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AMERICAN INTRAGASTRIC BALLOONS ARE SAFE AND EFFECTIVE FOR WEIGHT REDUCTION

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ABSTRACT: *The bioenteric balloon (BIB) or spatzs ballon are widely applied in the management of obesity. This is a report on the efficacy and safety of Ballon device in the first 106 cases. Patients referred for Balloon between 2015 till 2016 were evaluated retrospectively. Balloon was inserted for 6 months according to predetermined inclusion and exclusion criteria. In 106 cases, 22 cases were males (16.8%) and 84 cases were females (83.2%), mean age 33.2 (±10.44) years, mean BMI 35.9 (±4.65) kg/m2. None of the patients exhibited balloon migration or perforation. The balloon was removed upon request in 3 patients due to exaggerated intolerance (2.9%). The mean weight loss was 15.5 kg (±4.67), mean EWL 64.12% (±23.48%). The mean BMI at extraction was 29.7 kg/m2 (±4.48) with a BMI loss of 6.2 kg/m2 (±2.0). 87 patients (88.7%) achieved target EWL (32.1% of excess weight), and 87 patients lost >12.2% of their basal weight (88.7%). 70 patients achieved BMI loss >5.7 kg/m2 (71.4%). BIB and spatzs balloon achieves acceptable success with minimal complications. In further long term, prospective studies are needed to evaluate obesity related comorbidities when using such modality and to compare it to* other available devices.

KEYWORDS: Bioenteric Balloon, Spatzs Balloon, Obesity, Weight Loss, American Balloon

INTRODUCTION

Between 1980 and 2004 the prevalence of obesity increased from 15% to 33% among adults and the prevalence of overweight in children increased from more than 6% to 19% in the United States. Once considered a high-income country problem, overweight and obesity are now on the rise in low- and middle-income countries, particularly in urban settings [1].

The real burden of obesity as a social health problem is its association with an increased risk of numerous chronic diseases, type II diabetes, coronary heart disease, cerebrovascular stroke and even malignancy. Consequently, the obesity epidemic exerts a heavy toll on the economy with its massive healthcare costs. The problem of overweight and obesity has therefore emerged as one of the most pressing global issues for the coming several decades, and demands attention from the healthcare community, researchers, and policy makers [2] [3].

Broadly, management of obesity comprises primary management of obesity, management of obesity-related diseases and management of complications of bariatric surgery like bleeding, anastomotic strictures and fistulae [4]. The spectrum for endoscopic management of obesity is wide. It comprises gastric volume reduction procedures by balloon insertion, stapling or plication devices as well as small bowel approach procedures like the duodenal- jejunal bypass sleeve [5].

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The intragastric device had to be fluid filled, adjustable to various sizes, andhad a smooth durable and non-ulcerogenic surface. It should also contain a radio-opaque marker to be seen on X-ray in follow-up and should be made of durable materials that do not leak [6]. The most known intragastric balloon for treatment of obesity are the BIB (balloon of BioEnterics, USA) and spatzs adjustable balloon . After its insertion, Balloon exerts a restrictive effect causing a sense of fullness, decreasing gastric emptying and thus producing early satiety. Additionally, it may be believed to cause decrease in plasma levels of ghrelin [7] [8].

The balloon insertion is an easy procedure done under conscious sedation or full sedation . It is filled with an average of 500 cc-700cc saline colored with 10 ccs methylene blue, serving as a marker of early leak from the balloon (being excreted in urine). In 2001. Evans and Scott reported an 18.7% EWL (excess weight loss) among 63 studied cases with a mean BMI (body mass index) of 46.3 kg/m2. The BIB migration rate in their series was 4.7%. In a larger scale study on 2515 cases with a mean BMI of 44.4 kg/m2 Genco and co-workers reported an EWL of 33.9% [9].

Although the ballon is considered safe, some complications have been reported. The most common of these is the early intolerance occurring in the first few days following insertion and may rarely extend up to few weeks necessitating patient hospitalization to ensure hydration and blood chemistry homeostasis. Intolerance seen as abdominal pain, nausea and vomiting are usually variable from one patient to another. Rare complications that have been reported include gastric bleeding, ulcerations and regurge without necessitating premature balloon removal 1% - 2.5% [7] [9] [11].

