INTRAGASTRIC BALLOON (BIB SYSTEM) IN THE TREATMENT OF OBESITY AND PREPARATION OF PATIENTS FOR SURGERY – OWN EXPERIENCE AND LITERATURE REVIEW

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Despite the recognition of bariatric surgery as the only effective method of weight reduction, we remain in search of minimally invasive methods, both for the treatment of obesity and preparation of patients for surgical procedures.

**The aim of the study** was to determine intragastric balloon (Allergan) implantation results as the only method of treating obesity, and patient preparation for further stages of abdominal hernia operations, as well as other surgical procedures.

**Material and methods.** The study presented own results considering the use of Bioenteric Intragastric Balloons (BIB system) in the treatment of pathological obesity, and preparation of patients for bariatric surgery and abdominal hernia operations. The study group comprised 18 female and 7 male patients. Average patient age amounted to 50.6 and 54 years, respectively. Indications for intragastric balloon insertion were as follows: preparation for hernia (10 cases) and bariatric (5 patients) operations, and weight reduction management (8 patients). In two cases the implantation of the intragastric balloon served the preparation for gynecological and orthopedic (vertebral column) operations. One female patient was prepared for both bariatric and hernial surgery. The procedure was performed under general anesthesia. Statistical analysis considered 22 patients (one female patient was excluded from analysis, due to death, two other were excluded because of lack of sufficient data).

**Results.** In case of two patients the intragastric balloon system was removed before 6 months had elapsed because of intolerance. One female patient died during the observation period for reasons not related to the procedure. The obtained BMI reduction ranged between 2 and 6 kg/m², which amounted to a maximum weight loss of 24 kg. In one patient a weight gain of 2 kg was observed. Considering patients prepared for abdominal hernia operations weight reduction was greater and better maintained after the removal of the BIB system.

**Conclusions.** According to the authors of the presented study the intragastric balloon serves its role as a bridge to bariatric procedures and weight reduction, before planned extensive postoperative hernia operations. The use of the intragastric balloon only to reduce weight has no medical and economic justification.

**Key words:** intragastric balloon, preparation for surgery, treatment of obesity

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Obesity in developed countries has been recognized by the WHO in 1997 as an epidemic (1). Worldwide, there are 400-500 million obese people (1). Also in Poland, NATPOL and WOBASZ studies demonstrated that nearly 50% of the society has weight problems (2, 3). Obesity with a BMI exceeding 35 leads towards numerous complications, which can result in patient death, reduced quality of life, shortening the expected survival rate even by 20 years (4).

In recent years studies have been published that explicitly consider bariatric surgery as the only method to effectively reduce weight, and maintain the above-mentioned condition, as well as manage patients with type 2 diabetes mellitus and metabolic syndrome (5, 6).

Obesity is an independent factor responsible for the development and recurrence of abdominal hernias. Mesh implantations should be used in case of postoperative hernia prophylaxis in bariatric surgery (7). Surgery in case of a large postoperative hernia in patients with the BMI exceeding 35 is burdened with the high risk of complications and recurrence, due to increased intraabdominal pressure.

Bariatric surgery, despite the proven efficacy has extremely slowly gained the acceptance of the medical environment. Even in the USA only 15.4% of physicians direct their obese patients to the bariatric surgeon (8). There is search for other less radical weight reduction methods. The intragastric balloon is one such method, being implanted under endoscopic control causing a feeling of satiety, reducing the amount of ingested food. The above-mentioned method was introduced in the beginning of the eighties of the past century by Nieben et Harboe after a series of experimental investigations (9).

In Poland the method has gained some popularity during recent years. Żurawiński et al. presented a precise description of the method, both from the technical and historical side (10). Considering Europe, only in Spain there is a greater number of patients treated by means of the above-mentioned method. There are relatively few publications concerning the matter (11, 12). Thus far, balloon therapy was not considered in the preparation of patients for surgical procedures. In order to fill this gap and present results from the Polish population our own experience was summarized.

The aim of the study was to determine intragastric balloon (Allergan) implantation results as the only method of treating obesity, and patient preparation for further stages of abdominal hernia operations, as well as other surgical procedures.

