Short-term outcomes of the new intragastric balloon End-Ball® for treatment of obesity

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Abstract

Introduction: *Intragastric balloons (IGBs) have been successfully used to treat obesity for the last 18 years. These balloons are made of different materials and filled with either air or saline. It seems that balloons filled with saline result in more effective weight loss, but are associated with worse tolerance after implantation. In contrast, balloons filled with air are associated with excellent tolerance, but result in less effective weight loss.*
Aim: *To report the early safety and effectiveness results of the End-Ball® balloon and to encourage discussions on how to best use this new-generation IGB for endoscopic weight loss management.*
Material and methods: *Twenty obese patients (mean age: 40.5 years; mean body mass index: 34.8 kg/m^2) were included in a 6-month study. Balloons were inflated with 300 ml of saline containing 5 ml of methylene blue and 300 cm^3 of air.*
Results: *No serious adverse events occurred during treatment. Patients experienced varying degrees of nausea, vomiting (mean: 3.7 times the first day), and abdominal pain after implantation. Six months (23–29 weeks) after End-Ball® balloon insertion, we observed a significant decrease in body weight (13.9 ±5.1 kg) and percent excess weight loss (37.9 ±12.9%). We also found a significant decrease in the levels of glycated hemoglobin ($p < 0.001$), C-peptide ($p < 0.002$), and triacylglycerols ($p < 0.001$) and an increase in the concentration of high-density lipoprotein cholesterol ($p < 0.025$).*
Conclusions: *The End-Ball® IGB is a safe and effective treatment for morbid obesity, with positive effects on weight loss and saccharide metabolism.*

Key words: *intragastric balloon, obesity, weight loss, safety, End-Ball®.*

Introduction

Treatment of obesity is a demanding and long-term undertaking with no shortcuts or quick fixes. The current data clearly show that no weight loss regimen involving only pharmacotherapy or diet therapy remains effective in the long term [1]. Conservative treatment appears ineffective in morbidly obese patients (body mass index (BMI) of ≥ 40 kg/m^2) [2]. From a long-term perspective, bariatric surgery is currently the most effective procedure, with the best outcomes in severely obese patients. Nevertheless,

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like any other surgical procedure, bariatric surgery carries its own risks [3, 4]. Although cure of associated co-morbidities cannot be guaranteed, more than 75% of obese patients experience complete or partial post-operative remission of most obesity-associated health conditions (e.g. type 2 diabetes, dyslipidemia, and hypertension) [5].

Obese patients who do not qualify for or provide consent for bariatric surgery constitute a therapeutic problem. Endoscopic treatment of obesity using an intragastric balloon (IGB) can be an option for such individuals [6].

The use of a gastric space-occupying balloon to achieve weight reduction in obese patients was first reported in 1982 [7]. The 1980s generation of air balloons was associated with many complications [8, 9] and placement problems, leading to a new generation of IGBs that adopted the recommendations of the 1987 Tarpon Springs Conference [10]. The distinctive structural features of these new balloons (silicone, liquid-filled, spherical, and smooth without traumatic edges) differ from those of the previous intragastric devices; the new devices are associated with lower rates of complications and side effects, creating new interest in the use of this technique for obesity treatment [11]. Nevertheless, the current generation of IGBs has limitations; these IGBs have been associated with deflation and bowel obstruction, loss of effect after 2 to 3 months, limitation to a 6-month implantation time, and significant nausea, vomiting, and discomfort in the early implantation period [12, 13]. A new nonsterile, saline/air-filled IGB with a smooth radiopaque valve (End-Ball®; Endalis, Brignais, France) has renewed interest in the use of IGBs for obesity.

Aim

The aim of this pilot human study was to report the early safety and effectiveness results of this IGB and to encourage discussions on how to best use this new-generation IGB for endoscopic weight loss management.