Aim of the work: The aim of the current study is to assess the efficacy and safety and tolerance of BIB and spatzs balloons device in terms of weight reduction and management of obesity.

PATIENTS AND METHODS

Patients who were referred for balloon insertion during the period between January 2015 and December 2016 were evaluated retrospectively. Before the procedure, patients were subjected to clinical assessment, weight, height, and BMI calculation. The procedure was done after both written and informed consents were obtained. Patients were well informed about the procedure, its potential success and potential complications. All patients were given a dieting and medical treatment regimen program for the post procedural period extending for 4 -6 weeks, and they were referred to a specialized nutritionist to carry out a specified nutritional and behavioral educational program for the six months to follow the procedure until extraction of the device. Patient enrollment was according to pre-determined inclusion and exclusion criteria. The inclusion criteria were patients aged 18 years or older who failed to achieve adequate weight loss within a supervised weight-control program, BMI more than or equal to 30 kg/m2. The exclusion criteria were considered in case of hormonal or genetic causes for obesity, neoplastic disease, pregnancy or a desire to become pregnant within the following six months, large hiatus hernia, gastro esophageal reflux disease (GERD), peptic ulceration, esophageal or gastric varices, and previous bariatric surgery.

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The Balloon

Is made of an inert, nontoxic silicon elastomer that is resistant to gastric acid. The balloon has a radiopaque self-sealing valve that allows adjustment of the volume in a range of 400 to 700 ml.

The Technique as Provided by the Manufacturer Instructions

Implantation

Diagnosis endoscopy is performed to rule out abnormalities that would preclude implantation. The device is introduced down the esophagus gently till the 40 cm mark on the tube is reached.

The endoscope is then passed to the stomach side by side with the placement assembly tube to aid further introduction of the balloon under direct vision to the stomach (just before the antrum).

The inflating fluid is injected through a one-way valve allowing suction of the inflating material from the container and re-injecting it into the balloon.

Procedure is done under direct vision. The used volume was a standard of 500 ml saline solution mixed with 10 ml Methylene blue.

The latter served as a color indicator in case of leakage, where any leakage can be noticed through urine excretion being bluish or greenish in color[12]-[14].

To release the balloon, gentle suction is exerted on the assembly tube by withdrawing the plunger of the syringe, this creates negative pressure that seals the self-adhesive valve in the balloon, then the balloon is released by a short pull on the fill tube setting the balloon free in the gastric body without any antral impaction.

(Figure 1 BIB)

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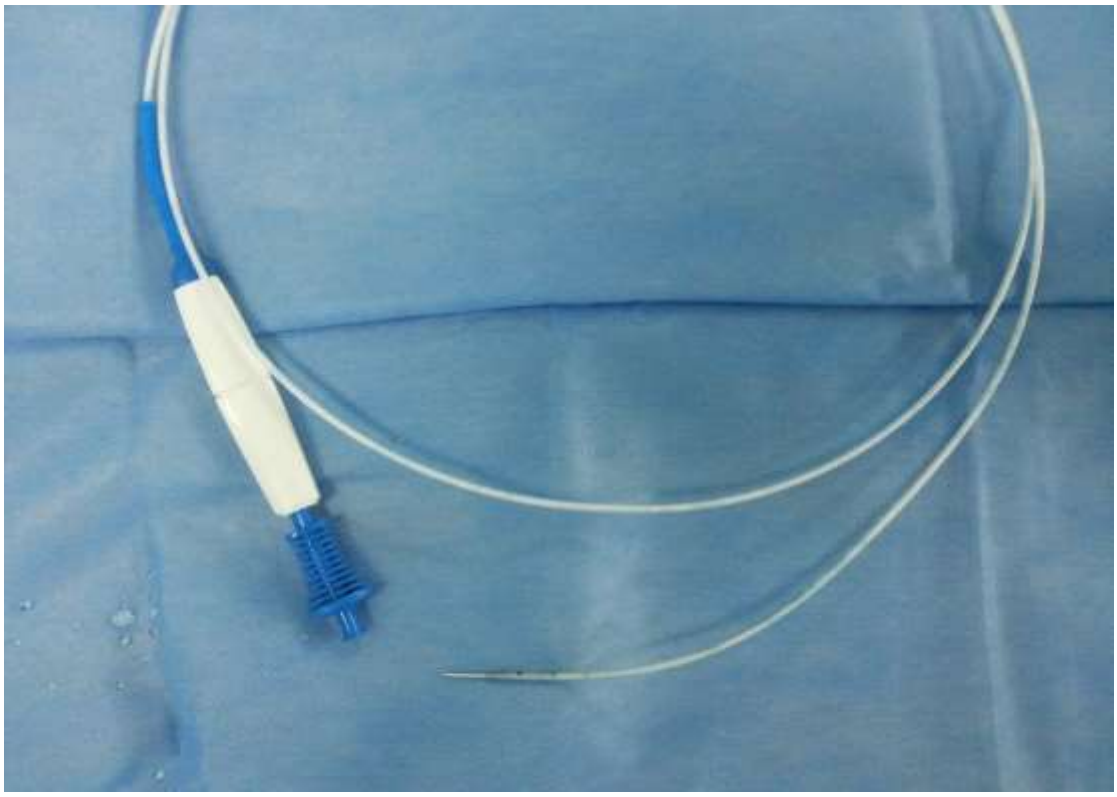
(Figure 2 spatzs balloon)