MATERIAL AND METHODS

The study group comprised 25 patients treated during the period between 2008 and 2009 by means of the BioEnterics® Intragastric Balloon system (BIB, manufactured by Allergan, USA). The balloons were inserted and removed at the Endoscopic laboratory, Department of Gastroenterology, University Hospital in Bydgoszcz. The study group comprised 18 female (mean age: 50.6 years) and 7 male (mean age: 54 years) patients. Indications for BIB implantation consisted in the preparation of obese patients for surgery (n=23): large abdominal (n=9) and bariatric hernias (n=5; in both cases patients were directed to the Chair and Department of General and Endocrinological Surgery), as well as one case of a gynecological and orthopedic operation. Seven other patients were directed from the bariatric outpatient surgical clinic. The intragastric balloon was supposed to be the only weight reduction method.

Eight (32%) patients were diagnosed with type 2 diabetes mellitus treated by means of hypoglycemic drugs or insulin (n=3). Arterial hypertension was observed in 6 (64%) patients – all had diabetes.

The intragastric balloon was typically implanted, according to the manufacturer’s instructions. Both during implantation (propophol sedation) and removal of the BIB system (anesthesia and intubation) complications were not observed. Gastric balloon rupture was not observed. In two cases the balloon was removed before the completion of the planned six-month therapeutic period. After the procedure patients were recommended to take proton pump inhibitors (20 mg of pantoprazol). Only two patients continued the above-mentioned therapy, while the remaining discontinued treatment after 2-3 weeks. Follow-up data after BIB removal was obtained the day before the surgical procedure or in case of non-operated patients- after several months, on the basis of a phone conversation or letter. The time elapsed between BIB removal and the control examination ranged between 1 and 14 months -median of 6 months (1, 3. quartile: 3-13).
Statistical analysis

The Body Mass Index (BMI) was calculated on the basis of the following formula: weight in kg/height in meters\(^2\). On the basis of height the ideal patient body weight was estimated. Thus, the Initial Excess Weight (IEW) value was calculated. The percentage of excess weight loss (% EWL) was estimated: weight loss after treatment/IEW x 100. After BIB removal the IEW was once again estimated, and during the control examination we calculated the % EWL.

Initial data (described as „before BIB”) was obtained on the day of the insertion of the intragastric balloon. Data described as „after BIB” concern measurements collected on the day of the intragastric balloon removal. “Control” data concern the preoperative period or phone survey (6 month median since BIB removal).

Analysis considered 22 patients, including 21 who had the intragastric balloon for six months, and one with the BIB for 5 months. One patient was excluded from analysis. The BIB system (used in the treatment of obesity, hyperlipidemia, and resistant hypertension) was removed after one month, due to uncontrollable vomiting. Three months thereafter the patient died, due to asystole. We were unable to obtain data from two patients (lack of contact after balloon removal).

Variables with a normal distribution were determined on the basis of mean values and standard deviation. Those without a normal distribution were estimated on the basis of the median, and 1. and 3. quartiles—the U Mann-Whitney test was used. The independent T test was used to compare the combined variables, before and after therapy. Variable dependency was calculated on the basis of Spearman’s correlation R index. p≤0.05 values were considered as statistically significant.

RESULTS

The full, six-month BIB treatment cycle was performed in 21 patients, while one had the BIB removed after 5 months. Earlier removal of the balloon was connected with abdominal pain (gastritis). Table 1 presented weight loss changes and BMI values in the analysed group.

The T test demonstrated that the body weight after balloon removal and during the control examination was significantly lower, as compared to initial values (p<0.001). The body mass was determined after balloon removal and during control examinations, being significantly different. Similar dependencies concerned the BMI.

The EWL percentage (% EWL) after BIB treatment ranged between 63.2% +6.7%. The positive value is connected with the fact that one patient, despite the intragastric balloon, gained weight, while another maintained the same weight. The mean % EWL value was -26.2% (SD=18.5). During the time elapsed between BIB removal and the control visit the change in the % EWL value was significantly lower (mean: -2.3% (ranging between -42% and +64.4%).

Considering the 22 study group patients, 7 were smokers, 8 were diagnosed with diabetes mellitus, and 16 with arterial hypertension. There was no correlation (U Mann-Whitney test) between the occurrence of one of the above-mentioned and significantly greater weight loss after BIB therapy (both concerning the BMI and % EWL). Patient gender was of no significance.

Spearman’s correlation test demonstrated that the older the patient the worse outcome—poor body weight loss during BIB treatment. These changes were observed when evaluating the absolute weight, BMI, and % EWL. However, the above-mentioned effect was statistically insignificant. An inverse relation was observed when assessing the correlation between the therapeutic result and initial patient weight: the greater the weight before BIB treatment the better the therapeutic effect. Once again, statistical significance was not attained.