Material and methods

Patients

A group of 20 patients (13 female, 7 male) with a mean age of 40 ±12 (range: 19–62) years underwent endoscopic treatment with the saline/air-filled End-Ball® IGB at the Endoscopy Centre of the University Hospital Ostrava Department of Internal Medicine from May to October 2014. All procedures performed in our study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki as revised in 2000 and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study. Each patient was evaluated for suitability of IGB implantation by an endoscopist, endocrinologist, and dietitian. All patients had a > 5-year history of obesity and had undergone failed conservative management such as diet therapy, behavioral therapy, and pharmacotherapy. Obesity-related morbidity was present in 80% of the patients, including 2 patients with obstructive sleep apnea syndrome, 6 patients with hypertension, and 3 patients with joint problems involving knee pain. The inclusion criteria were a BMI of > 30 kg/m^2 and a need for preoperative weight loss. Patients with acute gastritis, a history of stomach surgery, gastric or duodenal ulcers, or hypolipidemic or antidiabetic treatment were excluded. All patients' characteristics are summarized in the left part of Table I.

Endoscopy

The saline/air-filled End-Ball® has a different implantation technique than other similar devices. It does not have an independent introduction kit that is introduced separately before the scope. The balloon is packed in the cap, which is fixed to the end of the scope. Thus, the scope and balloon are introduced together; the scope is used as a guide for passage of the balloon into the stomach and enables direct visualization of inflation and release of the balloon. In this study, all procedures were performed under sedation with midazolam (5–9 mg) in an outpatient setting.

First, diagnostic upper endoscopy was conducted to exclude any patients with contraindications. The scope was then connected to the implantation set and introduced into the stomach, and the balloon began to be filled. When the first two syringes were applied, the balloon was pushed out of the cap and filled to its designated volume under endoscopic control. The endoscopist was able to choose any ratio of air and saline; a 1 : 1 air : saline ratio was used in the present study. When the balloon was fully inflated, it was pulled and removed from the

Table I. Patients' characteristics and baseline data

Patient no.	Gender	Age	BW [kg]	BMI [kg/m²]	Obesity-related diseases	IGB size [cc]	Ratio saline : air	Sedation [mg]	Hospital stay [days]	Treatment period [weeks]	Vomiting during follow-up for 3 days after End-Ball® insertion [number per day]		
											D1	D2	D3
1	F	19	87	30.7	O	600	1 : 1	7	0	26	4	–	–
2	M	53	84	30.6	H	550	1 : 1	7	0	27	3	2	2
3	M	53	88	35.3	O	600	1 : 1	8	0	24	2	–	–
4	M	53	100	37.2	IHD, H	600	1 : 1	8	0	25	4	–	–
5	F	55	95	34.9	O	550	1 : 1	6	0	26	2	2	1
6	F	38	105	35.1	O	550	1 : 1	8	0	26	4	–	–
7	M	33	115	35.5	H	600	1 : 1	9	0	23	1	1	–
8	M	29	135	45.1	H	600	1 : 1	9	0	26	6	1	–
9	F	62	105	39.5	DPL	600	1 : 1	5	0	28	4	–	–
10	F	28	95	32.1	O	550	1 : 1	5	0	29	3	–	–
11	F	51	114	37.2	O	600	1 : 1	9	0	25	6	2	1
12	M	35	92	30.0	O	550	1 : 1	7	0	26	1	–	–
13	M	42	99	36.4	H	600	1 : 1	7	0	24	2	–	–
14	F	44	108	36.9	H	600	1 : 1	6	0	29	5	3	1
15	F	49	89	33.1	O	600	1 : 1	6	0	28	3	–	–
16	F	32	96	34.4	O	600	1 : 1	5	0	26	5	1	–
17	F	45	87	33.2	O	600	1 : 1	8	0	29	6	1	–
18	F	23	101	34.9	H	550	1 : 1	6	0	27	3	–	–
19	F	28	99	35.9	DPL	550	1 : 1	7	0	26	4	–	–
20	F	38	108	30.1	O	600	1 : 1	7	0	28	5	2	1
Median		40	99	35.0						26.0	3.65	0.75	0
(Range)		(19–62)	(84–135)	(30–45.1)						(23–29)	(1–6)	(0–3)	(0–2)

H – hypertension, IHD – ischemic heart disease, DPL – dyslipidemia.

feeding catheter. The implantation time varied from 12 to 19 min. After implantation, the patient stayed in the recovery room for 2 h for observation. Following the procedure, the patient took an antiemetic (metoclopramide or thiethylperazine) at home for approximately 3 days depending on the severity of symptoms.

