Performance of the Obalon Balloon in Commercial Use

Background

The Obalon Balloon received CE Mark Approval and was commercially launched on a limited basis in Europe beginning in July 2012. The balloon is designed to be swallowed in a gelatin capsule and remotely inflated with gas to 250 cc without endoscopy or sedation. Additional balloons can be swallowed and inflated to increase total resident volume throughout the three-month treatment period to stimulate further weight loss. All balloons are intended to be removed at the end of the three-month period in a short endoscopy using standard, commercially available tools. Safety and efficacy data were collected and reported on the first commercial product uses at eleven centers throughout Belgium, Germany, Italy and Spain.

Methods

Baseline weight information was recorded at the time of first balloon placement in commercial patients. Additional balloons were placed throughout the three-month treatment period as determined by physicians monitoring patient satiety, weight loss progression and symptoms. Adverse event data were collected throughout the therapy period and final weight data were recorded at the time of balloon removal.

Results

119 patients (75.6% female), with a baseline BMI (mean ± SD) of 33.0±5.5 kg/m^2, mean baseline weight of 93.7±20.6 kg, and mean age of 41.8±12.2 years initially received a single 250 cc balloon. Fifty-seven (47.9%) patients received a second balloon and 6 (5.0%) received a third balloon during the treatment period. 110 patients completed at least 8 weeks of treatment with mean excess weight loss of 50.2±72.5%, percent of total body weight loss of 8.3±4.2%, decrease in BMI of 2.8±1.9 kg/m^2, and mean weight loss of 8.0±5.8 kg. These weight loss results were all highly statistically significant ($p<0.001$). Seventy-five (68.2%) patients had excess weight loss of 25% or greater and 84 (76.4%) had percent of total body weight loss of 5.0% or greater in only three months of treatment. The most commonly reported adverse events were nausea (10.1%) and vomiting (6.7%). 9 patients (7.6%) requested early removal of balloons, which was primarily due to a lack of commitment to the full 3-month therapy period. One (0.8%) small (<1 cm), non-hemorrhagic ulcer was observed during the endoscopy to remove balloons at the end of the treatment period and was reported as possibly related to the contraindicated use of NSAIDs. One esophageal laceration (0.8%) was observed after balloon removal in a patient diagnosed with eosinophillic esophagitis.

Conclusions

The results reported in this data collection from the first commercial uses of the Obalon Balloon after CE Mark approval further validate the outcomes from prior controlled clinical studies. The high responder rate and 3-month weight loss results, combined with very low adverse events rate and favorable tolerability, are encouraging for the use of the Obalon Balloon for weight loss.

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1. Indications for use

The Obalon Gastric Balloon System is indicated for temporary use in weight loss in overweight and obese adults with a BMI of 27 or greater who have previously failed a supervised weight control program. The Obalon Gastric Balloon System is intended to be used in conjunction with a diet and behavior modification program.

Up to 3 Obalon Gastric Balloons may be placed in the stomach across a 3-month (12 week) period based on the individual's weight loss progress and satiety levels.

The maximum placement period for the Obalon Gastric Balloons is 3 months (12 weeks) and all balloons must be removed at that time or earlier.

2. Contraindications

- Anatomical abnormalities of the upper gastrointestinal (GI) tract
- Functional disorders of the upper GI tract
- Inflammatory and other pathophysiological conditions of the GI tract
- Chronic or acute use of medications known to affect integrity of the GI tract and/or weight
- Prior GI tract surgeries excluding uncomplicated appendectomies
- Untreated hypothyroidism or untreated Cushing's disease or syndrome
- Severe, unstable/uncontrolled medical conditions of major organ systems
- Alcohol and/or illicit drugs abuse
- Undergoing chronic steroid or immunosuppressive therapy
- Pregnant or breastfeeding or intention of becoming pregnant during the study
- Have Type 1 diabetes mellitus
- Must not undertake scuba diving or travel in an unpressurized airplane cabin
- Known allergies to products/foods of porcine origin
- Untreated Heliocobacter pylori infection

Weight loss data* (n=110)

	MEAN ± SD
% Excess Weight Loss (EWL)	50.2 ± 72.5
% Weight Loss (WL)	8.3 ± 4.2
BMI Decrease	2.8 ± 1.9
Weight Loss (kg)	8.0 ± 5.8

P-value <0.001

* Excludes patients who received therapy ≤8 weeks

Responder rates*

% EWL	Responders (%)
≥ 35%	54 (49.1)
≥ 30%	68 (61.8)
≥ 25%	75 (68.2)
≥ 20%	82 (74.5)
≥ 15%	94 (85.5)

% WL	Responders (%)
≥ 9%	47 (42.7)
≥ 8%	57 (51.8)
≥ 7%	69 (62.7)
≥ 6%	76 (69.1)
≥ 5%	84 (76.4)

Reduction BMI	Responders (%)
≥ 3.0	45 (40.9)
≥ 2.5	59 (53.6)
≥ 2.0	75 (68.2)
≥ 1.5	89 (80.9)

WL (kg)	Responders (%)
≥ 9.0	29 (26.4)
≥ 8.5	34 (30.9)
≥ 8.0	40 (36.4)
≥ 7.5	52 (47.3)

* Excludes patients who received therapy ≤8 weeks

Most commonly reported adverse events**

Reported event	Events (% Subjects) (n=119)
Nausea	12 (10.1)
Vomiting	8 (6.7)
Stomach pain	6 (5.0)
Gastroesophageal reflux	4 (3.4)
Stomach cramps	3 (2.5)
Heartburn	3 (2.5)
Other Adverse Events	
Esophageal Laceration[1]	1 (0.8)
Endoscopically Detected Ulcer[2]	1 (0.8)

1. Esophageal laceration observed after balloon removal in patient diagnosed with eosinophillic esophagitis
2. Small (<1 cm), non-hemorrhagic, possibly NSAID-related

**All patients receiving at least one balloon

Patient demographics**

n (%) or Mean ± SD	European LMR
Sites	11 (BE, DE, IT, ES)
Subjects	119
Age	41.8 ± 12.2
Female	90 (75.6)
Baseline (kg)	93.7 ± 20.6
Height (cm)	167.9 ± 9.4
Baseline BMI	33.0 ± 5.5

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