When dividing the study group in terms of indications a subgroup was isolated, consider-

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Before BIB</th>
<th>After BIB</th>
<th>Control</th>
</tr>
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<tbody>
<tr>
<td>Body weight (kg)</td>
<td>115 (81-171); SD 25,1</td>
<td>101,3 (57-162); SD 27,1</td>
<td>102,4 (57-165); SD 28,9</td>
</tr>
<tr>
<td>BMI (kg/m(^2))</td>
<td>43 (32,4-70,3); SD 9</td>
<td>37,7 (25,7-63,7); SD 9,1</td>
<td>38,1 (25,7-65,3); SD 9,8</td>
</tr>
</tbody>
</table>
The different behavior of patients awaiting hernia surgery is confirmed, when comparing the weight changes throughout the observation period: from BIB implantation to control visit. During the above-mentioned period patients with hernias obtained better results, and the intragastric balloon enabled them too effectively reduce weight. Considering the % EWL parameter changes in case of BIB therapy for other reasons were statistically significant (p=0.02). Weight loss and BMI value changes were also greater—the difference between patients treated, due to other indications was on the border of statistical significance (tab. 3).

**DISCUSSION**

The obtained results allow too consider the implantation of the BIB system as a temporary method of weight reduction (2-6 kg/m²) during

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**Table 2. Mean value differences of estimated parameters, since BIB removal to control visit in case of patient weight reduction, due to planned hernia operations and other indications**

<table>
<thead>
<tr>
<th>Before BIB – control</th>
<th>Hernia</th>
<th>Other indication</th>
<th>p=</th>
</tr>
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<tbody>
<tr>
<td>% EWL</td>
<td>-8,6</td>
<td>12,9</td>
<td>0,07</td>
</tr>
<tr>
<td>Loss of body weight (kg)</td>
<td>-2,9</td>
<td>3,8</td>
<td>0,05</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>-0,9</td>
<td>1,3</td>
<td>0,06</td>
</tr>
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</table>

**Fig. 1. Excessive weight loss (% EWL) in patients qualified to BIB during the preparation for abdominal hernia (B) or other operations (A). The 0 value shows the time of BIB implantation, while vertical line % EWL values – the time after BIB removal (after 6 months, in one case after 5); the points located to the right of the line correspond to control values**

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Intragastric balloon (bib system) in the treatment of obesity and preparation of patients for surgery

Although the BIB system has been considered for the past 30 years as one of many methods of weight reduction, Dumonceau in his meta-analysis of nearly 5000 patients demonstrated that there are no clear indications for the implantation of the BIB system, and that body weight reduction and the maintenance of the above-mentioned condition are relatively short (13). Dumonceau et al. and Lopez-Nava et al. investigated the possibility and results of double treatment. It is safe, but over a longer observation period (5 years) does not influence the rate of patients subject to bariatric surgery, as well as attaining a ≥ 10% decrease in initial body weight, as compared to one-time therapy (14, 15). Angrisani et al. showed that patients not subject to bariatric surgery after six months of BIB system therapy returned to their initial body weight during the consecutive 12 months (16).

In our study, indications for intragastric balloon implantation considering most patients comprised the preparation for planned bariatric surgery or abdominal hernia operations. The authors believe that this is the only reasonable indication for the above-mentioned method. The group of subjects prepared for abdominal hernia procedures increased by consecutive patients (2010 data) will be the subject of detailed analysis. According to the authors the above-mentioned indication may in the future designate the basic pathway of minimally invasive weight loss, considering patients that pose a challenge to bariatric and hernia surgery. Best results were obtained in this group, which might be connected with the strong psychological motivation.

The relationship between the development and recurrence of abdominal hernias, and obesity remain unclear. However, the increase in intraabdominal pressure, technical difficulties, wound dehiscence, increased expression of metalloproteinases, and collagen synthesis disturbances are significant factors. This is reflected by the use of special techniques protecting bariatric patients from hernia development (7, 17, 18).

Obesity increases the risk of surgical site infections in case of colorectal, transplantology and plastic surgery (19, 20, 21). However, mortality after oncological, cardiosurgical, and gastroenterological procedures in morbidly obese patients does not seem to be increased, as compared to patients with normal weight (obesity paradox). The coexistence of the metabolic syndrome and other disorders incline patients to lose weight preoperatively (22, 23, 24).

