In search of the ideal patient for the intragastric balloon – short- and long-term results in 70 obese patients

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Abstract

Introduction: *Treating concomitant diseases in obese patients generates costs which are twice as high as the costs of the therapies in individuals with a normal weight. The conservative management of obesity involving lifestyle and dietary modifications and medical treatment shows only short-term efficacy and carries a 90% risk of recurrence. The intragastric balloon causes a permanent feeling of satiety, thus reducing the amount of food consumed by the patient.*

Aim: *To assess the early and long-term effect of intragastric balloon treatment in obese patients.*

Material and methods: *In 2012, we performed 75 intragastric balloon procedures in obese patients. A total of 70 patients were enrolled in the study. The balloon was removed at 6 months. The patients were interviewed 2 years after removal.*

Results: *Upon balloon removal, mean total weight loss (TWL) was 15.9 kg, and excess weight loss (EWL) was 41 ±19.6% ($p < 0.001$). Only one patient was classified as a non-respondent. Satisfactory results (> 10% TWL) were achieved in all other patients. The mean body mass index (BMI) reduction was 5.8 kg/m^2 (15.5%) ($p < 0.001$). Two years later 45 patients still maintained reduced weight, 7 returned to baseline body weight, whereas 18 subjects experienced a full yo-yo effect (mean gain of 2.7 kg). During 2 years following the balloon removal, mean total weight increased by 10.9 kg, and mean BMI increased by 3.9 kg/m^2 (12.5%). A satisfactory effect (> 10% TWL) was achieved in only 19 patients.*

Conclusions: *Obesity management with the intragastric balloon is a safe treatment method, which effectively induces weight loss. Poor tolerance and lack of response occurring in some individuals should be taken into consideration. The best results are achieved in women with class 1 obesity.*

Key words: *obesity, intragastric balloon, weight loss, follow-up.*

Introduction

Treating concomitant diseases in obese patients generates costs which are twice as high as the costs of the same therapies in individuals with a normal body weight [1]. A significant proportion of obese individuals develop hypertension, diabetes, hyperlipidaemia as well as cardiovascular complications. Total body weight reduction by just 6.8 kg as compared to baseline decreases the risk of diabetes by 58% in a 3-year period [2]. Morbid obesity increases the risk of death 12-fold in the group of 25–35 year-olds [3]. The conservative management of obesity, which involves lifestyle and dietary modifications as well as medical treatment, is related to only short-term efficacy and carries a 90% risk of recurrence [4, 5].

Obesity is a chronic disease. Its treatment should be based on steady, long-term weight loss. Once the conservative strategies prove ineffective, open surgical or endoscopic procedures may be used. The

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Orbera Intragastric Balloon (Allergan, Santa Barbara, CA, USA) is a soft, saline-filled, silicone balloon placed in the stomach during a short endoscopic procedure. Its presence in the stomach causes a permanent feeling of satiety, thus reducing the amount of food consumed by the patient. Obesity treatment using the intragastric balloon is a temporary, reversible, minimally invasive alternative to other therapies. It is particularly recommended in those patients who did not benefit much from dietary modifications or pharmacotherapy but who are not eligible for bariatric surgery. It can also be used as a very convenient tool to induce weight loss prior to the scheduled bariatric surgery or other elective surgical procedures in obese patients, where it reduces the risk of perioperative complications associated with concomitant diseases in these individuals.

Aim

The aim of our prospective, single centre, cohort analysis was to assess the early and long-term effect of intragastric balloon treatment in obese patients.

Material and methods

Between January and October 2012, we performed 75 gastric balloon procedures in obese patients. Informed consent was obtained from all individual participants included in the study. Two patients were excluded from the study, as they underwent additional bariatric surgery during the follow-up period after intragastric balloon removal. One female patient was excluded due to pregnancy present during the data collection period. Furthermore, we were unable to obtain data from 1 patient, who was lost to follow-up. Another one was excluded as she had the balloon removed prematurely, 2 weeks after the primary procedure, due to withdrawal of consent and poor treatment tolerance. A total of 70 patients were enrolled in the study. Tables I and II show the demographic parameters of our cohort, including sex, age, body weight, body height, body mass index (BMI) and obesity stage (according to the American Society of Metabolic and Bariatric Surgery).

