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ORIGINAL CONTRIBUTIONS

Effectiveness of Online Aftercare Programs Following Intragastric Balloon Placement for Obesity Is Similar to Traditional Follow-up: a Large Propensity Matched US Multicenter Study

Eric J. Vargas[1] · Fateh Bazerbachi[1] · Andrew C. Storm[1] · Monika Rizk[1] · Andres Acosta[1] · Karen Grothe[2] · Matt M. Clark[2] · Manpreet S. Mundi[3] · Carl M. Pesta[4] · Ahmad Bali[5] · Eric Ibegbu[6] · Rachel L. Moore[7] · Vivek Kumbhari[8] · Trace Curry[9] · Reem Z. Sharaiha[10] · Barham K. Abu Dayyeh[1]

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Abstract

Background The combination of intragastric balloons (IGB) with comprehensive lifestyle and behavioral changes is critical for ongoing weight loss. Many community and rural practices do not have access to robust obesity resources, limiting the use of IGBs. Online aftercare programs were developed in response to this need, delivering lifestyle coaching to maximize effectiveness. How these programs compare to traditional follow-up is currently unknown.

Methods Using propensity scoring (PS) methods, two large prospective databases of patients undergoing IGB therapy were compared to estimate the difference in percent total body weight loss (%TBWL) between groups while identifying predictors of response.

Results Seven hundred fifty-eight unique patients across 78 different participating practices (online $n = 437$; clinical registry $n = 321$) was analyzed. The mean %TBWL at balloon removal was 11% ± 6.9 with an estimated treatment difference (ETD) between online and traditional follow-up of − 1.5% TBWL (95% CI − 3–0.4%; $p = 0.125$). Three months post-balloon removal, the combined %TBWL was 12.2% ± 8.3 with an ETD of only 1% TBWL (95%CI – 3–3%; $p = 0.08$). On multivariable linear regression, each incremental follow-up was associated with increased %TBWL ($\beta = 0.6\%$ $p = 0.002$).

Conclusion Online IGB aftercare programs provide similar weight loss compared with traditional programs. Increased lifestyle coaching whether in person or remotely is associated with more %TBWL at removal and during follow-up. Close follow-up for clinical symptoms is still warranted.

Keywords Obesity · Online · Treatment · Balloon · Endoscopic

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✉ Barham K. Abu Dayyeh
AbuDayyeh.Barham@mayo.edu

1 Division of Gastroenterology and Hepatology, Mayo Clinic School of Medicine, Mayo Clinic, 200 First Street SW, Rochester, MN 55905, USA

2 Department of Psychology and Psychiatry, Mayo Clinic, Rochester, MN, USA

3 Division of Endocrinology, Diabetes, Metabolism and Nutrition, Mayo Clinic, Rochester, MN, USA

4 Allure Medical Spa, Shelby Township, MI, USA

5 Bali Surgical Practice, South Charleston, WV, USA

6 Atlantic Medical Group, Kinston, NC, USA

7 Tulane Medical Center, New Orleans, LA, USA

8 Division of Gastroenterology, John Hopkins University School of Medicine, Baltimore, MD, USA

9 Journey Lite Surgery Center, Cincinnati, OH, USA

10 Gastroenterology and Hepatology, Weill Cornell Medical College, New York, NY, USA

Introduction

Lifestyle and behavioral recommendations remain the foundation for obesity management. As standalone therapy, however, the rates of success are marginal, with marked heterogeneity in outcomes ranging from 1 to 3% long-term total body weight loss [1]. Anti-obesity medications such as liraglutide and combination phentermine-topiramate have improved obesity management, providing increased effectiveness (3–7% total weight loss), but leave a wide therapeutic gap between medications and bariatric surgery particularly in patients with BMI 30–40 kg/m^2 (body mass index).

This BMI group represents the majority of the comorbidity burden and mortality associated with obesity, much more so than those with BMI > 40 kg/m^2 [2–5]. Given this significant management gap, endoscopic and metabolic endoscopic therapies were designed to mimic the procedural successes of bariatric surgery, delivering higher efficacy than lifestyle or anti-obesity medications alone could offer, but with an improved safety profile as compared with surgery, given the minimally invasive nature of endoscopic procedures [6]. These developments have positioned gastroenterologists, surgeons and endoscopists at the forefront with other obesity specialists in the multidisciplinary management of patients with classes I–II obesity [7–10].