In case of planned abdominal hernia surgery weight reduction is without doubt beneficial, considering the obtained results. In case of obese patients subject to surgery for other reasons the above-mentioned situation is not so clear. According to de Goederen-van der Meij et al. six months of intragastric balloon treatment does not predict the success of gastric banding, including BMI values one year after the procedure (25). Genco et al. compared the BIB system and “sleeve gastrectomy” in patients with BMI values exceeding 50 prepared for bariatric surgery (BDP). The authors observed a comparable weight reduction during a period of 12 months. Considering the potential significant postoperative complications they recommended the BIB system, prior to the BDP procedure (26). Milone et al. came too opposite conclusions (27).

There only exist casuistic publications concerning the use of the intragastric balloon in the preparation for other operations. Waele et al. recommended the preoperative use of the BIB system in case of two obese patients with abdominal hernias and coxarthrosis demonstrating the uneventful postoperative course (28).

Own research has shown that the use of the BIB system only to reduce weight does not give

<table>
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<th>p=</th>
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<tbody>
<tr>
<td>% EWL</td>
<td>-17,8</td>
<td>-7,28</td>
<td>0,02</td>
</tr>
<tr>
<td>Weight loss (kg)</td>
<td>-18</td>
<td>-8,85</td>
<td>0,07</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>-0,9</td>
<td>1,27</td>
<td>0,06</td>
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the expected results. Six of the eight study patients significantly gained weight after balloon removal nearly attaining their initial weight (long observation period). Considering the significant costs of the BIB system the above-mentioned is uneconomic. Fernandes et al. came to similar conclusions on the basis of the meta-analysis of publications concerning BIB (29). Mathus-Vliegen in his meta-analysis of 15 publications evaluating the BIB system demonstrated that the method is valuable, although burdened with the risk of intolerance, inefficiency and the “yo-yo” effect (30). Crea et al. observed the rapid return to the initial weight after BIB system removal. However, a 10% weight reduction maintained for a period of one year enabled to reduce metabolic syndrome parameters (31). Mui et al. obtained very good results, considering weight and metabolic parameters reduction, and quality of life improvement. They came to the conclusion that the above-mentioned method is more effective in the Asian population, as compared to the European population (32). Investigators from Singapore disagree with the above-mentioned. Success after BIB system implantation was only observed in 4 of 20 patients. The authors recommend the method only in case of contraindications to bariatric surgery (33).

The major complications after BIB system implantation include gastroesophageal reflux, gastritis, duodenitis, and ulcerations. The above-mentioned lesions were diagnosed in the study patients, which was responsible for the early removal of the intragastric balloon. According to literature data, such management is required in 2.5-7% of patients. Nausea and vomiting are characteristic symptoms observed during the first day after balloon implantation, and in 7% of patients continue to be present, despite antiemetic drugs administered for more than seven days (13). According to the authors of the study the early removal of the intragastric balloon was necessitated twice, due to intolerance (30 days—the patient died after 3 months), and gastritis (5 months), which represented 8%.

Significant complications connected with intragastric balloon implantation, such as intestinal occlusion and perforation, are rarely observed – 0.2%. A casuistic case concerned a patient with cardiac arrest several hours after the implantation of the intragastric balloon (34). Patient death was connected with the progression of circulatory insufficiency, and was not related to the implantation procedure.

The five-year experience with the BIB system in Poland was described by physicians from the MSWA Hospital in Warsaw. They obtained similar results to those observed in the above-mentioned study (mean BMI reduction of 5 kg/m²). The rate of early BIB system removal was also similar (8.3%). Indications for balloon implantation were as follows: preparation for bariatric procedures or adjunctive therapy in the absence of consent or possibility to perform surgery. In selected cases the BIB system may serve as adjunctive treatment to conservative therapy (11). Konopko-Zubrzycka et al. investigated the influence of the BIB system in obese patients on the plasma levels of ghrelin, leptin and adiponectin, as compared to patients treated by means of a diet. The authors observed a decrease in the leptin level and transient increase of ghrelin levels (35). Currently, there are 64 patients included in the material of the above-mentioned authors, and weight reduction results are similar to those presented in this study (12).

In conclusion, intragastric balloon implantation has limited value, as the method of weight reduction. The average weight reduction after a 6-month BIB system therapy amounted to 15 kg (Brazilian population) and 20 kg (European population). However, the effect is unstable. The BIB system may be used in the preparation of morbidly obese patients for abdominal hernia operations, which significantly reduces the perioperative risk. The efficacy of BIB in the preparation of obese patients for other procedures may not be clearly assessed, due to insufficient data.

REFERENCES


