

Intragastric Balloons for Overweight Populations—1 Year Post Removal

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Abstract

Background Endoscopic balloons have been used for years to treat obese seeking weight loss. This study evaluated the safety and effectiveness of our lifestyle modification program.

Methods Retrospective analysis of prospectively collected data from patients who underwent End-ball® (Endalis) intragastric balloon insertion with a multidisciplinary follow-up program. Demographic data, weight loss complications, and satisfaction rates were assessed.

Results In total, 114 overweight/obese individuals from July 2012 to December 2015 were included. Mean age 36.5 years (72% females). Initial body mass index (BMI) was 33.5 kg/m². Twelve early removals (10.52%) due to intolerance ($n = 7$), dissatisfaction ($n = 4$), and esophagitis ($n = 1$); 102 patients completed the program. BMI reduction ranged 5.5–6.4 at balloon removal and 4.1 1-year post removal. Average excess BMI loss (EBMIL) was 46–48% at balloon removal and 39.1% after 1 year; 75% of participants maintained > 60% of their weight loss 1 year after removal. EBMIL was 17 and 48% when initial BMI > 35 and ≤ 35 kg/m², respectively. At removal, 80% of patients were satisfied with the process.

Conclusion The End-ball® program resulted in significant weight loss that continued for 1 year after balloon removal, with minimal complications. When treating overweight/obese populations, the main principles of the balloon insertion process should be no complications, high safety, and significant effectiveness. The process was most beneficial in the overweight and class I obese populations since average BMI was 33 and the class II obese had less weight loss and can possibly prevent future bariatric surgery.

Keywords Bariatric endoscopy · Intragastric balloons · Obesity treatment · Weight loss

Introduction

Obesity is a major cause of premature death, and its prevalence is constantly increasing worldwide [1]. Obesity also predisposes individuals to much comorbidity [2]. Obese

populations have a decreased life expectancy. Moreover, increased body mass index (BMI) results in a proportionally shorter lifespan [3, 4]. However, nonoperative management with diet, exercise, behavior modification, and medications rarely achieves adequate durable weight loss [5, 6]. Even a modest weight loss of 5–10% is associated with significant health benefits [7, 8], and sustained weight loss has been related to further health improvement [9]. Endoscopic balloons have been used as an adjunct to assist in weight loss by reducing gastric capacity and providing a constant increased sense of fullness. In the past years, there has been increasing number of papers on balloon therapy. Balloons were approved for use in Europe already in 1997, and recently, the Food and Drug Administration (FDA) has approved three endoscopic devices for use [10, 11]. In this study, we evaluated the safety and effectiveness of our lifestyle modification program involving End-Ball® (Endalis) insertion and 1-year follow-up after removal.

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Methods

Retrospective analysis of the End-ball® program was conducted from July 2012 to December 2015.

Intragastric balloon insertion is a part of our program for lifestyle modification and weight loss. Participants commit themselves to routine follow-up consultation with a dietician and psychologist. At 6–12 months after insertion, the balloon is routinely removed through upper gastrointestinal (GI) endoscopy.

Prior to balloon positioning, all patients ($\text{BMI} \geq 27$) were evaluated by a bariatric team comprising a gastroenterologist, dietician, and psychologist. The initial interview was conducted by a bariatric gastroenterologist, who collected information regarding the patients' full medical history, previous attempts at weight loss, and comorbidities.

Patients were counseled that expected weight loss was 30–50% from their excess weight, and only those who were willing to commit themselves to follow-up recommendations and routine clinic visits were accepted into the program. At initiation, we emphasized that patients who did not adhere to the program would be requested to remove the device.

All patients went through the same routine prebariatric examinations: blood tests, chest radiography, upper GI series, or endoscopy, electrocardiography, abdominal ultrasound, and endocrinologic evaluation.

Patients were not accepted if their BMI was $>45 \text{ kg/m}^2$. Additional exclusion criteria were obesity due to hormonal or genetic causes, history of alcohol or drug abuse, history of malignancy, pregnancy within the following 6 months, history of bariatric surgery, large diaphragmatic hernias, esophagitis, peptic ulcer, varices, motility disorders, and ongoing anticoagulant or antiplatelet therapy.

The multidisciplinary team remained in close contact with all the patients. They provided constant support (for 24 h a day/7 days a week) through web forums, telephone, mail, and regular clinic visits.

