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Single Fluid-Filled Intra-gastric Balloon Safe and Effective for Inducing Weight Loss in a Real-world Population

Eric J. Vargas, M.D.¹, Carl M. Pesta, D.O., FASMB², Ahmad Bali, M.D.³, Eric Ibegbu, M.D., FACG⁴, Fateh Bazerbach, M.D.¹, Rachel L. Moore, MD, FACS, FASMB⁵, Vivek Kumbhari, M.D.⁶, Reem Z. Sharaiha, M.D., MSc.⁷, Trace W. Curry, M.D.⁸, Gina DosSantos³, Ramsey Schmitz, RN, CBN⁵, Abhishek Agnihotri, M.B., B.S.⁶, Aleksey A. Novikov, M.D.⁷, Tracy Pitt, D.O., FACOS⁸, Margo K. Dunlap, RN⁶, Andrea Herr, ANPBC⁷, Louis Aronne, M.D.⁷, Erin Ledonne⁸, Hoda C. Kadouh, Ph.D, R.D.¹, Lawrence J. Cheskin, MD, FACP, FTOS^{6,9},

CORRESPONDING AUTHOR: Barham K. Abu Dayyeh, M.D. MPH, Associate Professor of Medicine, Mayo Clinic School of Medicine, Mayo Clinic - Rochester, 200 First Street SW, Rochester, Minnesota 55905, Phone: 507-266-2384, Fax: 507-538-5820, AbuDayyeh.Barham@mayo.edu.

Disclosures:

The following authors have nothing to disclose: Eric J. Vargas, Ahmad Bali, Eric Ibegbu, Fateh Bazerbach, Gina DosSantos, Ramsey Schmitz, Abhishek Agnihotri, Aleksey A. Novikov, Tracy Pitt, Margo K. Dunlap, Andrea Herr, Erin Ledonne, Hoda C. Kadouh, Manpreet S. Mundi, Louis Aronne,

Author Contributions:

Eric J. Vargas: Study concept and design, acquisition of data, analysis and interpretation of data, drafting of the manuscript, statistical analysis, revision of the manuscript
Drs. Bazerbach, Pesta, Bali, Ibegbu, Moore, Kumbhari, Sharaiha, Curry, Agnihotri, Novikov, Pitt, Aronne, Kadouh, Cheskin, Mundi, Acosta, and Gostout: acquisition of data and critical revision of the manuscript
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Dr. Abu Dayyeh: Study concept and design, analysis and interpretation of data, statistical analysis, revision of the manuscript

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Carl M. Pesta : Apollo EndoSurgery: Consulting fee, Speaking and Teaching
Rachel L. Moore: Apollo EndoSurgery, Self: Consulting Fee, Speaking and Teaching; Olympus, Self: Consulting Fee, Speaking and Teaching
Vivek Kumbhari: ABE, Self: Salary, Advisory Committees or Review Panels; Boston Scientific, Self: Consulting fee, Consulting; Apollo EndoSurgery, Self: Consulting fee, Consulting, ERBE, Other financial benefit, Grant/Research Support
Reem Z. Sharaiha: Boston Scientific, Self: Consulting fee, Consulting, Apollo EndoSurgery; Self: Consulting fee, Consulting; Abbvie, Self: Consulting fee, Speaking and Teaching; BMS, Self: Consulting fee, Advisory Committees or Review Panels; BMS, Self: Consulting fee, Independent Contractor; Intercept, Self: Consulting fee, Advisory Committees or Review Panels
Trace Curry: Apollo EndoSurgery, Self: Consulting fee; ReShape, Self: Consulting fee
Louis Aronne: Consultant for: Novo Nordisk; Zafgen; Eisai Inc.; VIVUS Inc.; GI Dynamics, Inc.; Pfizer Inc; Gelesis. Served as a speaker or a member of a speakers bureau for: Novo Nordisk; Takeda Pharmaceuticals North America, Inc.; Received grants for clinical research from: Eisai Inc. Owns stock, stock options, or bonds from: Jamieson Labs; MYOS Corporation; Zafgen; BMIQServes on board of directors for: Jamieson Labs; MYOS Corporation
Lawrence Cheskin: Medifast, Inc., Self: Chair, Scientific Advisory Board
Andres Acosta: Gila Therapeutics, Inc, Self: Ownership interest (e.g.; stocks/stock options), Stock Shareholder; General Mills, Self: Consulting fee, Consulting
Christopher J. Gostout: Apollo EndoSurgery, Other financial benefit, Grant/Research Support, Apollo EndoSurgery, Self: Ownership interest (e.g.; stocks/stock options), Consulting, Olympus Medical Systems, Self: Consulting fee, Consulting, EndoChoice, Self: Consulting fee, Consulting, Olympus Medical Systems, Other financial benefit, Grant/Research Support, Apollo EndoSurgery, Self: Consulting fee
Barham K. Abu Dayyeh: Apollo EndoSurgery, Self: Consulting fee, Consulting; Aspire Bariatrics, Other financial benefit, Grant/Research Support; Metamodix, Self: Ownership interest (e.g.; stocks/stock options), Consulting; GI Dynamics, Other financial benefit, Grant/Research Support; Olympus, Self: Consulting fee, Speaking and Teaching.

