ENDOSCOPIC TREATMENT OF OBESITY WITH AN INTRAGASTRIC BALLOON

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Loss of body weight observed in patients with bezoar underlies attempts to use an intragastric balloon in the treatment of obesity (1). A saline filled balloon decreases gastric volume by approximately 40% and distends its walls, producing feeling of satiety (2, 3, 4). A continuous feeling of satiety and restriction in the volume of ingested food result in reduction of body weight.

First intragastric balloons were used in the early 1980’s in the USA (Garren-Edwards Bubble –1984 r.) and Denmark (Ballobes) (5). These balloons were filled with air of 220-500 ml volume and could be left in the stomach for 3-4 months. However, these balloons resulted in unsatisfactory reduction of excessive body weight due to being filled with air and due to low filling volume. Concurrently they resulted in numerous complications, including bedsores (3-7%) and spontaneous balloon deflation associated with high risk of mechanical intestinal obstruction (5-11%).

In 1987, during a scientific conference in Tarpon Springs, Florida, requirements were established that an intragastric balloon should meet. Among others, it was emphasized that a balloon should be filled with fluid (5).

Between 1986 and 1989 clinical trials were conducted in the USA with a first fluid-filled intragastric balloon SIB-001 (2,4). In 1989, when an improved balloon version (referred to as SIB-002) was approved, another series of clinical trials were started. The largest European study was conducted then in the Netherlands (prof. Lisbeth Mathus –Vliegen 1992-1993). This study enrolled 43 patients in whom three successive balloons were used, replaced every 4 months. One year of treatment supplemented with diet, exercise and psychological support, resulted in an average body weight reduction of 26.3 kg (6).

Between 2000 and 2006, a first large clinical trial of the most recent balloon type, BIB System (BioEnterics Intragastric Balloon), in the treatment of obesity, was conducted in Brazil, enrolling 1000 patients. Reduction of an excessive body weight of 48.3 ± 28.1 was observed after 6 months of treatment.

BIB System is composed of a silicone catheter connected with a sheath that harbors a balloon. The other end of the catheter has a luer connector that can be connected to a filling system. A leader is placed inside the catheter that facilitates balloon insertion into the stomach (fig. 1).

Currently used intragastric balloons have a round or elliptic shape. They can be equipped with a valve that allows for multiple changes of a balloon volume via an attachable catheter or a permanent catheter and lead out through the nasal cavity. Balloons that are inserted via percutaneous endoscopic gastrotomy are also available. In 2004, a balloon with a biodegradable valve that allowed for spontaneous balloon deflation after a specified time and its excretion through gastrointestinal tract, was patented.
Indications for treatment with an intragastric balloon (5-11) can be classified into four groups depending on body mass index (BMI). The first group includes patients with body mass index below 35 with obesity associated disorders, patients who were unsuccessfully treated medically for at least 3 years or who have contraindications to pharmacological treatment of obesity. Indications for balloon insertion in patients with BMI 35 to 39.9 include: obesity associated disorders, patients who were unsuccessfully treated medically with contraindications to bariatric surgery. This group also includes patients who do not agree for surgical treatment of obesity. The third group includes patients with body mass index from 40 to 49.9. These are patients in whom treatment with intragastric balloon is indicated to reduce perioperative risk related to elective bariatric procedures, general surgery procedures, cardiac surgery and orthopedic procedures. Patients with BMI over 50 may have the balloon inserted to undergo preliminary qualification for restrictive bariatric surgery (so called BIB test).

Before insertion of an intragastric balloon, performance of the following laboratory tests is recommended: complete blood cell count, coagulogram, glucose concentration, electrolyte (Na, K) concentration, creatinine, triglyceride, albumin level, as well as additional tests such as: ECG, chest X-ray, spirometry, US imaging of the abdominal cavity and psychological consultation (6).

Endoscopy of the upper gastrointestinal tract with testing for Helicobacter pylori is absolutely required. This should be done within 30 days before the balloon insertion.

The procedure of intragastric balloon insertion can be performed during one-day hospitalization. The balloon should be inserted in a fasting, sedated patient. After the balloon has been inserted to a stomach, its location should be verified with an endoscope and then the balloon should be filled with 0.9% NaCl solution with addition of 10 ml methylene blue, to a maximum final volume of 700 ml. Minimum filling volume is 400 ml (fig. 1, 2, 3). A filling catheter should not be stressed during the balloon filling. The balloon should be filled slowly, continuously, to prevent buildup of high pressure at the valve. Before the filling catheter is disconnected from the balloon, negative pressure should be created with a syringe to seal the valve. After the catheter has been disconnected, the seal should be assessed visually. A balloon with leaking valve should be removed immediately. A filled balloon should freely move inside the stomach. Leaking balloon valve should be determined.
when more than 5 ml of fluid can be aspirated after the balloon has been filled.