Weight loss is expressed as percent excess weight loss (EWL) based on the Metropolitan Life Tables [12]. BMI was also used to report weight loss, which was expressed as BMI reduction and percentage of excess BMI loss (%EBMIL). A BMI of 25 kg/m^2 was the lowest limit of overweight. Accordingly, calculation of the %EBMIL was performed using the following formula: $([\text{operative BMI} - \text{follow-up BMI}] / [\text{operative BMI} - 25]) \times 100$ [13]. The use of this relative parameter is superior because it is more descriptive and allows for objective comparisons among series.

End-ball® (Endalis, Brignais, France) intragastric balloons (Fig. 1) were placed under deep sedation as an ambulatory procedure. Patients were placed in the left lateral decubitus position and sedated with midazolam (1 mg) and propofol (2 mg/kg i.v.). After diagnostic endoscopy, the balloon was inserted into the gastric fundus. Balloons were inflated under

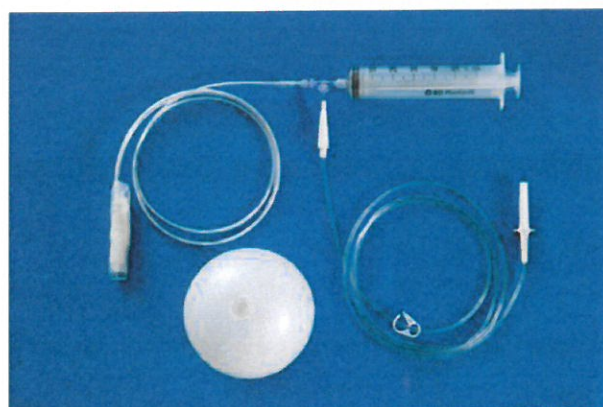


Fig. 1 End-Ball®

direct vision, primarily with 100 ml of air, followed by 500 ml of saline. After recovery, the patients were discharged to home with instructions to take proton pump inhibitors (PPI) throughout the balloon period (Caps. esomeprazole 20 mg $1 \times 2/\text{d}$ or Caps. omeprazole 20 mg $1 \times 2/\text{d}$). In the first period, we also prescribed antiemetics, antispasmodics, and pain killers (Tab. metoclopramide, Tab. papaverine hydrochloride, and Gutt. dipyrone).

Balloons were removed using the same sedation protocol. The decision for removal or perhaps further continuation with the program was based on the patients' satisfaction/weight loss at the 6-month clinic visit and balloon intolerance presenting as persistent nausea and/or pain. Those that showed significant weight loss and who were satisfied with the program were permitted to continue with the program for up to a year, with close monitoring.

On the day of removal, patients were interviewed regarding their satisfaction with the process and whether they would recommend the device to others.

One year after removal, the patients were contacted by telephone or requested to visit the clinic, and data concerning their weight, comorbidities, and satisfaction with the process were retrieved.

The study protocol was approved by the hospital ethical committee.

Results

Over a 42-month period (July 2012–December 2015), 114 overweight/obese individuals were included in this study, with a mean age of 36.5 years. As shown in Table 1, 32 patients were male (28%) and 82 (72%) were female. The initial BMI was 33.5 kg/m^2 , with an excess BMI of 11.5 kg/m^2 (range, 2–17 kg/m^2). Eighteen patients had a BMI of $>35 \text{ kg/m}^2$, and the remaining 96 patients had a BMI of $\leq 35 \text{ kg/m}^2$. Both groups had the same male/female distribution.

Table 1 Demographics of the 114 patients treated for obesity by endoscopic insertion of the Endalis End-ball®

Patients	<i>n</i> = 114
Sex	Male—32; female—82
Age (years)	Mean 36.5
Initial BMI (kg/m ²)	Mean 33.5 (range 27–42)
Initial weight	107.3 (71–155)
Initial excess BMI (kg/m ²)	11.5 (range 2–17)

Mean time for End-ball® positioning was 17 min (range, 10–23 min), with no difficulties in balloon positioning. In one morbidly obese (BMI, 41 kg/m²) patient with a short neck, we could not traverse the angulation of the oropharynx. During the 10 days after balloon insertion, all patients experienced some degree of abdominal pain and nausea and vomiting; these symptoms were mostly controlled with medical therapy (Tab. metoclopramide 10 mg 1 × 3/day; Tab. papaverine hydrochloride 80 mg 1 × 3/day; Gutt. dipyrone—20 gutts as needed). None of the patients needed any refills on the initial post balloon prescription.