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Manpreet S. Mundi, M.D.¹⁰, Andres Acosta, M.D. Ph.D¹, Christopher J. Gostout, M.D.¹, and Barham K. Abu Dayyeh, M.D., MPH¹

¹Division of Gastroenterology and Hepatology, Mayo Clinic, Rochester, MN, United States

²Allure Medical Spa, Shelby Township, MI, United States

³Bali Surgical Practice, South Charleston, WV, United States

⁴Atlantic Medical Group, Kinston, NC, United States

⁵Tulane University, New Orleans, LA, USA

⁶Division of Gastroenterology, John Hopkins University School of Medicine, Baltimore, MD, United States

⁷Gastroenterology and Hepatology, Weill Cornell Medical College, New York, NY, United States

⁸Journey Lite Surgery Center, Cincinnati, OH, United States

⁹Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, United States

¹⁰Endocrinology, Diabetes, Metabolism and Nutrition, Mayo Clinic, Rochester, MN, United States

Abstract

Background & Aims—The Orbera Intra-gastric Balloon (OIB) is a single fluid-filled intra-gastric balloon approved for induction of weight loss and treatment of obesity. However, little is known about the effectiveness and safety of outside clinical trials, and since approval, the Food and Drug Administration has issued warnings to healthcare providers about risk of balloon hyper-inflation requiring early removal, pancreatitis, and death. We analyzed data on patients who have received the OIB since its approval determine its safety, effectiveness, and tolerance in real-world clinical settings.

Methods—We performed a post-regulatory 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 years; 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 percent total body weight lost (%TBWL) at 3, 6, and 9 months. Primary and secondary safety outcomes were rates of early balloon removal, peri-procedural complications, dehydration episodes requiring intravenous infusion, balloon migration, balloon deflation or hyper-inflation, 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 in 16.7% of patients, at a median of 8 weeks after placement (range, 1–6 months). Use of selective serotonin or serotonin-norepinephrine re-uptake inhibitors at the time of balloon placement was associated with increased odds of remove before 8 weeks (odds ratio, 3.92; 95% CI, 1.24–12.41). TBWL at 3 months was $8.5\% \pm 4.9\%$ (n=204), at 6 months was $11.8\% \pm 7.5\%$ (n=199), and at 9 months was $13.3\% \pm 10\%$

(n=47). At 6 months, total body-weight losses of 5%, 10%, and 15% were achieved by 88%, 62%, 31% of patients, respectively. Number of follow-up visits and weight loss at 3 months were associated with increased weight loss at 6 months ($\beta = 0.5$ and 1.2 , respectively) ($P < .05$). Mean levels of cholesterol, triglycerides, low-density lipoprotein, and HbA1c, as well as systolic and diastolic blood pressure, were significantly improved at 6 months after OIB placement ($P < .05$).