(**Figure 3 Aspiration needle**)

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Post procedure care

To guard or to manage any patient discomfort or nausea in the first few hours after the procedure the following was given: I.V. proton pump inhibitor infusion, I.V. anti-spasmodic (e.g. Butylscopolamine (buscopan)), I.V. antiemetic (Ondansteron (Zofran)), I.V. paracetamol, in addition to 2500 - 3000 cc of IV fluid for the first 24 hours post procedure.

The following three days saps of water and diluted juice with I M buscopan , and PPI infusion and antiemetic on need.

After 3-5days patients were advised to follow up liquid diet gradually transient to solid diet to allow the stomach to adapt to the presence of the foreign body over a period of two weeks, after which they can start eating normal diet.

Patients were revised every 3weeks for the first two months then monthly for the remaining months. This involved weight record, offering psychological support, recording and managing complications. In case of intolerance (persistent severe nausea or vomiting, with intractable epigastric pain) patient were hospitalized, abdominal imaging (ultrasonography and/or plain X-ray) was performed to check balloon position, and IV fluids administered to nourish, correct electrolyte deficits if present and add antiemetic and spasmolytic drugs.

B-Extraction

The patient is instructed to be on clear liquid diet for 24 hours and prolonged fasting for 12 hours before extraction procedure to avoid presence of food and chime during the procedure. Special extraction kit is provided by the manufacturer, it is composed of a long puncture sharp needle attached to a wide sheath with few markings on the distal end which when inserted deep enough in the balloon after puncturing it, denote that the tip of the sheath is well inserted in the bottom of the balloon and the extraction forceps (balloon grasper) which has specially designed hooks to ensure a good grip on the balloon all the way through its extraction reducing the risk of slipping specially at the upper or lower esophageal sphincters.

Figure 4. Fully deflated balloon before extraction.

