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Treatment of Morbid Obesity with Intra-gastric Balloon, B.I.B. vs. Spatz: our institutional experience.

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ABSTRACT

BACKGROUND:

Obesity is considered a chronic disease, difficult to treat, and is the first cause of death in the world predictable. The surgical approach is limited to patients with severe obesity, there is an intermediate group who are not candidates for immediate surgery, The BioEnterics Intra gastric Balloon (BIB) and the Spatz Adjustable Balloon System (ABS) are actually recommended to weight reduction as a bridge to bariatric surgery (1-4-5).

METHODS:

We retrospectively studied patients with BMI range: 37-46, undergone BIB from January 2012 to July 2013 and prospectively studied patients undergone Spatz balloon from July 2013 to August 2014, aim of this study is the comparison of BIB with Spats in terms of weight loss, complications and maintenance of weight after removal. For both procedure median weight loss was 20 ± 3 kg and median BMI at the end of the therapy was 32 ± 2 and not important complication occurred.

RESULTS:

No complications occurred during the procedure and the removal of devices for both groups.

At 3 months follow-up weight gain was: 4 ± 2 kg with Spatz and 3 ± 2 kg with BIB.

At 6 months follow-up weight gain was: 6 ± 2 kg with Spatz and $6 \pm 1,5$ kg for with BIB.

At 9 months follow-up weight gain was: 10 kg with Spatz and 11 ± 2 kg with BIB.

CONCLUSIONS:

The BioEnterics Intra gastric Balloon (BIB) and the Spatz Adjustable Balloon System are and effective in treating overweight patients with BMI. The rate of complication reported is the same. According literature in our study there were not significant differences for two procedures.

Key words: Bioenterics Intra gastric Balloon – Spatz - Bariatric.

Introduction

Obesity is considered a chronic disease, difficult to treat, and is the first cause of death in the world predictable. The treatment may be medical, with the dietary and psychological support. The surgical approach is limited to patients with severe obesity, there is an intermediate group who are not candidates for surgery, which, however, do not respond to medical therapy, in this group is indicated for the implantation of an intragastric balloon, which is less invasive than surgery.

The use of a gastric space-occupying balloon for achieving weight reduction in obese patients was first reported in 1982. Since then, different kinds of free-floating balloons were described for the treatment of morbid obesity, but several problems and side-effects persuaded physicians to stop their use. However, the distinctive structural features of new balloons (silicone, liquid-filled, spherical, smooth without traumatic edges) differ from the previous intragastric devices by reducing complications and side-effects, and have created new interest.

The BioEnterics Intragastric Balloon (BIB) and the Spatz Adjustable Balloon System (ABS) are the most used devices to temporary treatment in obese patients (11). These systems are actually recommended to weight reduction as a bridge to bariatric surgery (1-4). The limits of the BIB, as the lack of adjustability, the short-term therapy (6 months), deflation and bowel obstruction, seem to be overcome by Spatz balloon (2). This is a dynamic bariatric device with a long implantation time (12 months), a system for inflation and deflation of the balloon and a safety mechanism that precludes its bowel migration despite an eventual deflation.

Objective

Aim of this study is the comparison of BIB with Spats in terms of weight loss, complications and maintenance of weight after removal.

Methods

From January 2012 to August 2014, 30 patients underwent to implantation of the two intragastric devices in our Department of Digestive Endoscopy. We retrospectively studied patients undergone BIB from January 2012 to July 2013 and prospectively studied patients undergone Spatz balloon from July 2013 to August 2014. Patients were selected according to NIH criteria (3-5). Inclusion criteria were: BMI 27-30, previous failure of dietary measures and the presence of one of the following co-morbidities: hypertension, diabetes, respiratory disorders, osteoarthropathy, dyslipidaemia.

BIB was placed in 20 patients (7 M, 13 F; age range: 19-57 years), BMI range: 37-46, weight range: 103-165 kg.

Spatz balloon was placed in 10 patients (3 M, 7 F; age range: 18-58 years), BMI range: 37-46, weight range: 103-165 kg.

All patients underwent EGDS before procedure. The complication of the procedure (7-8) (deflation, rupture of stabilizer band, bowel migration, gastric ulcer, gastrectasia, intolerance, nausea and vomit) were pointed out in the informed consent during medical interview. All patients were hospitalized, fasted for 12 hours before the procedure, and both devices were placed in operating theatre under unconscious sedation (6). The adjustment procedure of Spatz was performed with the endoscopic instruments, extracting the filling tube. In this way it is possible to deflate the balloon (to resume the normal diet) and to inflate the balloon with saline (200 ml) and methylene blue (when the weight loss was non significant).

Patients of both groups received the same medical treatment (9).

On the first postoperative day, intravenous saline (30-35 ml/kg/die) with omeprazole (40

mg/die), ondansetron (8 mg/die), and butyl-scopolamine bromide (20 mg x 3/die) were given to all patients.

On the second postoperative day, patients were discharged with drug therapy: omeprazole (40 mg/die) and a 1,000 Kcal diet.

In our study we evaluated the efficacy of the procedure considering:

- weight loss parameters after 6 months (time of BIB removal) and 12 months (time of Spatz removal)
- maintenance of weight after removal
- short-term and medium-term complication
- long-term complication for BIB

These results were collected with a medical interview for retrospective study of the BIB and with a 3-6-9 months follow-up for the prospective study of Spatz balloon.

Results

No complications occurred during the procedure and the removal of devices for both groups.

In 2 of 20 patients treated with BIB, balloon was removed for intolerance (1 patient) and for gastrectasia (1 patient). In only one patient balloon was removed for a bowel migration, a real complication of the procedure. In the other 17 patients balloon was removed after 6 months at the end of the therapy.

In 2 of 10 patients treated with Spatz, balloon was removed for vomit. The adjustment procedure of Spatz was performed in 3 patients. In the other 5 patients balloon was removed after 10 months of average time at the end of the therapy.

For both procedure median weight loss was 20 ± 3 kg and median BMI at the end of the therapy was 32 ± 2 .

At 3 months follow-up weight gain was: 4 ± 2 kg for 8 patients with Spatz and 3 ± 2 kg for 17 patients with BIB.

At 6 months follow-up weight gain was: 6 ± 2 kg for 5 patients with Spatz and $6\pm 1,5$ kg for 10 patients with BIB.

At 9 months follow-up weight gain was: 10 kg for 1 patients with Spatz and 11 ± 2 kg for 3 patients with BIB.

The 2 patients undergone the adjustment of Spatz balloon didn't obtained a significant weight loss.

At long-term follow-up no complications occurred for BIB.

Discussion

Endoscopic positioning of intragastric balloon is nowadays an effectiveness procedure to obtain a significant weight loss(10). BIB and Spatz balloon are actually the most used devices before surgery.

Spatz balloon has been introduced recently to overcome limits of BIB, infact Spatz has a longer intragastric life until 12 months, can be adjusted with a system for inflation and deflation and has a safety mechanism that precludes its bowel migration.

According literature [*] in our study there were not significant differences for two procedures.

Conclusion

The BioEnterics Intragastric Balloon (BIB) and the Spatz Adjustable Balloon System are and effective in treating overweight patients with BMI 27-30 (2-3). The rate of complication reported is the same. At this time, low information on safety of Spatz are defused through bariatric community, several studies regarding safety and efficacy are needed.

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