Conclusion—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 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

INTRODUCTION

Obesity continues to be pervasive in our society with over two-thirds of Americans being overweight or obese.(1) Although lifestyle interventions remain the cornerstone of therapy, due to 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% TBWL with lifestyle and pharmacological 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 (EBTs) 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 one of two fluid-filled gastric balloons recently approved by the FDA for patients with body mass index (BMI) between 30 to 40 kg/m² (8–10). Recent U.S. multicenter randomized clinical trial demonstrated superiority of the OIB plus lifestyle interventions over lifestyle interventions alone, with patients losing three times more weight 6 months into balloon therapy.(11) However, the effectiveness and safety of the OIB outside clinical trials in the U.S. in a commercial setting is currently unknown, and since approval, the FDA has issued two communications warning healthcare providers about the potential risks associated with fluid-filled intragastric balloons including the risk of balloon hyper-inflation, pancreatitis, and death.(12, 13) Therefore, we sought to report the safety, effectiveness, and tolerance of the OIB across the U.S in real-world clinical settings, including both academic and private practices involving surgeons and gastroenterologist and finally, 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 (REDCap) database that records demographics, outcomes both in term of weight loss and improvement in weight related co-morbidities, 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, 4 gastroenterologists) participated. All centers received access to the REDCap database and were prompted at regular intervals to enter data. Quality checks were manually conducted and center-specific inquiries were obtained to ensure data integrity and completeness. (14) Participating institutional review boards (IRB) approved the protocol and those without an IRB 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 18–65 years with BMI > 30 kg/m² who received the OIB for the treatment of obesity in the U.S. post-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 multi-disciplinary team that included a nutritionist and/or a psychologist.

Study Outcomes

Primary effectiveness outcomes for the study were percent total body weight lost (%TBWL) at 3, 6, and 9 months. %TBWL was defined as weight lost at specific time point (3, 6 or 9 month) 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, triglycerides, low density lipoprotein (LDL), high density lipoprotein (HDL), fasting blood sugar, hemoglobin A1c, and resolution of hypertension, dyslipidemia, impaired fasting glucose, or type 2 diabetes at 6 months. Primary and secondary safety outcomes were rates of early balloon removal, peri-procedural complications, dehydration episodes, balloon migration, balloon deflation or hyper-inflation, pancreatitis, and other complications were collected.

Statistical Analyses

Continuous variables were described by their means and standard deviations. Categorical variables were described by their frequencies. %TBWL at 3, 6 and 9 months was compared to baseline weight using the paired *t*-test with a 0.05 two sided significance level. Paired *t*-test was additionally used to compare baseline blood pressure and laboratory markers at 6

months. Exploratory multivariable linear and logistic regression analyses were performed to identify predictors of success and early balloon removal. All statistical analyses were conducted using JMP Pro Version 13.0. Cary, NC.

RESULTS

Patient characteristics

321 consecutive patients across 8 centers were included in the study. Mean age of the patients was $48.1 \text{ years} \pm 11.9$, 80% were female, and their mean baseline BMI was $37.9 \pm 6.9 \text{ kg/m}^2$ (Table 1). At time of data-analysis, 63% of the cohort had the OIB removed after completion of therapy and 37% still had the balloon in place.

Balloon Insertion

Out of 321 patients, 99% (n=317) of the patients underwent balloon placement. Four patients did not receive balloon due to pathology at endoscopy (n=1) and prior undisclosed gastrointestinal surgery (n=3). Average insertion procedure time was $8 \text{ min} \pm 4.2 \text{ min}$. Further procedural details can be found in Table 2. All patients were on a proton pump inhibitor for the duration of balloon therapy. All patients were started on at least one anti-emetic and anti-spasmodic medication for accommodative symptoms after OIB insertion, and only 86 (27%) patients received Aprepitant (Emend) in addition to other anti-nausea medications prophylactically for nausea prior to placement. There were no serious intra-procedural complications reported, with only one balloon malfunctioning during placement that was followed by a successful immediate balloon replacement. Three patients (1%) were admitted for observation after the procedure.