The most extensively studied endoscopic bariatric therapy to date are intragastric balloons, with three FDA-approved devices available in the USA with level 1 evidence supporting superiority over lifestyle interventions alone [11–15]. Post-regulatory approval studies of these devices have also revealed similar efficacy to randomized trials, providing evidence that these devices work in clinical practice as part of a comprehensive obesity management plan [16–18]. However, given their temporary position in the patient's stomach, with the majority approved for a 6-month duration, intragastric balloons are to be viewed as acute weight loss tools. Their long-term benefit is likely derived from their ability to better engage patients in incorporating lifestyle and behavioral interventions critical for long-term weight maintenance after device removal. In practice, gastroenterologists may not have access to multidisciplinary teams including registered dieticians and health coaches to maximize weight loss and weight maintenance, posing concerns and acting as a major barrier for implementing endoscopic bariatric therapies in the community.

Given these concerns, online aftercare programs are offered with intragastric balloon systems to assist in delivering regular lifestyle and behavioral interventions when they are otherwise not immediately available. They provide wireless scales and food diaries that seamlessly integrate into convenient web and mobile applications accessible from anywhere, along with monthly one-on-one electronic coaching and group sessions. When combined with endoscopic bariatric therapies, these aftercare programs have the potential to expand the delivery and improve effectiveness of these interventions. While electronic programs have been successful in traditional lifestyle intervention trials, their success with intragastric balloons is currently unknown. Our primary aims were to compare the effectiveness of traditional face-to-face programs with online aftercare programs using the Orbera (Apollo Endosurgery, Austin, Texas) single fluid-filled intragastric balloon system (OIB) and to explore predictors of weight loss in these cohorts.

Methods

Patients

A prospective cohort of patients from a multicenter US administrative database of patients using the Orbera Coach online aftercare program following OIB placement (online) was compared with a prospective cohort of patients from a US multicenter clinical registry of ORBERA balloon patients (traditional follow-up) for the treatment of obesity from 2015 to 2017 [16]. Patients were male or female with a BMI of 30–40 who received the intragastric balloon for the treatment of obesity. Both databases are comprised of a mix of academic and community practices across the USA with the online database being de-identified without further details outside of the number of follow-up sessions and weight loss to preserve patient and center anonymity. This study was approved by the local IRB.

Intervention

The Orbera intragastric balloon (OIB) is an endoscopically placed and removed single fluid-filled balloon system that is designed to remain in the stomach for 6 months. Both cohorts received the intragastric balloon at baseline, and then either received traditional face-to-face follow-up with healthcare professionals (dieticians, MD/DO, health coaches) or participated in the Orbera Coach online aftercare program, through which patients log-in for follow-up with health coaches and receive nutritional advice from dieticians in addition to tracking their caloric intake, exercise, and weight loss progress. The Orbera Coach aftercare program is an online service offered by a third party that provides real time access to dieticians, health coaches, and weight loss suggestions on a regular, convenient, and voluntary basis for patients.

Data and Statistical Analyses

Subjects' age, sex, weight (kg), BMI (kg/m^2), and the total number of follow-up sessions whether online or face-to-face were collected. Main outcome of interest was percent total body weight lost (%TBWL) at 3, 6, and > 6 months after IGB placement. Rates of 5%, 10%, 15% TBWL at 6 (balloon removal) and > 6 months after IGB placement were calculated. Percent excess body weight lost (%EWL) and change in BMI were secondary outcomes. Ideal body weight and excess body weight were calculated using a BMI of 25 kg/m^2. Continuous variables were reported as means and their standard deviations, and qualitative variables were expressed as proportions. Two sample t test was used to compare %TBWL, %EWL, and the number of follow-up sessions at 3, 6 (balloon removal), and ≥ 6 months between the two cohorts. The chi-square test was used to compare proportions across the two groups for each category of 5, 10, and 15% TBWL given that the expected counts were greater than 5.