Explantation of the End-Ball® is performed as with other IGBs, such as the Orbera balloon. After the patient has fasted for at least 24 h, he or she is sedated and the endoscopist punctures the balloon with the injector. Because the balloon is made of polyurethane, puncture is more difficult than with a balloon made of silicone. The material is firmer and tougher, and the surface is slippery; therefore, it is difficult to penetrate the wall of the balloon. Upon successful puncture, the filling medium can be suctioned out. The empty balloon is then caught with an extraction grasper and explanted. For this step, the firmer material is an advantage because balloons made of silicone often rupture when they pass through the esophagus. The maximum explantation time in the present study was 5 min.

Measurements

At the screening visit, which took place the morning after a fast, each patient underwent a routine clinical examination and collection of information on medical history and anthropometrics. Height and weight were measured with the patients wearing light clothing and no shoes. Venipuncture was also performed. Blood samples were processed for subsequent analysis 20 min after venipuncture. The serum concentrations of glucose, triacylglycerols, total cholesterol, high-density lipoprotein (HDL) cholesterol, and low-density lipoprotein (LDL) cholesterol were assayed (AU 5420; Beckman Coulter, Inc., Brea, CA, USA). The C-peptide concentration was determined by a solid-phase, competitive chemiluminescent enzyme immunoassay (Unicel Dxi 800; Beckman Coulter, Inc., Brea, CA, USA). Glycated hemoglobin was measured in whole blood by ion exchange high-performance liquid chromatography (Tosoh G8; Tosoh Bioscience, Inc., South San Francisco, CA, USA). After obtaining the results of these assays, the IGB was endoscopically placed in the stomach. The patients were invited to return for follow-ups 3 and 6 months after endoscopy. The follow-ups included a clinical examination and collection of blood samples.

Statistical analysis

To determine the effects of different post-implantation time intervals on the patients' weight, repeated-measures ANOVA was performed for analysis of body composition and biochemical parameters. The time intervals after implantation were coded as categorical variables. Data were not normally distributed; therefore, we transformed the data by decimal logarithm. For multiple comparisons among different times after implantation, we used a pairwise *t*-test with adjustment of *p*-values by Holm correction. All statistical data were processed with statistical software R version 2.14.1. (R Development Core Team 2013) [14].

Results

Adverse events

There were no deaths or serious complications (ulceration, alimentary tract bleeding, perforation, bowel obstruction, significant hemorrhage, electrolyte disorders, or balloon deflation) during treatment with the End-Ball® IGB. Patients experienced varying degrees of nausea, vomiting, and abdominal pain after implantation. Early episodes of persistent nausea, vomiting, and abdominal pain were recorded. The patients vomited an average of 3.7 ±0.8 times on the first day and 0.75 ±0.14 times on the second day after IGB insertion. These symptoms were relieved spontaneously in a few days in all patients (right part of Table I).

Weight loss outcomes

All patients exhibited a significantly reduced body weight compared with the baseline measurement, with a mean weight loss and excess BMI loss of 13.9 ±5.1 kg (range: 4.0–24.0) and 53.4 ±20.6 kg/m^2 (range: 11.8–92.8), respectively, at the end of the IGB program. The percentage excess weight loss (%EWL) was 37.9 ±12.9% (range: 8.8–66.8). The weight and body composition parameters are summarized in Table II.

