Research Article

Integrative Gastroenterology and Hepatology

Spatz3 Adjustable Balloon: Weight Loss and Response Rates in Brazil

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Abstract

Background: The degree of efficacy and duration of effect of Intra-gastric Balloons (IGBs) can be variable and unpredictable. The Spatz Adjustable Intra-gastric Balloon (AIGB) was developed to address these issues by extending implantation to 1 year, decreasing balloon volume for intolerance and increasing volume for decreased balloon effect.

Aims: To determine the efficacy and response rate of the Spatz3 AIGB.

Methods: Results of 379 consecutive patients (pts) implanted with the Spatz3 AIGB were retrospectively reviewed (3 lost to follow up). Mean BMI 35.5; mean weight (wt) 97.5 kg; mean excess wt 29.1 kg; mean balloon volume 600ml. Balloon volume adjustments were offered: Down adjustments for intolerance and up adjustments for decreased balloon effect.

Results: The mean implantation time of 376 pts was 10.6 months yielding mean wt loss 14.9 kg; mean 15.1% Total Body Wt Loss (%TBL) and 58% Excess Wt Loss(%EWL). Response rate (> 25%EWL) was achieved in 79% (297/376) of pts. Down adjustments in 95 pts (mean 2.4 months; mean -152.4 ml) allowed 76/95 (80%) to continue IGB therapy for at least 6 months (mean 9.1 months). Up adjustments in 205/376 (54.5%) pts (mean 5.8 months; mean + 179.2 ml) yielded additional mean wt loss of 6.5 kg. There was 1 gastric ulcer (0.27%). One balloon deflated at 7.4 months and 4 others deflated after 1 year (13-23 months).

Conclusions: In this retrospective review of 376 Spatz3 AIGB patients, up adjustments yielded a mean 6.5kg extra wt loss for those with wt loss plateau, and down adjustments alleviated early intolerance. These two adjustment functions may be instrumental in yielding a successful outcome (> 25% EWL) in 79% of pts.

Keywords: Obesity, Wt loss, Intra-gastric balloons, Adjustable gastric balloon, Wt loss plateau, Intolerance

Introduction

Intra-gastric balloons (IGBs) have been successfully used for wt loss for the last 30 years. The published results reveal an average wt loss of 12–15 kg, and 25–35% EWL over 6 months with an excellent safety profile [1-16]. The Spatz Adjustable balloon was introduced in 2010 as the first adjustable IGB approved for one year implantation. The adjustability function was developed to improve patient response by decreasing balloon size for intolerance and increasing balloon size when balloon effect wears off. Intolerance, with nausea vomiting or pain

requiring early balloon extraction has been documented in the literature and ranges from 3-7% [1,2] – this was recently confirmed in the FDA trials for Reshape Duo and Orbera IGBs where there was a reported 14% and 22% early extraction rate, respectively [17,18]. Balloon effect wears off in many patients within the first 3-4 months [3,16,19].

Studies have reported the results of the Spatz adjustable balloon system with wt losses of 24.4 kg (48.8% EWL), 21.6 kg (45.7% EWL), 17.2 kg (42.9% EWL), and 16.3 kg (67.4% EWL), respectively [20-23]. It is possible that

alleviating intolerance with a downward adjustment and renewing wt loss after balloon upward adjustment may be able to improve weight loss results.

Patients and Methods

The Spatz3 Adjustable IGB (Spatz FGIA, Inc. NY, USA) was implanted at Salles clinic in Brazil. Patients were selected according to the well-established criteria for intragastric balloon implantation, consistent with Anvisa guidelines. Indications for Spatz3 Adjustable IGB implantation included one of the following: (1) temporary wt loss treatment in a patient with body mass index (BMI) in the range of bariatric surgery (>35) who refuse surgery or are at high risk for surgery, (2) temporary wt loss treatment for a patient without indications for surgery ($\text{BMI}>27$). All patients underwent upper gastrointestinal endoscopy using conscious sedation with Propofol, and Midazolam.

Balloons were inflated with Normal saline with the addition of 2 ml of a 1% solution of Methylene Blue. Patients were recovered for 45 minutes and discharged the same day on Digeplus TID (metochlopramide 7 mg, dimethicone and Pepsin) Zofran 4 mg BID (Ondansetron); Dramin 100 mg BID (dimenhydrinate); Sucrafilm prn; Hyoscine prn; and Clonazepam prn. After the first 2 days a 1,000 Kcal liquid diet was prescribed followed by a 5 day 1,000 Kcal pasty diet and thereafter advance as tolerated. The nutritionist saw the patients twice in the first month and then once a month. The endocrinologist and gastroenterologist alternated and saw the patient every other month. Visits with the psychologist were done every 2-4 weeks as needed. Psychiatric evaluation was available as needed. A physical exercise program in a gym was provided with office staff confirming attendance by the patient. Patients who were intolerant to the balloon could be adjusted to decrease the balloon size. Patients were offered upward adjustments of the balloon volume when balloon effect wore off. After 12 months the balloon was deflated by aspiration via standard balloon needle or deflation utilizing the valve, and extraction was completed using a grasping forceps or a polypectomy snare – all under conscious sedation.