Estimating Treatment Effects

In order to compare the online vs traditional interventions from the two observational databases, propensity score methods were employed to estimate the treatment effect while eliminating some residual confounding from the non-randomized design [19]. The propensity score represents the overall probability that a particular subject is assigned to a certain treatment group based on a set of covariates and estimates counterfactual outcomes if they were to be assigned to the other treatment group. The differences in potential outcomes from both groups are used to estimate the average treatment effect (ATE). The augmented inverse propensity weighting method (AIPW), a “doubly robust” estimator, was used to estimate the average treatment effect of an online follow-up group vs the traditional follow-up on %TBWL at 6 months and post-balloon removal [20, 21]. Common support was visually tested using a propensity score overlap graph. Balancing was assessed using standardized differences after AIPW method and was considered balanced if less than 10% [22].

Predictors of %TBWL Response

An exploratory multivariable linear regression was performed to identify predictors of %TBWL at balloon removal (6 months) and post-balloon removal, adjusting for the propensity score, treatment group, and number of follow-ups. If after the propensity score weighting, the standardized differences were outside ± 0.10, they were included in the multivariable model to adjust for the remaining imbalance. Interactions between follow-ups, treatment group, and sex were assessed. Results were considered significant if their p value was less than 0.05. All tests were two-sided. Statistics were performed using STATA 15.1 (StataCorp LLC, College Station, TX, USA).

Results

A total of 758 unique patients across 78 different participating centers (both academic and community practices) were analyzed. (online $n = 437$; clinical registry $n = 321$). Overall, mean age was 46.5 ± 11.7, 82% were female, and baseline weight and BMI were 103.8 kg ± 25.1 and 36.6 kg/m^2 ± 6.4, respectively. Eighty-two percent of subjects were female. The baseline demographics by cohort are outlined in Table 1.

Weight loss data was available for 90% of subjects ($n =$ 682/758) at their latest follow-up. Overall mean %TBWL at 3 months was 6.5% ± 4.3 ($n = 295$), at 6 months (balloon removal) was 11% ± 6.6 ($n = 241$), and > 6 months (median 9 months) 12.4% ± 8.4 TBWL ($n = 146$). Overall %EWL at 3 months was 27% ± 29%, at 6 months (balloon removal) 37.1% ± 52.6%, and 52.8% ± 70.2% at > 6 months (Range 7–17 months). Three months into balloon therapy, %TBWL was higher in the traditional follow-up group vs online programs (8.2% ± 4.6% vs 5.8% ± 3.9%; p < 0.002). However, there was no statistically significant difference in %TBWL between the two groups at the time of balloon removal (11.5% ± 7.5% vs 10.3% ± 6%; $p = 0.16$) or longer-term follow-up at > 6 months at a median 3 months after removal (12.8% ± 10% vs 11.9% ± 7.4% $p = 0.58$), same trend was observed for %EWL (Table 2).

In terms of the proportion of individuals achieving the clinically significant 5, 10, and 15% total body weight loss thresholds, similar rates between the two cohorts at 6 months and > 6 months (Table 3) were observed. The global rates of 10% TBWL at 6 and > 6 months were 54% and 58%, respectively. The mean number of follow-up encounters in the online cohort was slightly higher at 6 months compared with the traditional groups but equivalent at the other time points (Table 2).

Estimating Treatment Effect

We examined the relative difference between online vs traditional follow-up groups on %TBWL using propensity scoring models to account for the non-randomized analysis of observational data. We used augmented inverse propensity-weighted analysis (AIPW) using the propensity score developed from available covariates in order to maximize the sample size for analysis. Compared with propensity score matching, regression-adjustment- or inverse propensity treatment weighting (IPTW), AIPW combines aspects of regression-adjustment and inverse propensity-weighted methods and are thus known as a “doubly robust” method. Balancing and common support assumptions are still assessed to minimize bias and residual confounding.