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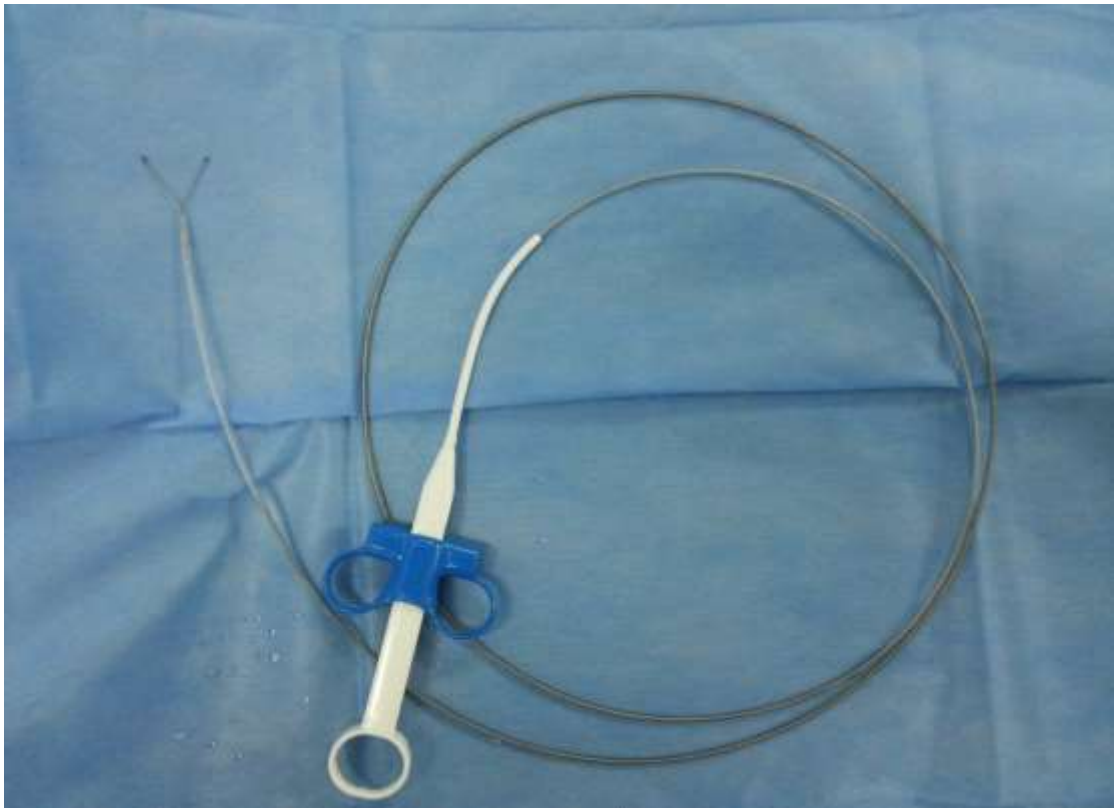

Figure 5. Balloon grasper.

Patients are discharged on the same day of extraction. Following extraction, patients were evaluated in terms of body weight, BMI, actual lost weight, and excess weight loss% (EWL%). The latter is calculated as the percent of the actual lost weight in relation to the ideal lost weight. Ideal lost weight is the weight loss needed so that the BMI is kept less than 25 kg/m2 and more than 18.5 kg/m2. A loss of 14.7 kg from initial weight, 5.7 kg/m2 from basal BMI, and 32.1% of excess weight were considered

RESULTS

101 cases enrolled in the study, 17 cases were males (16.8%) and 84 cases were females (83.2%). With male:female ratio of approximately 1:5. Their mean age was 33.2 (±10.44) years. Hypertension was reported in 26 cases (25.7%), Diabetes Mellitus in 30 cases (29.7%), and none of the patients had ischemic heart disease. males and females characteristics are shown.

Following balloon insertion, almost all patients developed variable grades of abdominal pain and vomiting during the first week post procedure. Re-hospitalization for symptoms of intolerance seen as abdominal pain and vomiting were reported in 30 cases (29.7%). None of these patients exhibited balloon migration or had perforation.

However, the balloon was removed upon request in 3 patients due to exaggerated intolerance (2.9%). There were no procedure related mortalities, No balloon leakage, or perforations. At

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extraction, small gastric erosions were reported in 2 patients (1.98%) while one patient developed grade A reflux esophagitis (0.99%). The over-all complication rate was 5.9%

At the time of balloon extraction the mean weight loss of the studied patients was 15.5 kg (±4.67), with a mean EWL of 64.12% (±23.48%). The mean BMI at extraction was 29.7 kg/m2 (±4.48) with a BMI loss of 6.2 kg/m2 (±2.0). Also, 87 patients (88.7%) achieved the target EWL (32.1% of excess weight), 87 patients lost >12.2% of their basal weight (88.7%). Based on BMI loss (>5.7 kg/m2), 70 patients achieved this target (71.4%). After excluding the early balloon extraction (3 cases), 98 patients fulfilled the study period. They were regrouped into those who achieved target BMI loss (71 patients) and those who failed to achieve target BMI loss (33 patients). Their data are shown in **Table 1**.