Post balloon insertion (0–6 months)

After balloon placement, mean total number of follow-up visits was 4.7 ± 3.7 during the first 6 months of therapy. Adverse events while the OIB were in place are summarized in table 3. Eight percent of patients (n=26) experienced dehydration due to vomiting requiring a median of 1 IV infusion [range 0–1] at an outpatient infusion center. Eight patients (3%) required a hospital admission to manage symptoms related to the OIB during balloon therapy, with 3 of those (1%) patients admitted for observation after OIB placement.

Early balloon removal rates were 16.6% (n=54) with median time to removal 8 [range 4.5–19.5] weeks. Early removals were secondary to excessive symptoms in 75% of cases and the remainder 25% were based on patients' request (work and travel schedule) with no troublesome symptoms. Symptoms necessitating early balloon removal included: vomiting (36%), nausea (21%), abdominal pain (8%), troublesome gastroesophageal reflux (8%), and combination of the above symptoms (4%). One balloon spontaneously deflated but did not cause small bowel obstruction or require surgical intervention. No balloon hyperinflations, pancreatitis, gastroesophageal perforations, or deaths were reported during the duration of follow-up.

Predictors of OIB intolerance and early removal

Table 4 summarizes predictor of OIB intolerance and early balloon removal (<8 weeks). On univariable logistic regression concurrent use of selective serotonin or serotonin-norepinephrine re-uptake inhibitors (SNRI/SSRI) at the time of balloon placement, symptomatic GERD at time of insertion, and diagnosis of depression were associated with increase odds of early removal. Only SSRI/SNRI use remained a significant predictor after adjusting for age and gender (odds ratio 3.32 (95% CI 1.01–10.88). Aprepitant use appeared to be protective 0.41 (0.17–0.99; $p=0.049$) on univariable and multivariable analysis after adjusting for age and gender.

Balloon Removal

Balloon removal was uncomplicated in all patients with 54% undergoing endotracheal intubation and the remainder done under MAC. The balloon was successfully removed endoscopically in all patients without any need for surgical conversion. Mean time for removal was 12.5 min $\pm$ 5.8. Food was found in the stomach at the time of removal in 28% of patients with 1 reported case of aspiration under MAC following balloon removal that was managed with antibiotics. At balloon removal, 7% ($n=12$) of patients had esophagitis (grade A 50%, Grade B and C 25% each). Small clean base ulcers were found in 1 patient, and 1 patient experienced a superficial esophageal tear managed with endoscopic clips placement as a prophylactic measure. About 3% of patients ($n=11$) were admitted after removal for observation (Table 2).

Post Balloon Removal (6–12 months)

Following balloon removal, mean number of follow-up visits across all patients during the three months after balloon removal was 0.4 ± 1.25 visits. Only 6 percent ($n= 19$) reported using anti-obesity medications as a weight loss maintenance tool after balloon removal. Forty patients had follow-up visits at 9 months.

Weight loss, comorbidity improvement, and predictor of weight loss

Data was available on 204, 199, and 47 patients at 3, 6, and 9 months after OIB insertion, respectively. Mean %TBWL at 3, 6, 9 months was $8.5 \% \pm 4.9$, $11.8\% \pm 7.5$, and $13.3\% \pm 9.5\%$, respectively. Patients continued to lose significant weight beyond 3 months with %TBWL at 6 and 9 months significantly higher than that at 3 months ($P < 0.01$). The proportion of patients reaching 5%TBWL, 10%TBWL and 15%TBWL at 6 months was 88%, 62% and 31%, respectively (Supplementary Figure 1). (Table 5) Subgroup analysis of OIB patients with obesity related co-morbidities are summarized in table 4. Statistically significant changes in mean SBP, total cholesterol, LDL and triglycerides were seen. Hemoglobin A1C (HbA1c) was significantly improved by 0.7% at 6 months in pre-diabetic and diabetic patients (6.87 vs 6.1 $p=0.006$). Forty-one patients (45% of those with hypertension) were taken off their hypertension medication, and 25 patients (50% of those with type II diabetes) stopped or decreased their diabetes medication at 6 months.