Statistics

%TBL, %EWL, and change from pre-implant in body wt were analyzed by two-sided, one-sample t tests, such that a statistically significant result indicates a mean different from zero. Two-sided 95% confidence intervals are also provided. For those with balloon extraction prior to 12 months their last observation was carried forward (LOCF).

Results

From March 2015 to February 2017, 379 consecutive patients (320 female, 59 male) underwent Spatz3 Adjustable IGB placement. There were three patients lost to follow up because they were from other states in Brazil and never returned after balloon placement.

The patient demographics of the 376 patients are displayed in table 1. Wt loss results and response rates are displayed in table 2 and table 3.

Adjustments

Downward adjustments: Downward balloon volume adjustment was performed in 95/376 (25.3%) patients who were intolerant to the balloon characterized by recurrent nausea, daily or sporadic vomiting or recurrent abdominal pain. The downward adjustment at a mean 2 months alleviated symptoms immediately for all 95 patients, however, 31 had recurrent symptoms which necessitated a repeat removal of fluid at a mean 2.8 months. The mean volume of fluid removed was 152.4 ml (100-315 ml) for the first adjustment and 117.4 ml (60-150 ml) for the second adjustment. Out of the 95 that were down adjusted 86/95 (90.5%) continued balloon treatment for at least 3 months; 76/95 (80%) continued for at least 6 months; 51/95 (53.7%) continued balloon therapy for at least 9 months. The mean balloon implantation time for the down adjusted group of 95 patients was 9.1 months.

The wt loss result of the 95 patients after down adjustment (using LOCF) was 15.5 kg; 16.3%TBL; 62.8% EWL as displayed in table 4. There were 8 patients that refused downward adjustment and had their balloon extracted prior to 3 months.

Upward adjustments

Upward balloon volume adjustments were performed on 205/376 (54.5%) pts: 149 had 1 up adjustment; 51 had 2 up adjustments; 5 had 3 up adjustments. The mean timing of the first upward adjustment was a mean 5.2 months with a mean additional volume 179.2 ml (120-400 ml); the second upward adjustment was done at a mean 7.2 months with a mean additional volume of 156.3 ml (60-400 ml); the third up adjustment was done at a mean 9.1 months with a mean additional volume of 180 ml (120-240 ml).

Patient demographics in this group of 205 patients was very similar to the entire group with a mean wt 96.8 kg; mean BMI 35.4; and mean excess wt 29.1 kg. There

were several reasons for patient request for upward adjustment including wt loss plateau; requested renewal of the initial strong balloon effect in order to achieve a second round of rapid wt loss; and decrease in overeating induced symptoms (nausea, pain, vomiting, eructation, heartburn etc.) and wanted this balloon effect renewed.

The additional mean wt loss following upward adjustment was 6.5 kg which is an additional 6.7% TBL and 22.3% EWL. This additional weight loss is calculated from the last weight prior to the first upward adjustment to the final weight at the time of balloon extraction.

Laboratory and Medical Improvements Complications

Nausea (91%), vomiting (70%) and abdominal pain (56%) for 2-4 days following implantation were reported by patients.

One gastric ulcer was noted at 8 month and the balloon was extracted with complete healing of the ulcer at a subsequent endoscopy 2 months later. One balloon deflated at 7.4 months; another 4 balloons deflated after the 1 year period, at 13.3, 15.7, 18.1 and 23.1 months, respectively, when patients delayed their appointment for balloon extraction. There were no reported episodes of bleeding, gastric perforation or bowel obstruction.

Discussion

The introduction of the Spatz3 adjustable balloon to Brazil in 2015 has brought new dimensions to the use of intragastric balloons for Obesity. Prolonging implantation from 6 months to one year as well as adding adjustability has outfitted bariatric endoscopists with the tools needed to improve overall results. Our experience alleviating intolerance and preventing early extraction with balloon volume down adjustments is consistent with previously published Spatz3 studies [22-25]. Similarly, our use of upward adjustments (for decreased balloon effect) which added a mean 6.5kg extra weight loss is consistent with previously published Spatz3 data, which reported additional weight loss after upward adjustments of 8.2 kg, 8.9 kg, 5 kg and 5.7 kg [22-25]. These balloon volume manipulations have produced an impressive percentage of patients that have a successful outcome- 79% (297/376) had > 25% EWL in our retrospective series. This is a significant improvement over the results of 6-month, non-adjustable balloons which have reported response rates (>25% EWL) of 48% and 46.4% in FDA studies [17,18] and 45.6%, 71.4%, 24%, 75%, and 63%, respectively, in several published studies [13,19,26-28].

Based on our retrospective review of our first 376 consecutive patients, the Spatz3 IGB is an effective device for wt loss with limited morbidity. It appears to have a higher rate of patient responders compared with standard non-adjustable 6 month balloons, however this needs to be further clarified with prospective studies.

Disclosure: Dr Leonardo Salles has no conflict of interest to report.

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