Table 1. Comparison between those who achieved the target BMI loss to those who failed to achieve target BMI loss.

Variables	Target BMI achieved (70)		Target BMI not achieved (28)		P
	Mean/Number	SD%	Mean/Number	SD%	
Males	10	14.2	7	25	0.46
Females	60	85.7	21	75	0.04 (S)
Age (years)	33.7	10.5	31.8	10.6	0.42
Pre-balloon BMI (kg/m²)	23.3	4.83	35.6	4.38	>0.01
Pre-balloon weight (kg)	87.12	19.65	95.2	19.8	0.07*
Group pf BMI					
30.0 - 34.9	54	77.1	22	78.5	
35 - 39.9	15	21.4	6	21.4	0.82
> 40	1	1.4	0	0	
BMI at extraction (kg/m²)	29.1	4.3	31.3	4.45	0.03(S)

DISCUSSION

There are Earlier reports on successful weight reduction (more than 5% of basal body weight) in 28% of overweight and obese patients using only diet control and physical exercise regimes.

Restrictive procedures such as laparoscopic sleeve gastrectomy and laparoscopic gastric plication and minigastric bypass are the mostly applied bariatric surgical procedures in iraq . While, more invasive operations as gastric bypass and bilio-pancreatic diversion are generally reserved as a second-stage intervention [15]-[18].

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Generally, endoscopic management of obesity has found its way between diet and physical activity on one hand and surgical intervention on the other hand. Endo-luminal devices have been introduced in an attempt to balance the equation of management of obesity. Such equation comprises the invasiveness and risks of bariatric surgery as well as the sole dependence on patients'compliance and tolerance seen in the diet-physical activity combination[13].

Intra-gastric balloons have evolved as one of the popular endo-luminal devices that reside in the stomach and cause early satiety. After many modifications in the specifications of an ideal intra-gastric balloon, has been successfully developed [19] [20]. This study represents the Iraq experience using the intra-gastric balloon (BIB®) system and spatzs .

Patients under treatment for obesity have variable individual response rates, depending on compliance, motivation, feeding habits, etiology of obesity (familial, genetic), physical activity and drug therapy.

Although the balloon inflation volume ranges between 400 - 650 ml [13] we standardized the fill volume to 550 ml. All included patients were referred after balloon insertion to their referring dietician, againto maintain the suitable calculated daily caloric diet devoid of any weight lowering medications.

In our study the majority of studied patients were females (83.2%) compared to males (16.8%). Decreased physical activity, sedentary lifestyle and multiple pregnancies may explain this difference. Interestingly, despite the higher prevalence of obesity among females, all the weight and anthropometric measurements in the current study were highly significant among males (Weight, excess weight, BMI and grade of obesity).

Although variable grades of abdominal pain and vomiting were encountered in the first week following insertion, only 30 cases (29.7%) required re-hospitalization and were kept under observation. They received I.V. fluids, antiemetic and underwent imaging to ensure balloon position. In all of them the balloon was confirmed in place and accordingly they were re-assured.

However, in 3 patients (2.9%) intolerance necessitated balloon removal upon request. The overall reported complications were 5.9% with no reported cases of perforation or migration.

After 6months of studying 40 obese patients with BMI 42.8 ± 7.12 kg/m2, subjects undergoing BIB had significant changes of BMI, weight, liver biochemical profile, HbA1c, insulin, HOMA-IR, fat mass, fat free mass, and MRI-LS. On the other hand, diet-treated obese subjects had no significant change of any parameter under study [20].

CONCLUSION

Finally, we conclude that, in the Iraq experience, after proper patient selection, BIB and spatzs balloon achieves acceptable success with minimal or insignificant complications. The current study limitations are the lack of long term follow-up prospective design, and also the absent record on the impact of weight loss on obesity related comorbidities.

However, since this work represents our initial experience with the procedure, further long term, prospective studies are recommended so as to evaluate the effect of weight reduction

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using Balloon on the quality of life,and also to compare it to other available procedures whether endoscopic or surgical ,so the intragastric balloon are safe and effective method for weight loss.

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