Table 6 summarizes the univariate and multivariate predictors of weight loss at 6 months after the OIB using a linear regression model. On multivariable analysis adjusting for age, gender and pre-balloon weight, the number of follow-up visits was significantly associated

with improved weight loss ($\beta = 0.40$; $p = 0.024$). Early weight loss at 3 months remained the strongest predictor of 6 months on both univariate and multivariable analysis ($\beta = 1.16$; $p = 0.0001$).

DISCUSSION

This prospective post US regulatory approval registry study of consecutive patients receiving a single fluid-filled intragastric balloon (OIB) in a variety of clinical practice settings demonstrated similar efficacy at 6 months as that reported in the pivotal US randomized clinical trial, a more favorable safety profile and durable weight loss three months after balloon removal.(11) Furthermore, we were able to demonstrate an impact on obesity related co-morbidities including hypertension, dyslipidemia, and diabetes.

Both the global burden of obesity study and a recent large individual-participant data metaanalyses of 239 prospective studies limited to never smokers with no pre-existing disease showed that patients with mild-to-moderate obesity (BMI 30–40kg/m²) contributed significantly more to its co-morbid diseases burden and mortality (15, 16). This is secondary to disproportionately higher percent of patients in these obesity classes given the normal distribution of the disease, and the lack of effective weight loss interventions available. Standard lifestyle interventions typically only result in 3–5% TBWL that is not durable over the long-term and bariatric surgery is of limited appeal, cost, and risk profile to be a feasible or applicable strategy for this large cohort of patients with mild-to-moderate obesity.(17)

The scientific literature is clear in showing that the magnitude of weight loss is highly relevant and strongly associated with improvements in obesity-related co-morbidities and long-term weight maintenance.(18) The odds of clinically-significant improvement in obesity related co-morbidities are much higher when %TBWL exceeds 10%. (5) Thus, both government agencies (the Agency for Healthcare Research and Quality [AHRQ], and national societies (American Society of Bariatric and Metabolic Surgery and ASGE now recognize that a significant management gap exists for patients with mild-to-moderate obesity.(19–21) In our study, the OIB resulted in > 10% TBWL in the majority of patients with improvement in obesity related co-morbidities. Furthermore, supplemented by a comprehensive multifaceted weight-maintenance program the weight loss can persist after balloon removal. Given the demonstrated efficacy of OIB in producing significant weight loss and its excellent safety profile, it is a much needed weight loss tool to bridge the management gap between medical and surgical obesity interventions.(22)

The paradigm for managing obesity has shifted to a model of chronic disease with an initial effective weight-loss strategy followed by an aggressive weight-maintenance phase that counteract the physiological and behavioral adaptations resulting from the weight loss using both obesity pharmacotherapies and behavioral interventions. In response to significant caloric restriction and loss of body fat stores, there are physiologic counter-regulatory processes that increase hunger, decrease satiety, and increase metabolic efficiency.(23) We have previously shown that the OIB modulates this compensatory hunger in response to caloric restriction by delaying gastric emptying, a fundamental physiologic regulator of appetite.(24, 25) (26) This delay in gastric emptying is reversed a few weeks after balloon

removal; thus, it is intriguing to envision a strategy of sequential use of the OIB and anti-obesity medications with synergistic mechanisms of action in patients who have favorably responded to OIB therapy. The GLP-1 mimetic Liraglutide (Saxenda) (Novo Nordisk, Denmark) is a potential synergistic candidate given its both central and peripheral mechanisms of action that delay gastric emptying and improve satiety. (27) Offering such a step-up, personalized-medicine approach that tailors the use of OIB and pharmacotherapies will likely minimize non-responders and enhance the efficacy-to-risk ratio by providing an effective and durable non-surgical weight loss option to this undertreated cohort with mild-to-moderate obesity.