The propensity score model estimating the probability of being assigned to the online vs traditional follow-up interventions was developed using age, sex, and starting weight (kg). The propensity score weighting was balanced since the

Table 1 Baseline characteristics

Variable	Online ($n = 437$)	Traditional ($n = 321$)	p value
Age (years) (mean ± s.d.)	45 ± 11.3	48.1 ± 12.1	0.0005
Female (%)	84%	80%	0.14
Baseline weight (kg)	100.5 ± 21.9	108.2 ± 28.5	< 0.001
Baseline BMI (kg/m^2)	35.9 ± 5.9	37.6 ± 6.3	0.0003

BMI, body mass index

standardized differences are less than ± 0.10 after weighting. We assessed the common support requirement using an overlap plot (Fig. 1). On augmented inverse propensity-weighted analysis, the estimated average treatment difference between the online and traditional follow-up groups at 6 months was not statistically or clinically significant at − 1.5% TBWL (95% CI − 3–0.4%; $p = 0.125$). Post-balloon removal, the estimated average treatment difference was also not statistically significant at 1% TBWL (95% CI − 3–3%; $p = 0.08$). However, the standardized differences for age and start weight covariates after weighting were slightly above ± 0.10. Common support assumption on visual inspection of the overlap plot was still satisfied **(**Fig. 2**).**

Predictors of %TBWL Response at Balloon Removal and Post-Removal

On exploratory multivariable linear regression, adjusting for the propensity score, treatment group, and number of follow-ups, each incremental follow-up was associated with greater %TBWL at 6 months ($\beta = 0.6\%$ $p = 0.002$) whether performed in person or remotely. In the 3 months post-balloon removal, the multivariable model adjusted for propensity score, age, and start weight (due to standardized differences after weighting being ± 0.10 for those two covariates), each incremental follow-up was not significantly associated with greater %TBWL ($\beta = 0.2\%$ $p = 0.34$).

Discussion

In this large prospective database, propensity-weighted comparison of patients who underwent a single fluid-filled intragastric balloon placement for the treatment of obesity, we have demonstrated several important findings. First, we revealed that weight loss was similar between those who underwent traditional face-to-face aftercare programs vs online aftercare programs at the time of balloon removal (6 months), and at a median 3 months after the balloon was removed. Second, we revealed that weight loss was comparable with that of randomized clinical trials with the balloon, with the key difference that patients receiving aftercare coaching continued to lose weight a median 3 months after balloon removal whether it was provided electronically or in person. Finally, we revealed that completing follow-up encounters remains a key predictor of continued weight loss, demonstrating that online aftercare programs may offer gastroenterologists and surgeons the ability to incorporate intragastric balloons in their otherwise independent practice, so long as suitable patients remain engaged and actively participate in such programs, and adequate practice resource are available to offer patients adequate support and follow-up to manage any medical and psychological issue that arise during therapy.

The efficacy of electronically delivered interventions for weight loss and weight maintenance has previously been investigated in the context of traditional lifestyle and behavioral

Table 2 %TBWL and %EWL differences between online aftercare and clinical registry IGB data

Variable (mean ± s.d.)	IGB online aftercare	IGB clinical registry	p value
3 month %TBWL	5.8% ± 3.9% ($n = 229$)	8.8% ± 4.9% ($n = 66$)	< 0.0001
%EWL	24% ± 23%	38.1% ± 44%	0.012
≻ Follow-up	0.7 ± 1.0	0.7 ± 1.7	0.81
6 month %TBWL	10.3% ± 6% ($n = 104$)	11.2% ± 7.0% ($n = 137$)	0.28
%EWL	34.3% ± 71%	39.3 ± 31%	0.51
≻ Follow-up	1.9 ± 2.4	1.2 ± 2.6	0.03
> 6 month %TBWL	11.9% ± 7.4% (n = 104)	13.8% ± 10.5% ($n = 42$)	0.29
%EWL	57% ± 80%	43% ± 35%	0.14
≻ Follow-up	2.6 ± 3.4	2.7 ± 4.5	0.89

%TBWL percent total body weight lost

%EWL percent excess weight lost

Table 3 Rates of 5, 10, 15% TBWL at 6 and > 6 months (median 9 months)

Outcome	Overall	Online	Traditional	*p* value
6 months	*N* = 241	*N* = 104	*N* = 137	
5% TBWL	84.2%	85.5%	83.2%	0.618
10% TBWL	53.9%	52.9%	54.7%	0.774
15% TBWL	25%	20.1%	29%	0.220
> 6 months	*N* = 146	*N* = 104	*N* = 42	
5% TBWL	80.8%	79.8%	81%	0.624
10% TBWL	58%	58.6%	57%	0.717
15% TBWL	32%	31.7%	34%	0.340