Early removals were performed in 12 patients (10.52%); seven in the first 6 weeks (intolerance), four at weeks 7–16 (dissatisfaction) and the last one at 5 months.

These patients were due to balloon intolerance presented with continuing nausea and discomfort despite medications. One of those patients had food impacted by the balloon (Fig. 2), which necessitated early removal under general anesthesia and patient intubation to prevent aspiration. An early removal at 5 months was performed due to symptomatic esophagitis; the presenting symptom was chest pain, and the patient had not adhered to the mandatory proton pump inhibitor dosage. The four patients who underwent removals at weeks 7–16 were not satisfied with their weight loss and requested to leave the program. All these patients were in the BMI > 35 kg/m² group.

During the follow-up period, at 2–4 months, 20 patients complained of some degree of transient increased dyspepsia, bloating, and halitosis due to residual food content because of balloon-induced delayed gastric emptying. All patients, except for the one described previously, were treated successfully with only fluid administration for 24 h.

There were no balloon migrations into the intestinal loop. None of the balloons were deflated at removal time, and there were no complications.

In total, 102 patients completed the program; 82 of the balloons were removed at 6 months, 12 at 7–8 months, six at 9–10 months, and two at 11–12 months.

Table 2 and Fig. 3 depict the weight loss. BMI reduction ranged 5.5–6.4 at balloon removal and 4.1 1-year post removal. Patients' EWL was 36.5% (0–115%) at 6 months, 39.2% (22–90%) at 7–8 months, and 38.6% (24–85%) at 9–12 months (later removal). One year after removal, average EWL was

35.3% (1–76%). Average EBMIL was 46–48% at removal and 39.1% after 1 year. Seventy-five percent of the participants maintained > 60% of their weight loss at 1 year after removal.

EBMIL was 17% in patients with BMI > 35 kg/m² and 48% in those with BMI ≤ 35 kg/m². The early removals in the group with BMI > 35 kg/m² were due to dissatisfaction with their results and not due to intolerance or adverse reactions.

At removal, 80% of the patients were satisfied or very satisfied with the process, and most of them stated that they would recommend the device to others.

Discussion

In the battle against obesity and comorbidities, the use of endoscopic devices has been reported for many years, with both successful and unsuccessful results [14, 15]. These devices are gaining increasing acceptance, and the Food and Drug Administration (FDA) has approved three endoscopic devices for use. This approval being issued after the Garren Edwards balloon was withdrawn from the market in 1992 due to complication rate, spontaneous deflation, small bowel migration, and obstruction [10, 16, 17].

Overweight patients seeking bariatric consultation are seen primarily by medical staff well acquainted with the different options for obese populations (endoscopic devices, bariatric surgery, along with dietary and psychological counseling and medications). The patients are then accordingly referred for appropriate consultation.

All patients (BMI ≥ 27) contemplating whether to undergo intragastric balloon insertion are seen by a bariatric gastroenterologist. This field encompasses knowledge of the pros and cons of different obesity treatments (both endoscopic and surgical). Patients are thoroughly evaluated nutritionally and medically and advised regarding the most appropriate route for them. Suitable patients are then referred for preballoon dietary and psychological assessment.

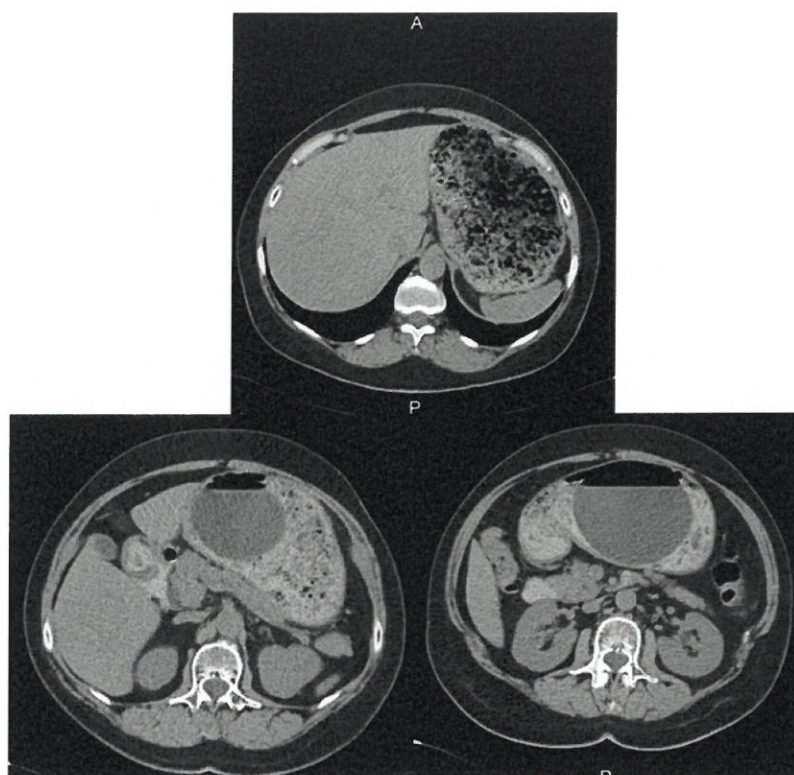
This is the first report to describe the use of the End-ball®.