This prospectively maintained clinical registry representing real-life US clinical practice have yielded multiple key observations about OIB tolerance, efficacy, and safety that were not obvious within the confounds of the US pivotal clinical trial and from studies outside the US. These observations are of critical value to inform a safe and effective use of the OIB in the US. First, despite careful history, physical examination, judicious screening prior to OIB use, 4 patients did not receive the balloon due to pathology found at the time of endoscopy including previously undisclosed gastroesophageal surgery, which is an absolute contraindication for use given the associated increased risk of perforation. Thus, careful endoscopic examination at the time of upper endoscopy; especially for evidence of previous surgery, peptic ulcer disease, large hiatal hernia, and undiagnosed eosinophilic esophagitis is mandatory prior to OIB placement. Second, accommodative symptoms remain common after OIB placement. Although most of these symptoms resolved or improved within days after balloon placement, rates of early OIB removal due to intolerance remain high at 16.6% compared to 7.5% reported outside the US, despite liberal use of medication to treat these symptoms and the self-pay nature of the procedure.(21) This argues that a certain percentage of patients will not tolerate OIB therapy. Identifying this cohort prior to balloon placement, will be important. However, until better baseline clinical, psychological and physiological predictors are defined, close patient follow-up and careful screening of those with history of anxiety and depression for eligibility, ideally by a psychologist, is warranted. Of interest, SSRI/SNRI use was associated with balloon intolerance, a phenomenon that may be related to alterations in gastric emptying rates or related to underlying visceral hypersensitivity that predisposes patients to worse accommodative symptoms. The use of Aprepitant (Emend) was only mildly beneficial in preventing early balloon removal due to intolerance; thus, given its high cost it's unlikely a cost-effective intervention in this cohort.

Equally important to predicting intolerance is predicting poor weight response. The hope for the future is to be able to stratify patients based on baseline gastric physiological measurement to precisely identify and offer those who are unlikely to respond alternative therapies. For now, early weight loss at 3 months was the strongest predictor of 6 months weight loss in addition to the number of follow-up visits with a multi-disciplinary team. Thus, maximizing patient follow-up and intensifying therapy for those who achieve less than 7% TBWL at 3 months by the addition of anti-obesity medications and or enhanced early behavioral intervention is warranted. In the future, physiological predictors of intolerance and response will likely be identified to individualize patient care using office based tools. (28) Once such tool could be the recently FDA approved 13C-Spirulina Gastric Emptying Breath Test (GEBT) (Cairn Diagnostics, Brentwood, TN).(29)

Through medical device reporting (MDR), the FDA has issued two alerts to educate providers on the potential risks of acute pancreatitis, spontaneous balloon hyper-inflation, and five reports of unanticipated deaths that occurred in patients with fluid-filled IGB systems to treat obesity.(12, 13) None of these complications were observed in our large cohort. Furthermore, the FDA was very careful to point out that they have not been able to definitely attribute the deaths to the balloons or the procedures to insert or remove the balloons. Previous publications have evaluated incidence of death in patients treated with fluid filled intragastric balloons. In 2015, ASGE Bariatric Taskforce published a meta-analysis on the Orbera, which was the only IGB at the time with a sufficient number of publications to perform a meta-analysis.(21) Data was pooled from a manual review of adverse events from 68 studies. A total of 4 deaths occurred in this cohort for a 0.08% incidence rate of death. Since receiving FDA approval in August 2015, the incident rate remains well below 0.01%. Compared to metabolic surgery, this rate is well below the risk of death associated with bariatric surgery, which ranges between 0.1 to 0.5% depending on the surgical procedure. (22)

