Single Fluid-Filled Intragastric Balloon Safe and Effective for Inducing Weight Loss in a Real-World Population

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BACKGROUND & AIMS: **The Orbera intragastric balloon (OIB) is a single fluid-filled intragastric balloon approved for the induction of weight loss and treatment of obesity. However, little is known about the effectiveness and safety of the OIB outside clinical trials, and since approval, the Food and Drug Administration has issued warnings to health care providers about risk of balloon hyperinflation requiring early removal, pancreatitis, and death. We analyzed data on patients who have received the OIB since its approval to determine its safety, effectiveness, and tolerance in real-world clinical settings.**

METHODS: **We performed a postregulatory approval study of the safety and efficacy of the OIB, and factors associated with intolerance and response. We collected data from the Mayo Clinic's database of patient demographics, outcomes of OIB placement (weight loss, weight-related comorbidities), technical aspects of insertion and removal, and adverse events associated with the device and/or procedure, from 8 centers (3 academic, 5 private, 4 surgeons, and 4 gastroenterologists). Our final analysis comprised 321 patients (mean age, 48.1 ± 11.9 y; 80% female; baseline body mass index, 37.6 ± 6.9). Exploratory multivariable linear and logistic regression analyses were performed to identify predictors of success and early balloon removal. Primary effectiveness outcomes were percentage of total body weight lost at 3, 6, and 9 months. Primary and secondary safety outcomes were rates of early balloon removal, periprocedural complications, dehydration episodes requiring intravenous infusion, balloon migration, balloon deflation or hyperinflation, pancreatitis, or other complications.**

RESULTS: **Four patients had contraindications for placement at the time of endoscopy. The balloon was safely removed in all instances with an early removal rate (before 6 months) in 16.7% of patients, at a median of 8 weeks after placement (range, 1–6 mo). Use of selective serotonin or serotonin-norepinephrine re-uptake inhibitors at the time of balloon placement was associated with increased odds of removal before 6 months (odds ratio, 3.92; 95% CI, 1.24–12.41). Total body weight lost at 3 months was 8.5% ± 4.9% (n = 204), at 6 months was 11.8% ± 7.5% (n = 199), and at 9 months was 13.3% ± 10% (n = 47). At 6 months, total body weight losses of 5%, 10%, and 15% were achieved by 88%, 62%, and 31% of patients, respectively. Number of follow-up visits and weight loss at 3 months were associated with increased weight loss at 6 months (β = 0.5 and 1.2, respectively) ($P < .05$). Mean levels of cholesterol, triglycerides, low-density lipoprotein, and hemoglobin A1c, as well as systolic and diastolic blood pressure, were significantly improved at 6 months after OIB placement ($P < .05$).**

Abbreviations used in this paper: BMI, body mass index; FDA, Food and Drug Administration; OIB, Orbera intragastric balloon; SNRI, serotonin–norepinephrine re-uptake inhibitor; SSRI, selective serotonin re-uptake inhibitor; TBWL, total body weight lost; %TBWL, percentage of total body weight lost.

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1542-3565/$36.00
https://doi.org/10.1016/j.cgh.2018.01.046

CONCLUSIONS: **In an analysis of a database of patients who received endoscopic placement of the OIB, we found it to be safe, effective at inducing weight loss, and to reduce obesity-related comorbidities in a real-world clinical population. Rates of early removal (before 8 weeks) did not differ significantly between clinical trials and the real-world population, but were affected by use of medications.**

Keywords: SF-IGB; SNRI; SSRI; Overweight; Bariatric Surgery; Obesity; Balloon; Endoscopy.

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Obesity continues to be pervasive in our society, with more than two thirds of Americans being overweight or obese.[1] Although lifestyle interventions remain the cornerstone of therapy, because of a lack of long-term effectiveness, pharmacotherapies are becoming increasingly used as an adjunctive therapy.[2–4] Unfortunately, the proportion of patients that achieve greater than 10% of total body weight lost (TBWL) with lifestyle and pharmacologic therapies is limited. Achieving this magnitude of weight loss is needed to achieve resolution of more resistant comorbidities such as fatty liver and obstructive sleep apnea.[5] Bariatric surgery continues to be the most effective option for durable weight loss, but it carries its own set of risks and costs.[6,7] Therefore, endoscopic bariatric therapies were developed to help bridge the gap between effectiveness and procedural risk to offer patients with obesity significant weight loss that allows them to better engage in a comprehensive lifelong weight maintenance program.

The Orbera intragastric balloon (OIB) (Apollo Endosurgery, Austin, TX) is 1 of 2 fluid-filled gastric balloons recently approved by the Food and Drug Administration (FDA) for patients with a body mass index (BMI) between 30 and 40 kg/m^2.[8–10] Recent US multicenter randomized clinical trials showed the superiority of the OIB plus lifestyle interventions over lifestyle interventions alone, with patients losing 3 times more weight 6 months into balloon therapy.[11] However, the effectiveness and safety of the OIB outside clinical trials in the United States in a commercial setting is currently unknown, and, since approval, the FDA has issued 2 communications warning health care providers about the potential risks associated with fluid-filled intragastric balloons including the risk of balloon hyperinflation, pancreatitis, and death.[12,13] Therefore, we sought to report the safety, effectiveness, and tolerance of the OIB across the United States in real-world clinical settings, including both academic and private practices involving surgeons and gastroenterologists and, finally, to derive predictors to optimize patient selection for this endoscopic bariatric therapy.

Methods

Study Design

This research study was an investigator-initiated, post-FDA regulatory approval, multicenter study using prospectively collected data. Since FDA approval of the OIB, the Mayo Clinic–Rochester created and hosted a comprehensive Research Electronic Data Capture database that records demographics, outcomes both in terms of weight loss and improvement in weight-related comorbidities, technical aspects of insertion and removal procedures, and detailed assessment of all potential adverse events associated with the device and or procedure. Eight US centers (3 academic, 5 private, 4 surgeons, and 4 gastroenterologists) participated. All centers received access to the Research Electronic Data Capture database and were prompted at regular intervals to enter data. Quality checks were conducted manually and center-specific inquiries were obtained to ensure data integrity and completeness.[14] Participating institutional review boards approved the protocol and those without an institutional review board followed the principles outlined in the Declaration of Helsinki. Written informed consent was obtained from all subjects. All authors agreed to publish the manuscript and vouch for the completeness and accuracy of the data at their respective centers.

Intervention

Eligible patients included adults ages 18 to 65 years with a BMI greater than 30 kg/m^2 who received the OIB for the treatment of obesity in the United States after regulatory approval. All centers carefully followed the directions for use approved by the FDA in selecting patients.[8] All centers recommended following a reduced-calorie diet along with increased physical activity in conjunction with OIB therapy and had a minimum of 3 follow-up visits with a multidisciplinary team that included a nutritionist and/or a psychologist.

Study Outcomes

Primary effectiveness outcomes for the study were the percentage of TBWL (%TBWL) at 3, 6, and 9 months. The %TBWL was defined as weight lost at a specific time point (3, 6, or 9 mo) divided by the baseline weight at balloon placement. Secondary outcomes were absolute weight loss at 3, 6, and 9 months; the proportion of patients achieving at least 5% and 10% TBWL at 6 and 9 months; improvement in systolic and diastolic blood pressure total cholesterol, triglyceride, low-density lipoprotein, high-density lipoprotein, fasting blood sugar, and hemoglobin A1c levels; and resolution of hypertension, dyslipidemia, impaired fasting glucose, or type 2 diabetes at 6 months. Primary and secondary safety