Most of the patients who participated in our program were female (approximately 80%), and this demographic is similar to that in other studies [18, 19].

After balloon insertion, the patients in our study were expected to undergo medical follow-up visits at every 4–6 weeks. All patients were provided round-the-clock medical/nutritional support for all questions and problems that may occur. The service was most extensively used in the first week, the acclimation period.

In our study, the average EBMIL was 46–48% at balloon removal and 39.1% at 1 year after removal. Single-center studies on Orbera (an FDA-approved balloon) have reported approximately 38–50% EWL after the 6-month balloon period [20–23]. Other recent weight loss reports have described an

Fig. 2 CT scans of stomach with and impacted food



estimated 50% EBMIL at balloon removal, with most of the patients maintaining the weight loss [23, 24]. The primary goal of the process is weight loss, and the 12-month follow-up report revealed that most patients sustained their weight loss, indicating that the patients had continued with the newly acquired dietary habits that had been implemented during the balloon period.

Most of the early removals (57%, 7 of the 12 patients) were performed in the first 2 months and were due to balloon

intolerance. All but one of the removals after this period were due to the patients' dissatisfaction with their weight loss, and these removals were primarily performed in patients with BMI > 35 kg/m². Further analysis of these four patients, the precounseling, and follow-up visits specifically addressed the expected weight loss. Although we constantly emphasized that the balloon process is not as effective as surgery, they mistakenly compared their initial weight loss to bariatric surgery patients and therefore were disappointed. Including

Table 2 Results—weight loss

	Baseline	3 Months	Removals				12 months post removal
			Month 6	Months 7–8	Months 9–10	Months 11–12	
Patients	114	105	102				105
Patients completed			82	12	6	2	
Weight loss		16.4 (1.5–23)	20.1 (2.2–48)	23.2 (3–37)	23.5 (15–28)		19 (0–59)
BMI median (range)	33.5 (27–42)		28 (23.9–33)	27.5 (23.6–33.2)	27.1 (24.1–30.5)		29.4 (25.8–33.2)
BMI reduction			5.5	6	6.4		4.1
Mean percent weight loss		13 (2.6–32)	17.1 (–3–39)	19.5 (4–37)	20.9 (10–41)		15.5 (2.4–42)
EWL (%)		21.2 (1.6–87)	36.5 (0–115)	39.2 (22–90)	38.6 (24–85)		35.3 (1–76)
EBMIL (%)		25 (0–58)	48.4 (–3–98)	49.2 (25–85)	46.2 (23–79)		39.1 (3–85)
TWL (%)		10.09 (0.76–41.42)	16.97 (0–53.48)	18.06 (10.13–41.47)	17.45 (10.85–38.46)		15.98 (0.47–34.53)

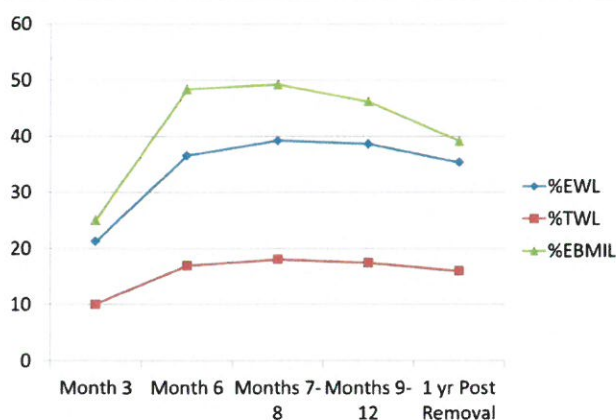


Fig. 3 Graph of weight loss

dissatisfaction as a removal criteria explains the higher percentage of early removals in our study.