The patients were considered eligible for the procedure based on the qualification procedure, during which their motivation to undertake efforts aiming at body weight reduction was assessed. The vast majority of our patients reported physical unattractiveness and obesity-related symptoms, such as joint pain, or difficulties controlling their hypertension or diabetes, as the main factors motivating them to undergo the treatment. The intragastric balloon procedure preceded elective abdominal surgery in 10 patients (abdominal hernia repair in 8 patients and sleeve gastrectomy in 2 patients). Four patients needed obesity management before the scheduled knee or hip arthroplasty. Four female patients with polycystic ovary syndrome (PCOS) needed obesity management as part of their infertility treatment. All patients eligible for treatment had a history of previous dietary or behavioural interventions with poor outcomes. Patients in whom persistent oversupply of simple carbohydrates was confirmed (i.e. sweet eaters) were disqualified. Similarly, the procedure was not performed in patients with large (over 4 cm)

Table I. Demographic data of study group (n = 70)

Parameter	Mean value	Range	SD
Gender (F/M)	62/8	–	–
Age [years]	39.8	17–65	10.9
Weight [kg]	104	78–140	14.3
Height [cm]	167	152–185	6.7
BMI [kg/m^2]	37.2	29.8–48.1	4.0
Excess weight [kg]	41.2	20.4–63.1	11.7

Table II. Patients' data related to obesity classification (n = 70)

Parameter	Obesity class I	Obesity class II	Obesity class III
Number of patients	22	28	20
Gender (F/M)	21/1	23/5	18/2
Mean weight (range) [kg]	90.2 (78–111)	104 (83–125)	118 (105–140)
Mean BMI [kg/m^2]	32.6	37.4	42.0
Mean excess weight	28.6	41.3	55.0

hiatal hernia, pregnant women or individuals with gastric ulcers.

All intragastric balloon insertion procedures were performed under general anaesthesia by the same endoscopic surgeon. The Orbera balloon was then filled with saline solution up to its mean volume (669 ±25.8 cm^3; range: 550–700 cm^3). The saline volume depended on the subjective gastric volume assessment following endoscopic insufflation as well as patient body height (Table III).

No dyes were used for early leakage detection during treatment. The patients were discharged on day 1 following the procedure. The discharge recommendations included the use of a proton pump inhibitor (omeprazole) and a gastroprokinetic agent (cisapride) for a few days. The patients were advised to follow a semi-liquid diet for the first week consisting of frequent, low-volume meals. In the subsequent period, they were instructed by the dietician to follow a 1100 kcal diet and to increase their physical activity. The intragastric balloon was removed at 6 months during the endoscopic procedure performed under general anaesthesia. On the day preceding the balloon removal, the patients were administered a liquid diet in order to empty the stomach. The patients were weighed on that day, and their BMI and excess body mass were calculated. After balloon removal, the patients were instructed to follow the same guidance as during the therapy and to monitor their body weight on a regular basis. The patients were interviewed by phone 2 years after intragastric balloon removal and provided information regarding their body weight at that time.

Table III. Balloon filling volume related to patients' height (n = 70)

Height [cm]	< 163	164–169	> 170
Number of patients	23	27	20
Mean volume [ml]	653	670	685
Range [ml]	550–690	600–700	650–700
SD	31.6	19.3	14.7

Statistical analysis

The statistical analysis of the basic data performed using Excel 2010 (Microsoft) allowed identification of mean values and standard deviation (±). The t-test was used for comparisons and values below 0.05 were considered statistically significant.