The strength of this study includes its registry prospective design allowing the investigation of real world effectiveness across multiple centers, including private and academic centers and involving gastroenterologists and surgeons. The limitations from this study include those inherent from a registry based trial, including a significant loss to follow-up rate after balloon removal. Furthermore, not all centers had all data points collected such as impact on obesity co-morbidity; thus allowing a more comprehensive analysis of OIB effects. However, a recent meta-analysis corroborated our findings and demonstrated improvement in fasting blood sugar levels, cholesterol levels and blood pressure results despite the low prevalence of co-morbidities in those analyzed trials.(30)

While the OIB results in significant weight loss in our multicenter study, weight maintenance is likely a function of adherence to a healthy lifestyle and behaviors with adjunct obesity pharmacotherapies in selected patients. Despite efforts by all centers participating in this registry to provide patients with a comprehensive weight loss program, follow-up rates dropped after balloon removal. Although this is in par with most other weight loss interventions, it highlights the need for more intensive patients' education, and setting realistic expectations and incentives for enhanced follow-up after balloon removal for better long-term outcomes.

Obesity is a chronic disease that warrants chronic management with lifelong lifestyle and pharmacotherapy like hypertension and type 2 diabetes. Endoscopic therapies such as intragastric balloons, may offer a paradigm shift in our management of obesity that targets current gaps in therapy and should be viewed as an initial or step-up option for effective weight loss that gets patients better engaged with lifelong changes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Baseline Patient Characteristics

Demographics	n = 321
Gender	
Male	20 %
Female	80 %
Age, years (mean $\pm$ s.d.)	48.1 $\pm$ 11.9
Weight, kg (mean $\pm$ s.d.)	108.3 $\pm$ 28.8
BMI, kg/m ² (mean $\pm$ s.d.)	37.6 $\pm$ 6.9
Hypertension	29 %
Dyslipidemia	19 %
Type 2 Diabetes	15 %
Impaired fasting glucose	4 %
NASH	4 %
Depression	16 %

Table 2

Procedure Characteristics Placement and Removal

Characteristic	Placement (n=317)	Removal (n=261)
Balloon not placed	--	--
<i>Prior gastrointestinal surgery</i>	n=3	--
<i>Large hiatal hernia</i>	n=1	--
Anesthesia	99 % MAC; 1 % GA	46% MAC; 54% GA
Methylene Blue Used	58 %	--
Volume (cc + s.d)	629 + 29.5	--
Procedure time (min + s.d)	8 min + 4.2	12.6 min + 5.8
Hiatal Hernia	14 %	NA
Esophagitis	3%	7%
Erosions	1%	0%
Ulcers	0.3%	0.5%
Balloon Malfunction	0.3%	0%
Esophageal Tear	0%	0.5%
Stomach tear	0%	0%
Food contents found	0%	28%

Table 3

Complications Following Balloon Placement

Complication/Event	% (n)
Early balloon removal Due to:	16.6 % (n=54)
<i>Nausea</i>	20.8 % (n=11)
<i>Vomiting</i>	35.8 % (n=19)
<i>Abdominal Pain</i>	7.5 % (n=4)
<i>Reflux</i>	7.5 % (n=4)
<i>Combination (Any)</i>	3.8 % (n=2)
<i>Patient Request (No symptoms)</i>	24.5 % (n=13)
Dehydration requiring IV infusion	8 % (n=26)
Hospital Admission	4 % (n=11)
Balloon Deflation	1 % (n=1)
Aspiration Event (during removal)	1% (n=1)
Pancreatitis	0 %
Perforation	0 %
<i>Esophageal</i>	0 %
<i>Gastric</i>	0 %
Balloon Migration	0 %
Small bowel obstruction	0 %
Surgical Removal	0 %

