



## Original research

# BioEnterics Intra-gastric Balloon (BIB) versus Spatz Adjustable Balloon System (ABS): Our experience in the elderly



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## ABSTRACT

The BioEnterics Intra-gastric Balloon (BIB) and the Spatz Adjustable Balloon System (ABS) are in fact recommended for weight reduction as a bridge to bariatric surgery. We retrospectively studied patients with body mass index (BMI) and age ranges of 37–46 and 70–80 years, respectively, who had undergone BIB from January 2010 to July 2012 and prospectively studied patients who had undergone Spatz balloon from July 2012 to August 2014. The aim of this study is to compare BIB and Spatz in terms of weight loss, complications, and maintenance of weight after removal. For both procedures, the median weight loss was  $20 \pm 3$  kg, median BMI at the end of the therapy was  $32 \pm 2$ , and no severe complication occurred.

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## 1. Introduction

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

## 2. Objective

The aim of this study was to compare BIB and Spatz in terms of weight loss, complications, and maintenance of weight after removal.

## 3. Methods

From January 2010 to August 2014, 30 patients underwent implantation of the two intra-gastric devices in our Department of Digestive Endoscopy. We retrospectively studied patients who had undergone BIB from January 2010 to July 2012 and prospectively studied patients who had undergone Spatz balloon from July 2012 to August 2014. The patients were selected according to NIH criteria [3–5]. The inclusion criteria were BMI 27–30, previous failure of dietary measures, and the presence of one of the following comorbidities: hypertension, diabetes, respiratory disorders, osteoarthritis, and dyslipidemia.

BIB was placed in 20 patients (7 male, 13 female; age range: 70–80 years, BMI range: 37–46; weight range: 103–165 kg).

Spatz balloon was placed in 10 patients (3 male, 7 female; age range: 70–80 years; BMI range: 37–46; weight range: 103–165 kg).

All patients underwent EGDS before procedure. The complications of the procedure (deflation, rupture of stabilizer band, bowel migration, gastric ulcer, gastrectasia, intolerance, nausea, and vomiting) were pointed out in the informed consent during medical interview [6–8]. All patients were hospitalized, fasted 12 h before the procedure, and both devices were placed on patients in the operating theater under unconscious sedation. Adjustment procedure of Spatz was performed with the endoscopic instruments, extracting the filling tube. In this way, it was possible to deflate (to resume the normal diet) and inflate the balloon with

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saline (200 ml) and methylene blue (when the weight loss was nonsignificant).

Patients of both groups received the same medical treatment, as described in the medical literature [9].

On the first postoperative day, intravenous saline (30–35 ml/kg/die) with omeprazole (40 mg/die), ondansetron (8 mg/die), and butylscopolamine bromide (20 mg × 3/die) were administered to all patients.

On the second postoperative day, the patients were discharged with drug therapy: omeprazole (40 mg/die) and a 1000-Kcal diet.

In this 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- and medium-term complications
- long-term complication for BIB.

These results were obtained by a medical interview for retrospective study of the BIB and with a 3- to 9-month follow-up of the prospective study of Spatz balloon.

#### 4. Results

No complication occurred during the procedure and removal of devices in either groups.

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

In two of 10 patients treated with Spatz, the balloon was removed due to vomiting. The adjustment procedure of Spatz was performed in three patients. In the remaining five patients, the balloon was removed after 10 months, the average time to the end of the therapy.

For both procedures, median weight loss was  $20 \pm 3$  kg and median BMI at the end of the therapy was  $32 \pm 2$ .

At 3-month follow-up, weight gains were  $4 \pm 2$  kg for eight patients with Spatz and  $3 \pm 2$  kg for 17 patients with BIB.

At 6-month follow-up, weight gains were  $6 \pm 2$  kg for five patients with Spatz and  $6 \pm 1.5$  kg for 10 patients with BIB.

At 9-month follow-up, weight gains were 10 kg for one patient with Spatz and  $11 \pm 2$  kg for three patients with BIB.

The two patients who underwent adjustment of Spatz balloon did not achieve significant weight loss.

At long-term follow-up, no complication occurred for BIB.

#### 5. Discussion

At present, endoscopic positioning of intragastric balloon has been proved as an effective procedure to achieve significant weight loss, even in elderly patients [10]. BIB and Spatz balloon are the most commonly used devices before surgery.

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

According to the medical literature, similarly to other studies in elderly patients [11–15], no significant difference was obtained between the two procedures.

#### 6. Conclusion

The BIB and the Spatz ABS are effective in treating overweight patients with BMI in the range of 27–30. The reported complications are the same. At present, there is only little information on the safety of Spatz, and hence further studies regarding safety and efficacy of these intragastric devices are needed.

#### Ethical approval

Ethical approval was requested and obtained from the “Azienda Universitaria Federico II” ethical committee.

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#### Author contribution

**Teresa Russo:** Participated substantially in conception, design, and execution of the study and in the analysis and interpretation of data; also participated substantially in the drafting and editing of the manuscript.

**Giovanni Aprea:** Participated substantially in conception, design, and execution of the study and in the analysis and interpretation of data.

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**Luigi Sivero:** Participated substantially in conception, design, and execution of the study and in the analysis and interpretation of data; also participated substantially in the drafting and editing of the manuscript.

#### Conflict of interest

The authors declare that they have no conflict of interest or financial support.

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