Results

We did not observe any complications associated with endoscopic intragastric balloon insertion or removal. The mean body weight upon balloon removal was 87.6 kg, and the mean BMI was 31.5 kg/m^2 (Table IV). Upon balloon removal, after the entire 6-month treatment period, the mean total weight loss (TWL) was 15.9 kg, which translates to 41 ±19.6% of excess weight loss (EWL) in this group, and the difference was statistically significant ($p < 0.001$). Only 1 patient was classified as a non-respondent. Satisfactory results, that is the reduction of > 10% of TWL, were achieved in all other patients. The mean BMI reduction was 5.8 kg/m^2 (15.5%) and

Table IV. Results of weight loss upon balloon removal and after follow-up of 24 months compared to initial weight before treatment (n = 70)

Parameter	Before treatment	Time of removal	24 months after balloon removal
Weight [kg]	104 ±14.3	87.6 ±15.0	98.5 ±17.4
Weight loss [kg]		15.9 ±6.5	5.0 ±7.8
Weight loss (%)		15.3 ±6.2	4.8 ±7.6
BMI [kg/m^2]	37.2 ±4.0	31.5 ±4.3	35.4 ±5.4
BMI loss [kg/m^2]		5.8 ±2.4	1.8 ±2.9
BMI loss (%)		15.5 ±6.6	5.1 ±8.0
Excess weight [kg]	41.2 ±11.7	25.3 ±12.2	36.2 ±15.1
Excess weight loss (%)		41.0 ±19.6	14.2 ±22.0

it was statistically significant ($p < 0.001$). The mean body weight of our patients 2 years later was 98.5 kg ($p = 0.065$), and the mean BMI was 35.4 kg/m^2 ($p = 0.025$). Forty-five (64.3%) patients still maintained reduced body weight (mean TWL of 8.9 kg) over this period, 7 (10%) patients returned to their baseline body weight, whereas 18 (25.7%) subjects experienced a full yo-yo effect, achieving a higher body weight as compared to baseline (mean weight gain of 2.7 kg). Among the patients who maintained body weight reduction, 18 (25.7%) subjects weighed over 10 kg less than before they started the treatment (mean TWL of 15.8 kg). During 2 years following intragastric balloon removal, the mean total body weight in our patient group increased by 10.9 kg, and their mean BMI increased by 3.9 kg/m^2 (12.5%). However, 6 patients continued to lose weight after treatment completion (mean TWL of 3.7 kg). Twenty-four patients gained less than 10 kg, and 40 other subjects gained more than 10 kg (including 11 patients who gained over 20 kg). A satisfactory effect involving maintained body mass reduction by at least 10% was achieved in only 19 patients (with a mean reduction by 15.7% in this subgroup). Female patients achieved greater weight loss as compared to males, both immediately after the treatment (16.2 kg vs. 13.1 kg; $p = 0.196$) and at 2 years (5.3 kg vs. 2.9 kg; $p = 0.203$) – Table V. Women also tended to lose a higher percentage of their excess body weight, both immediately after treatment and at 2 years: 42.7% vs. 27.7% ($p = 0.008$) and 15 vs. 6.5% ($p = 0.076$), respectively. At 2 years, women still maintained higher %TWL as compared to baseline body weight: 5.5% vs. 2.4% ($p = 0.038$). Early treatment outcomes were better in the subpopulation of patients over 40 years of age (Table VI) – body weight reduction 16.9 kg vs. 14.8 kg ($p = 0.19$), BMI reduction 6.2 kg/m^2 vs. 5.3 kg/m^2 ($p = 0.097$). This tendency reversed 2 years later, in favour of younger patients (below 40 years of age). The difference, however, was not statistically significant ($p = 0.55$ and $p = 0.068$, respectively). Patients with morbid obesity achieved the highest TWL (mean reduction of 17.5 kg) at the end of treatment. However, at the 2-year follow-up, the mean total body weight in this subgroup was lower from the baseline by only 2.6 kg. On the other hand, patients with class I obesity lost 14.8 kg on average, but at 2 years the mean total body weight in this subgroup was lower than the baseline by 6.8 kg. The same weight loss expressed as the percentage of excess body weight translated into 51.9% and 31.8% in patients with

