gastric banding versus nonsurgical controls. Surg Obes Relat Dis.2007; 3(5):496–502
6. Carvalho GL, Barros CB, Okazaki M, et al. An improved balloon procedure using a new balloon: Preliminary analysis of safety and efficiency. Obes Surg.2009;19: 237-42.
7. Dastis NS. *et al.* Intragastric balloon for weight loss: results in 100 individuals followed for at least 2.5 years. Endoscopy 2009: 41(7); 608-11

8. Genco A, Cipriano M, Bacci V, et al. Bioenterics Intragastric Balloon (BIB®): a short-term, double-blind, randomized, controlled, crossover study on weight reduction in morbidly obese patients. Int J Obes. 2006;30:129–33.
9. Herve J, Wahlen CH, Schaeken A, et al. What becomes of patients one year after the intragastric balloon has been removed? Obes Surg. 2005;15:864–70.
10. Evans JD, Scott MH. Intragastric balloon in the treatment of patients with morbid obesity. Br J Surg. 2001;88:1245–8.
11. Mathus-Vliegen EM. News and Views. Intragastric balloons-A bubble to combat the obesity bubble? Nature Reviews/Gastroenterology and Hepatology 2010;7:7-8
12. L. de Castro et al. Safety, efficacy and tolerance of two types of intragastric balloons placed in obese subjects. A double blinded comparative study. Gut 2009; 58 (Suppl II) A119
13. Mion F, Gincul R, Roman S, et al. Tolerance and Efficacy of an Air-filled Balloon inNon-morbidly Obese Patients: Results of a Prospective Multicenter Study. Obesity Surgery 2007; 17:764-769.
14. Forestieri P, De Palama GD, Formato A, et al. Heliosphere Bag in the treatment of severe obesity: Preliminary Exerience. Obes Surg 2007;16:635-637.
15. Crea N. et al. improvement of metabolic syndrome following intragastric balloon: 1 year follow-up analysis. Obes Surg 2009;19,1084–88
16. Genco A, Bruni T, Doldi SB, et al. Bioenterics Intragastric Balloon: the Italian Experience with 2515 patients. Obes Surg. 2005;15:1161–4.
17. Suter M, Giusti V, Worreth M et al. Laparoscopic gastric banding: a prospective, randomized study comparing the LAPBAND and the SAGB: Early results. Ann Surg 2005; 241(1):55–62
18. Shekelle PG, Morton SC, Maglione M et al. Pharmacological and surgical treatment of obesity. Evid Rep Technol Assess 2004;103(103):1–6
19. Dixon JB, O'Brien PE. Improvements in insulin sensitivity and beta-cell function (HOMA) with weight loss in the severely obese. Homeostatic model assessment. Diabet Med 2003;20(2):127–130
20. Khaitan L, Van Sickle K, Gonzalez R et al. Laparoscopic revision of bariatric procedures: is it feasible? Am Surg 2005; 71:6–10.