

Efficacy and tolerability of the Spatz3® intragastric balloon



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Background:

Intragastric balloons (IGB) have emerged as effective therapies in the management of obesity. The Spatz3® Adjustable Balloon System can be adjusted by fluid addition or extraction. It is not known how many adjustments are required for optimized balloon tolerance and procedure efficacy. The objective of this study is to assess the tolerance and weight loss parameters.

Methods:

197 patients with overweight or obesity underwent 223 episodes of intragastric balloon (IGB) therapy with the Spatz3 device from January 2014 - December 2016. 160 patients were naïve to IGB treatments and 37 were IGB experienced. Balloon adjustment aimed for optimized tolerability and weight loss efficacy. Retrospective outcomes included total weight loss (kg), ΔBMI (kg/m²), proportion of total body weight loss (TBWL %), excess weight loss (EWL %). Rates of gastric ulceration were also analysed. Multivariable regression analysis was performed to assess potential determinants of weight loss.

Findings:

Total weight loss was 16.6±9.2 kg (mean + SD; TBWL 16.2±8.4%; EWL 57.3±28.5%; ΔBMI 5.8±3.2) for IGB-naïve patients and 9.0±6.7 kg (TBWL 9.9±7.2%; EWL 47.8±31.9%; ΔBMI 3.2±2.4) for IGB-experienced patients (< 0.001). 66% of patients achieved > 10% TBWL, 40.7% achieved > 15% TBWL; 84.1% achieved > 25% EWL.

Mean balloon adjustments per patient was 1.6 (+ 1.2; Table 1). The strongest determinants for weight loss were number of adjustments - regardless of the direction of adjustment - and previous gastric balloon history.

Table 1. Balloon characteristics

Balloon characteristics	Mean ± s.d. / %	Range	Median
Length of balloon implantation (month)	11.4±3.7	0.2 – 17.3	12.2
Balloon volume at insertion ^a (ml)	517.4±99.6	350 – 600	500
Balloon volume at extraction (ml)	819.6±241.0	300 – 1250	800
Upward adjustment volume	248.1±72.9	80 – 500	250
Downward adjustment volume	201.9±111.8	100 – 600	150
Average no. of adjustment	1.6±1.2	0 – 8	2.0
Intolerance / early extraction	3.1 (N=7)		

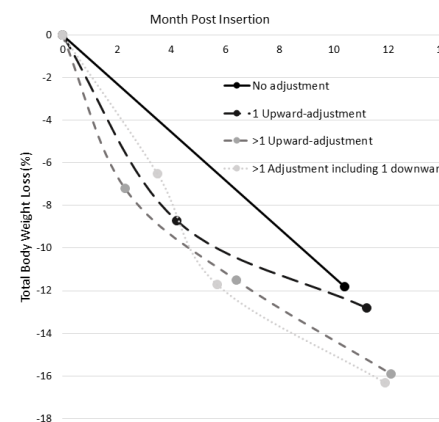


Figure 1: Timing of balloon size adjustments in relation to Total Body Weight Loss % Insertion, adjustment and removal are indicated by the round markers. Adjustments are either upward or downward. Balloon case N = 216; No adjustment: N = 30, 13.9%; 1 toward adjustment N = 74, 34.3%; > 1 upward adjustment N = 80, 37.0%; > 1 adjustment including downward N = 32, 14.8%

Adjustments were associated with higher weight loss (P = 0.03; Figure 1).

62% of patients experienced discomfort related to the balloon in the first four weeks. 14.3% of patient required a downwards adjustment due to significant symptoms. 3.1% of patients required early extraction due to intolerance.

The rate of ulceration was 10.6% and did not increase with the number of adjustments nor balloon size (P = 0.07, 0.10).

Discussion:

The adjustable intragastric balloon is a feasible and effective procedure for weight loss. Negative symptoms were common in the initial phase but rates of intolerance necessitating removal are lower than previously reported (1).

Our overall average of 14.5% TBWL is comparable to previous studies (2,3). More adjustments were associated with higher weight loss (16.2%). Previous IGB experience is associated with less significant weight loss, and patients should be counselled on this.

The observed ulceration rate at 10.6% was high, but within previously reported ulceration figures for the Spatz3® (1, 4). Of note, these were clinically silent, low risk lesions that did not require endoscopic intervention. Neither balloon volume nor number of adjustments was associated with an increased ulcer risk.

Greater emphasis to patients on the importance of proton pump inhibitor and diet adherence, and avoidance of alcohol and NSAIDs may help reduce this rate.

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