Table V. Weight loss according to sex of patients

Parameter	Time of removal		24 months later	
	Male	Female	Male	Female
Number of patients	8	62	8	62
BMI loss [kg/m^2]	4.1 ±1.8	6.0 ±2.4	0.9 ±1.3	1.9 ±3.0
BMI loss (%)	10.6 ±4.5	16.1 ±6.5	2.4 ±3.6	5.5 ±8.3
Excess weight loss [kg]	13.1 ±5.8	16.2 ±6.5	2.9 ±4.2	5.3 ±8.1
Excess weight loss (%)	27.7 ±11.5	42.7 ±19.8	6.5 ±10.2	15.2 ±23.0

Table VI. Weight loss according to age of patients

Parameter	Time of removal		24 months later	
Age at balloon insertion	< 40	≥ 40	< 40	≥ 40
Number of patients	34	36	34	36
BMI loss [kg/m^2]	5.3 ±2.2	6.2 ±2.5	2.0 ±2.8	1.7 ±2.9
BMI loss (%)	14.3 ±6.0	16.7 ±7.0	5.5 ±7.9	4.8 ±8.1
Excess weight loss [kg]	14.8 ±6.2	16.9 ±6.7	5.6 ±8.0	4.5 ±7.7
Excess weight loss (%)	37.9 ±17.8	43.9 ±21.0	14.8 ±21.6	13.6 ±22.7

Table VII. Weight loss according to obesity grade

Parameter	Time of removal			24 months later		
Type of obesity	Class I	Class II	Class III	Class I	Class II	Class III
Number of patients	22	28	20	22	28	20
BMI loss [kg/m^2]	5.4	5.7	6.3	2.4	2.0	0.9
BMI loss (%)	16.3	15.3	14.9	7.3	5.5	2.2
Excess weight loss [kg]	14.8	15.6	17.5	6.7	5.4	2.6
Excess weight loss (%)	51.9	39.0	31.8	22.9	14.2	4.7

class I obesity and morbid obesity, respectively (p = 0.002). The TWL 2 years later was 22.9% and 4.7%, respectively (p = 0.002) (Table VII). This means that the patients regained 68.4% of weight they lost during treatment (54% and 85.1% for obesity class I and III, respectively).

Discussion

The increasing prevalence of obesity has given rise to the search for effective weight reduction strategies to be offered to those patients in whom dietary modifications and behavioural therapy have proved to be insufficient. Bariatric surgery is a method of proven efficacy. Nevertheless, it is invasive and relatively inconvenient. Therefore, the search is still being continued for an alternative treatment which would mechanically induce permanent satiety by reducing gastric volume, while being completely reversible, repeatable at any moment and not posing a risk for the patient. Intragastric balloon therapy complies with these criteria. The international expert group which convened in 1987 developed guidelines on obesity treatment, including the endoscopic insertion of a soft, round, smooth intragastric balloon filled with 400–700 ml of fluid in order to minimise complications [6–8]. The Orbera balloon, which we used in the study, meets these criteria. Except for one female with poor tolerance of the intragastric balloon, who needed to have the device removed due to persistent vomiting, we did not observe any complications requiring surgical or endoscopic intervention.