After insertion of an intragastric balloon, Buscopan 5 mg can be given every 6 hours for three days after the procedure (6, 12). In the event of vomiting, Metoclopramide 60-40 mg daily or Ondansetron 32 mg daily should be given while in the event of epigastric pain, NSAIDs are used. A proton pump inhibitor at a dose up to 40 mg daily can be used until the balloon removal or at a dose up to 40 mg daily for 2 days after the balloon insertion, then 20 mg daily for 15 days and thereafter only in the event of complaints, at a dose of 40 mg daily. Follow-up visits should be scheduled in weeks 1, 2, 4 after the procedure and every month thereafter. A patient should be advised to pay attention to color of his urine and stool. In month three after the procedure, a follow-up US imaging of the abdominal cavity is recommended to assess the balloon volume. Dietary management is important after insertion of an intragastric balloon. Semi-liquid diet is indicated within the first three days after the procedure. Three to four meals daily are advised and at least one hour interval between the meals should be preserved. Small helpings of food should be ingested and spices, coffee, chocolate and other confectionary, cold foods, ice creams should be avoided. The recommended fluid intake is 1000-1500 ml daily. Gradual diet modification, from semi-liquid to solid, is done starting from day four after the procedure. Should vomiting occur, semi-liquid diet should be resumed for three consecutive meals. Drinking fluids during meals is not recommended. Fluids should be drank not sooner than one hour after a meal and carbonated soda should be avoided. Three to four meals per day are advised, with avoidance of coffee, confectionary, olive (no more than 4 spoons daily), ice creams and other high-caloric foods.

Throughout the treatment with an intragastric balloon, the patient should remain under close monitoring by a dietician, psychologist and physiotherapist.

The balloon should be removed within 6 months after its insertion. An average period of balloon staying in a stomach is 4 months (fig. 4, 7). When pregnancy is diagnosed during the treatment, the balloon should be removed. Before the balloon removal the patient should be on a liquid diet for 3 days. The procedure of balloon removal should be performed in a fasting, sedated patient. During an endoscopy, contents of the whole balloon should be aspirated (fig. 5), and Buscopan 5 mg should be given. Then the balloon should be grasped with endoscopic forceps at a site opposing the valve and gently removed from the gastrointestinal tract (fig. 6). After the balloon removal, the patient should be monitored in the department for approximately 30 minutes. When the bal-
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Intragastric BIB balloon after 6 months of treatment.

Fig. 4.

Intragastric BIB balloon after complete aspiration of its contents.

Fig. 6.


do not hallucinate.

An aspiration catheter for the balloon.

Fig. 5.


Fig. 7.

A balloon is left for more than 6 months or is filled with more than 700 ml of saline, the risk of its spontaneous emptying and resulting mechanical intestinal obstruction increases. An empty should be removed immediately.

Side effects of treatment with an intragastric balloon (6, 7, 8) include: nausea and vomiting lasting for up to two weeks after the procedure – 39%, epigastric pain – 20.1%, bloating – 8%. Complications occurring during the intragastric balloon therapy include: reflux esophagitis – 12.4%, dehydration – 4.6%, nausea and epigastric pain lasting for more than two weeks after insertion of the balloon – 3%, peptic ulcer – 1%, spontaneous balloon emptying – 0.25-1%, Candida albicans infection – 0.6%, mechanical intestinal obstruction resulting from translocation of spontaneously emptied balloon – 0.13-0.25%, gastric perforation – 0.05% (6, 7, 8). The risk of mechanical intestinal obstruction following spontaneous balloon emptying is higher in subjects with a history of abdominal and pelvis minor surgery and diabetes mellitus or intestinal motility disorders. Loss of feeling of satiety, increased appetite and increase of
body weight suggest balloon emptying. Increased number of bacteria in the fluid filling the balloon, may induce infection, fever, intestinal colic and diarrhea in the event of a sudden balloon emptying.

Endoscopic treatment of obesity involves insertion of an intragastric fluid-filled balloon. Its reversibility and low-invasive nature as compared to bariatric surgeries, are the principal advantages of this endoscopic method. However, predominantly unstable reduction of excessive body weight is its principal drawback. This method should be a first line treatment in extremely obese patients qualified for surgical treatment or in patients who do not qualify to bariatric surgery (13, 14).

REFERENCES


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