Metabolic outcomes

The IGB treatment resulted in a significant decrease in the levels of glycated hemoglobin ($p < 0.001$) and C-peptide ($p < 0.002$), but not glucose. Despite the lack of significant changes in the plasma levels of total and LDL cholesterol, the HDL cholesterol

Table II. Overview of weight and body composition parameters in all patients (N = 20)

Parameter	Baseline	3 months	6 months	*P*-value
Weight [kg] (min.–max.)	100.1 ±12.2 (84–135)	89.1 ±11.2 (73–115)	86.3 ±11.5 (68–111)	< 0.001
BMI [kg/m^2] (min.–max.)	34.8 ±3.7 (30.0–45.1)	30.9 ±3.2 (26.2–38.4)	29.9 ±3.1 (25.4–37.1)	< 0.001
Weight loss [kg] (min.–max.)		11.1 (3–20)	13.9 (4–24)	< 0.001
EBL % (min.–max.)		43.2 ±17.1 (8.8–73.1)	53.4 ±20.6 (11.8–92.8)	
EWL % (min.–max.)		30.5 ±9.7 (6.6–49.3)	37.9 ±12.9 (8.8–66.8)	

EBL – excess BMI loss, EWL – excess weight loss. Data are expressed as mean ± SD. P-values refer to significantly different values between baseline and 6 months following surgery (F-test).

Table III. Parameters of lipid and glucose metabolism before and at 3 and 6 months after insertion of balloon. Statistical significance was compared between the pre-surgery status and the post-surgery follow-up examination results, 6 months after the operation. Student's *t*-test at statistical significance of 0.05 was used

Parameter	Pre-surgery		3 months after surgery		6 months after surgery		*P*-value
	Average	SD	Average	SD	Average	SD	
Glucose [mmol/l]	5.58	0.67	5.45	0.68	5.29	0.65	NS
HbA_{1c} (%)	4.03	0.48	3.54	0.34	3.59	0.39	< 0.001
C-peptide [pmol/l]	1702.77	661.34	1286.89	783.97	1208.93	546.96	< 0.002
TC [mmol/l]	5.27	0.76	5.29	0.90	5.11	0.81	NS
TG [mmol/l]	1.97	0.78	1.60	0.50	1.31	0.49	< 0.001
HDL [mmol/l]	1.29	0.26	1.28	0.30	1.39	0.30	< 0.025
LDL [mmol/l]	3.06	0.72	3.28	0.75	3.18	0.69	NS

TC – total cholesterol, TG – triacylglycerols, HDL – high-density lipoprotein cholesterol, LDL – low-density lipoprotein cholesterol, HbA_{1c} – glycated hemoglobin.

concentration increased significantly (p < 0.025). All lipid and glucose metabolism parameters are summarized in Table III.

Discussion

Intragastric balloons have been used to treat obesity for the last 20 years. The most widely used IGB to date is the Bioenterics Intragastric Balloon (BIB; Allergan, Inc., Irvine, CA, USA), which fulfilled the specified requirements of the Tarpon Springs Conference in 1987 [10]. The BIB is a spherical elastic silicone balloon that is filled with 400 to 700 ml of saline solution with methylene blue as a marker of deflation. Imaz *et al.* [15] estimated the safety and effectiveness of the BIB for treatment of obesity in a meta-analysis involving 3442 patients. The authors found that early balloon removal occurred in 4.2% of cases, but half of these removals were voluntary. The main complications of BIB implantation were nausea and vomiting after the first week (8.6%), abdominal pain (5.0%), and balloon deflation and displacement (2.5%). Because it was subsequently assumed that postimplantation nausea and vomiting might be caused by the high weight of liquid within the IGB, air once again began to be used as a filling medium, and the Heliosphere Bag (Helioscopie, Vienne, France) was put on the market [16]. The Heliosphere Bag (650–700 cm^3, 30 g) showed better tolerance after implantation [17, 18]. However, its use was discontinued because of a high rate of system failure upon positioning, a high rate of spontaneous deflation, and difficult extraction [17, 19]. The next commercially available IGB was manufactured by Spatz FGIA, Inc. (Jericho, NY, USA). The Spatz adjustable balloon system (ABS) is a spherical silicone balloon filled with 400 to 800 ml of saline. The main advantage of the ABS is the ability to change the volume at any time during treatment and the longer

duration of use (up to 12 months) [20]. However, no significant differences in post-placement symptoms or weight loss parameters between patients who underwent BIB versus ABS placement were found in a 1-year case-control study by Genco *et al.* [21]. These authors also found that the Spatz ABS was associated with a higher device-related complication rate than was the BIB (17.5% vs. 2.5%, respectively).