Imaz *et al*. reviewed 15 studies reporting on the treatment of 3,608 patients and estimated that the mean TWL was 14.7 kg, which translated into 12.2% of baseline body weight (32.1% of excess body weight). They also determined that the mean BMI reduction was 5.7 kg/m^2 [9]. Dumonceau *et al*. analysed 22 studies in 4,371 patients treated with an intragastric balloon. They determined that the mean TWL was 17.8 kg (range: 4.9–28.5 kg) while the mean BMI reduction ranged between 4.0 kg/m^2 and 9.0 kg/m^2 [10]. The mean TWL in our study group was 15.9 kg, which translated into 15.3% of baseline body weight and 41% of excess body weight. The mean BMI reduction was 5.8 kg/m^2. Our results are therefore similar to those reported by other researchers and comply with our expectations. The expected body weight reduction is at least 10% as compared to baseline, in order to reduce the risk of obesity complications due to metabolic syndrome [11]. However, the long-term effects of treatment should be determined to provide thorough data for the assessment of efficacy. We observed gradual weight increase following the intragastric balloon removal in most patients. Only 19 (27.1%) patients managed to maintain body weight 10% lower than baseline. In a study conducted in Greece on 500 patients, the mean TWL upon balloon removal was 16.8%, which translated into 38.09 ±20.18% EWL [6]. However, 1 year later this value decreased to only 12.7% as compared to baseline. Two years after balloon removal the mean TWL in our patient group was 5.1% (n = 70). Nevertheless, it could be as high as 9.0% (n = 52) in the subgroup of patients who managed to keep their body weight below the baseline. That is why we aimed to identify those individuals who might benefit from intragastric balloon treatment also in the long-term, postoperative perspective. Women tended to lose more excess body weight than men. The difference, though, was statistically significant only for the comparison directly after balloon removal. However, when comparing the TWL from baseline at 1 year in male and female subgroups, the difference in the female subgroup was statis-

tically significant (p = 0.038). Patient age did not have a significant effect on treatment outcomes. The best early and long-term results were achieved in a group of individuals with BMI < 35 kg/m^2 (p < 0.002). It can be assumed that patients with BMI > 35 kg/m^2 are more likely to return to their baseline body weight. These patients may need bariatric surgery in the future. Hence, it is emphasized that the best indication for intragastric balloon treatment is the preoperative management of patients with morbid obesity and other severe concomitant diseases, as part of a perioperative risk reduction strategy [12]. Body weight reduction improves glycaemic control and facilitates management of hypertension [13]. Frutos observed that intragastric balloon treatment results in significant liver volume reduction, which creates more favourable surgical conditions [14]. Angrisani *et al*. referred to the intragastric balloon as an adjuvant therapy in obesity, but also as preparation for any surgery in the obese population [15]. In our cohort, intragastric balloon treatment preceded surgical or orthopaedic intervention in 14 cases (n = 75). Busetto *et al*. pointed out that preoperative intragastric balloon treatment significantly reduces the risk of intraoperative conversion to open surgery [16]. Another interesting point was made by a team from Naples, who reported intragastric balloon treatment outcomes in 175 subjects as part of the preoperative management prior to elective bariatric surgery [15]. After balloon removal, almost half of the patients (49.4%) eligible for further bariatric surgery unexpectedly refused to give their consent to it. They also refused further follow-up treatment and use of any dietary modifications. These patients returned to their baseline body weight within 1 year. This emphasizes the need for further bariatric treatment in this patient group, while pointing to the fact that neglecting and/or quitting dietary intervention after intragastric balloon removal leads to the loss of balloon treatment outcomes. Doldi *et al*. observed that 45% of patients would regain the weigh they lost during treatment within 6 months following intragastric balloon removal [17]. The patients with confirmed class 3 obesity in our material regained even 85.1% of the weight they lost during treatment within 2 years following its completion. Despite recommending further bariatric treatment, only 2 female subjects continued the treatment.

Conclusions

Obesity management with an intragastric balloon is a safe treatment method, which effectively induces weight loss. When planning treatment, poor tolerance and lack of response occurring in some individuals should be taken into consideration. The best results are achieved in women with class 1 obesity. Other patients should be considered as candidates for further bariatric treatment.

Conflict of interest

The authors declare no conflict of interest.

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