TBWL, total body weight lost

changes [23, 24]. Current obesity guidelines recommend with high level of evidence face-to-face high-intensity comprehensive interventions (> 14 sessions over 6 months) with a trained interventionist that produce an average of 8 kg weight loss in 6–12 months, with longer-term weight loss after 1 year showing gradual weight regain of 1–2 kg [25]. In turn, the efficacy of electronically delivered high-intensity comprehensive interventions has been shown to produce an average of 5–6 kg weight loss at 6–12 months, consistent with the results from our analysis, where the overall weight loss at balloon removal and post-removal are slightly lower in the online group, despite the mean follow-up rates for both cohorts being less than the recommended level of intensity for weight loss [25]. However, despite this lower engagement rate, weight loss results were slightly superior to the randomized clinical trials where patients followed a moderate intensity program alongside intragastric balloon therapy.

The main limitations of our analysis include selection bias inherent to prospective registries, attrition bias as a weight loss study, and lack of safety and early removal data in the online registry. The databases also lacked information on comorbidity improvement, socioeconomic status, level of education, race, ethnicity, and geographical location. However, the strengths of our study include the large number of centers including community and academic practices and the comparative effectiveness assessment of two real-world clinical scenarios using observational data methods to reduce residual confounding. Our analysis also comprises the largest intragastric balloon experience of both private and academic centers in the USA to date.

The results of our study should be interpreted with caution, given the recent FDA announcement of seven deaths in the USA during weight loss therapy using a fluid-filled intragastric balloon [26, 27]. Gastroenterologists embarking on incorporating endoscopic bariatric therapies into their practice should seek institutional or practice support, be comfortable managing post-procedural symptoms, and titration of a patient's diabetes and hypertension regimens similar to post-surgical management of bariatric surgery patients. Our practice is to have patients remain in close communication with their primary care provider or obesity medicine physician with ongoing collaboration [9]. Close attention to and treatment of intractable heaving and vomiting is crucial to avoid serious adverse events including perforation, as is monitoring for persisting abdominal pain which may be suggestive of pancreatitis or balloon hyperinflation which have been implicated in some of the deaths reported with the devices. [28] Safety and adverse events in clinical practice have been previously reported in the ASGE meta-analysis, consistent with what has