The most frequent symptoms were transient in nature and occurred while the stomach was adjusting to the inserted foreign body. These symptoms were usually discomfort, nausea, transient vomiting, and pain. Similar to previous reports, our patients responded well to medications, and the symptoms decreased over time [25, 26].

We observed no major complications such as mortality, gastric ulcers and perforations, balloon migration, and esophageal lacerations [27, 28], during the balloon period (from insertion to removal). Similar to previous studies, one of the patients developed symptomatic esophagitis, necessitating early removal. This patient did not adhere to the mandatory protein pump inhibitor dosage [29, 30].

In some patients, we extended the length of therapy beyond the recommended time. This was performed after a follow-up endoscopy to rule out any problems associated with the balloon. None of the patients exhibited balloon deflation, migration, or obstruction at follow-up endoscopy and at balloon removal. Another study investigated whether the balloon can safely be left in place for >6 months (range, 7–24 months). The authors reported no complications, and only two patients had asymptomatic deflation. They further reported an insignificant trend toward increased weight loss with extended therapy for up to 14 months [31].

Notably, the %EBMIL in the group with BMI ≤ 35 kg/m² was 48% compared with only 17% and in the group with BMI > 35 kg/m². The latter group also comprised more early removals due to dissatisfaction, at times due to high expectations despite the initial counseling. These findings suggest that the balloon program is more suitable for patients with a BMI of ≤ 35 kg/m².

There is an increasing need to efficiently treat the obesity epidemic. A growing number of bariatric surgery procedures are aimed at morbidly obese patients, and treatment options for obese patients with BMIs of < 35 kg/m² are not widely available. Our study has demonstrated that

the endoscopic insertion of an intragastric balloon as part of a lifestyle modification program is safe and effective. And patients could maintain significant weight loss even at 1 year after balloon removal.

Similar to all lifestyle modification programs dealing with obesity, intragastric balloon therapy must be administered by a multidisciplinary team providing medical, nutritional, psychological, and physical fitness guidance [27].

There are no international recommended guidelines for endoscopic bariatric devices, but the International Federation for the Surgery of Obesity and Metabolic Disorders published guidelines for safety, quality, and excellence in bariatric surgery, which can be applied to this field of bariatrics [32]. These guidelines state that along with surgical services, excellent bariatric institutions should provide lifetime follow-up for all patients undergoing bariatric surgery. A paper addressing issues of health behavior, food tolerance, and satisfaction after sleeve gastrectomy underlines the importance of long-term maintenance programs that should be implemented with balloon application [33].

Regarding our patients, we took this one step further by providing round-the-clock support. If patients do not have appropriate round-the-clock professional support, the entire process and success are at risk [34, 35]. Overall support time (mails, phone and clinic visits) was more pronounced in the compliant and successful patients, showing their dedication to the process and its supporting facilities. Support must continue after balloon removal, as mentioned by Dastis, who noted that in the absence of adjunctive measures, approximately three quarters of patients were unable to maintain a significant weight loss [36]. The weight loss effects of the balloon program along with constant dietary counseling were significantly higher than those of dietary modification alone. These effects persisted even at 2 years after removal [37].

The morbidly obese patients (BMI > 35 kg/m²) in our study did not experience any adverse events. However, they exhibited less weight loss and expressed more dissatisfaction with the process. Many of these patients also had a complex oropharyngeal anatomy, making balloon insertion difficult. These findings lead us to direct the program toward prebariatric patients with a BMI of ≤ 35 kg/m².

Our study is limited by its retrospective nature and small sample size. Although data were not obtained from a prospective trial, all included patients were available for reporting purposes.

In conclusion, we present our positive results with the Endalis End-ball®. Our lifestyle modification program with End-ball® application resulted in significant weight loss, which continued for 1 year after balloon removal, with minimal complications. When treating overweight/obese populations, the main principles of balloon therapy should be no complications, high safety, and significant effectiveness. Accordingly, the End-ball was most beneficial in the

overweight and class I obese populations since the average BMI was 33 and the class II obese had less weight loss and can possibly prevent future bariatric surgery.

Compliance with Ethical Standards

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study, formal consent is not required.

Conflict of Interest The authors declare that they have no conflict of interest.

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