A novel solution is the herein-described End-Ball® IGB. The End-Ball® is a spherical elastic balloon made of polyurethane, which allows for combinations of air and fluid in varying proportions. It is usually filled with 300 ml of saline solution with methylene blue as a marker of deflation and 300 cm^3 of air. This type of balloon was used in our study. A significant benefit of the End-Ball® is the low incidence of complications, especially in the first days after implantation. In particular, nausea and vomiting disappear within 48 h after balloon insertion. Previous studies showed that after BIB and Spatz ABS implantation, nausea and vomiting persisted after the first week in 8.6% and 10.0% of patients, respectively [15, 22, 23]. The lower rates of nausea and vomiting (Table I) after implantation of the End-Ball® might be explained by the lower weight of the End-Ball® than the BIB. This assumption also supports the low occurrence of vomiting after implantation of the Heliosphere Bag (average of 4.3 times the first day after implantation) [24]. Moreover, our data do not suggest any correlation between the degree of postimplantation symptoms and successful outcomes (defined as > 25% EWL).

The implantation times of the End-Ball® were comparable with those of both the BIB and Spatz ABS, varying from 12 to 19 min [23]. One advantage of the End-Ball® is its shorter explantation time (only 5 min); this is much shorter than the 15 and 27 min required for explantation of the BIB and Spatz ABS, respectively [23]. This difference may be associated with the balloon material; polyurethane is considerably thinner than silicone, and the balloon volume is thus significantly smaller, making implantation and removal very simple. Another advantage is the strength of polyurethane, which prevents release of the balloon from the extraction grasper in the esophagus; most endoscopists are familiar with this problem when using silicone balloons.

Significant weight loss and a decrease in BMI were observed 6 months after insertion of the End-Ball® into the stomach. Recent studies have shown good results with the BIB in morbidly obese patients (BMI of > 40 kg/m^2, or BMI of > 35 kg/m^2 with comorbidities), with a mean weight loss ranging from 9.5 to 18.4 kg [19, 25–28]. A review by Dumonceau [28] involving 30 studies and 4877 patients who underwent BIB implantation revealed a mean weight loss of 17.8 kg. In a meta-analysis by Imaz *et al.* [15], the estimated weight loss at the time of BIB removal 6 months after implantation was 14.7 kg with 32.1% EWL. Our study had similar results, with a mean loss of 13.9 kg and 37.9% EWL. Most of the weight loss occurred during the first 3 to 4 months.

The present study also demonstrated a positive effect on glucose tolerance. The observed decreases in the glycated hemoglobin and C-peptide levels were statistically significant. However, no significant changes occurred in the glucose level. Decreases in the glycated hemoglobin level in patients with IGBs have been reported in several studies. A 6-month Polish study of BIB implantation reported a significant decrease in the fasting glucose level and insulin response [27]. Sekino *et al.* described a decrease in the glycated hemoglobin level; however, this decrease was not statistically significant [29]. In other studies involving IGBs [30, 31], the HDL cholesterol levels increased and triacylglycerol levels decreased. However, although Tai *et al.* [25] found a decrease in the LDL cholesterol concentration after BIB implantation, the change in the LDL cholesterol concentration was not significant in the present study. In agreement with our data, changes in the total cholesterol concentration were not significant in other studies [25, 30].

The current study has some limitations. The patient group was relatively small, and the follow-up for evaluation of effectiveness after balloon removal was limited to 6 months. Larger and longer-term studies are required to further explore the spectrum of the metabolic/hormonal effects of End-Ball® implantation and to establish the role of this balloon in the treatment of obesity.

Conclusions

The End-Ball® IGB system is a safe and effective method associated with minimal clinical complications in the treatment of morbidly obese patients at 6 months. The IGB implantation is perceived as a restrictive surgery that is especially suitable before bariatric surgical treatment.

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Conflict of interest

The authors declare no conflict of interest.

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