Table 4

Predictors of Early Removal and Tolerance at < 8 weeks

Variable	Odds Ratio (95% CI; p value)	
	Univariable	Multivariable ^a
Age	0.97 (0.93–1.009; p=0.16)	0.97 (0.93–1.01; p = 0.19)
Gender (female)	1.54 (0.56–3.83; p= 0.37)	1.40 (0.5–3.53; p=0.48)
Depression comorbidity	2.71 (0.83–8.44; p=0.09)	2.31 (0.69–7.76; p=0.16)
SSRI/SNRI medication	3.92 (1.24–12.41; p=0.02)	3.32 (1.01–10.88; p=0.046)
Prior GERD	2.94 (0.94–9.18; p=0.06)	2.14 (0.62–7.26; p=0.22)
Aprepitant use	0.41 (0.17–0.99; p=0.049)	0.42 (0.17–1.01); p=0.0528

^aadjusted for age and gender

Table 5**Weight Loss and Comorbidity Outcomes**

Outcome/Metabolic Parameter	Baseline (mean $\pm$ SD) n=321	Month 3 (mean $\pm$ SD) n=204	Month 6 (mean $\pm$ SD) n=199	Month 9 (mean $\pm$ SD) n=47	P-value ¹
Mean Weight (kg)	108 $\pm$ 28.8	99.3 $\pm$ 24.8	96.6 $\pm$ 25	94.4 $\pm$ 23.9	<0.0001
Mean % TBWL	--	8.5 % $\pm$ 4.9	11.8 % $\pm$ 7.5	13.3 % $\pm$ 9.5 ^a	<0.0001 ²
Total Cholesterol (mg/dL) n=24	181 $\pm$ 39	N/A	167.1 $\pm$ 33	N/A	0.02
Triglycerides (mg/dL) n=27	174.6 $\pm$ 157	N/A	129.8 $\pm$ 87	N/A	0.02
LDL (mg/dL) n=26	101.6 $\pm$ 32.8	N/A	94.9 $\pm$ 32.3	N/A	0.045
HDL (mg/dL) n=26	48.5 $\pm$ 20.2	N/A	51.3 $\pm$ 18.1	N/A	0.18
Hemoglobin A1c (%) n=13	6.97 $\pm$ 1.6	N/A	6.1 $\pm$ 1.3	N/A	0.01
Fasting Blood sugar (mg/dL) n=26	118.2 $\pm$ 43.42	N/A	116.3 $\pm$ 51.6	N/A	0.43
Systolic Blood Pressure (mmHg) n=72	133.4 $\pm$ 19.9	N/A	128.7 $\pm$ 15	N/A	0.003
Diastolic Blood Pressure (mmHg) n=72	77.3 $\pm$ 11.8	N/A	75.6 $\pm$ 10.9	N/A	0.03
Alanine Aminotransferase n=6	33.4 $\pm$ 32.9	N/A	24.3 $\pm$ 10.8	N/A	0.11
Aspartate Aminotransferase n=17	32.8 $\pm$ 22.9	N/A	34.84 $\pm$ 24.1	N/A	0.28

¹ Compared to baseline weight using paired t-test² Compared to 3 months %TBWL^a %TBWL 9 month vs 6 month p=0.31

Table 6

Predictors of absolute weight loss (kg) at 6 months

Variable	Beta (p value)	
	Univariable	Multivariable ^a
Age	0.02 (p=0.74)	0.05 (p=0.34)
Sex (female)	4.69 (p= 0.024)	5.6 (p=0.014)
Pre-balloon weight	0.24 (p=0.0001)	0.07 (p=0.084)
Total # of follow ups 0–6 months	0.49 (p=0.08)	0.40 (p=0.024)
Total weight loss 3 months	1.16 (p=0.001)	1.16 (p<0.0001)
SSRI/SNRI medication	–1.45 (p=0.18)	– 1.0 (p=0.24)
Depression comorbidity	–1.47 (p=0.17)	*

^a adjusted for age, sex, baseline weight, total weight loss at 3 months

* removed due to collinearity with SSRI/SNRI variable