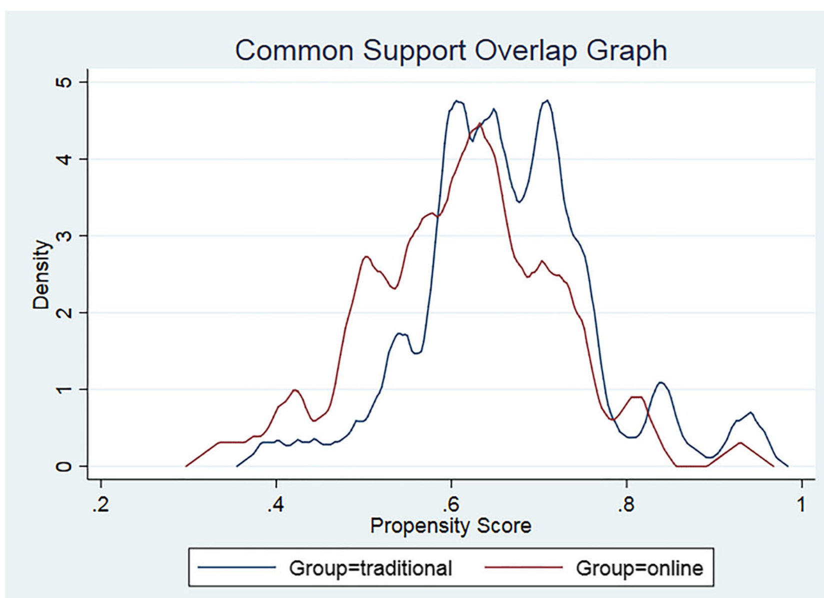

Fig. 1 Common support assessment for PS method at 6 months

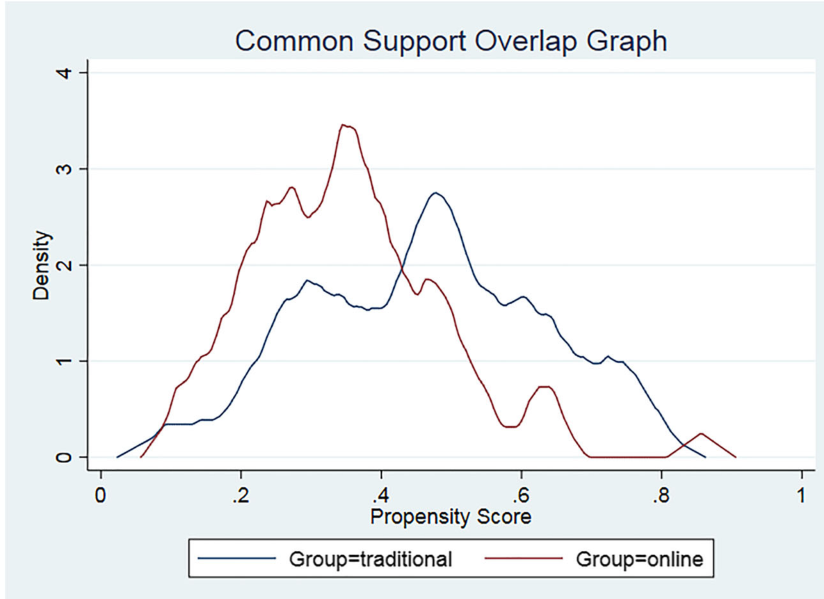

Fig. 2 Common support assessment for PS method post-balloon removal

been observed in clinical practice thus far [16, 18, 29]. Overall, intragastric balloons should continue to be viewed as weight loss tools that are used to engage patients in behavioral modification in preparation for lifelong lifestyle changes conducive to weight maintenance. Once the balloon is removed, obesity providers should continue to follow the patients through online or face-to-face means to battle behavioral change fatigue, prescribe anti-obesity medications for long-term weight maintenance and consideration for bariatric surgery. Obesity, as a chronic disease, requires a multipronged long-term treatment approach. Given its ease of use and patients acceptance as an anatomy preserving obesity intervention, intragastric balloons serve as a tool to jumpstart initial weight loss efforts and actively engage patient in a long-term weight loss program.

Conclusion

Online aftercare programs provide gastroenterologists the opportunity to incorporate intragastric balloons into their practice when face-to-face programs are unavailable. Such programs may also be a reasonable alternative for those patients' with schedules or travel restrictions that do not permit frequent face-to-face visits which would otherwise represent a barrier to ongoing management. With epidemiologic data reporting higher prevalence of obesity in rural areas, these online interventions may be exactly what gastroenterologists and surgeons need to improve access to comprehensive obesity management where resources are scarce. [30] More recent evidence from a primary care setting revealed improved weight loss outcomes in socioeconomically disadvantaged populations incorporating a digital intervention. [31] Thus, combining these online aftercare programs with low to moderate intensity programs may offer superior long-term outcomes than either one alone. Selecting patients with lower risk of intragastric balloon intolerance in combination with lifestyle, behavioral, and pharmacological therapies will improve medium- and long-term outcomes once the balloon is removed. [32]

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Compliance with Ethical Standards This study was approved by the IRB.

Conflict of Interest The following authors have nothing to disclose: Eric J. Vargas, Fateh Bazerbachi, Andrew C. Storm, Monika Rizk, Andres Acosta, Karen Grothe, Matt M. Clark, Manpreet S. Mundi, Ahmad Bali, and Eric Ibegbu. Carl Pesta received consulting, speaking, and teaching fees from Apollo EndoSurgery. Rachel L. Moore received consulting fee and research support from Apollo Endosurgery, Obalon Research Support Allurion, and Elira. Vivek Kumbhari received consulting fee and research support from Apollo EndoSurgery and ReShape Lifesciences. Trace Curry received consulting fees from Apollo Endosurgery and Reshape. Reem Sharaiha received consulting fees from Apollo Endosurgery. Barham K. Abu Dayyeh received consulting and research support from Apollo EndoSurgery.

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